

DRAFT FOR CONSULTATION

Food Law

Practice Guidance

FOOD LAW PRACTICE GUIDANCE

TABLE OF SECTIONS AND CHAPTERS

TABLE OF AMENDMENTS ISSUED	4
PREFACE	5
SECTION 1: ADMINISTRATION	6
CHAPTER 1.1: INTER-AUTHORITY MATTERS	6
CHAPTER 1.2: QUALIFICATIONS AND EXPERIENCE	7
CHAPTER 1.3: CONFLICTS OF INTEREST	8
CHAPTER 1.4: FOOD BUSINESS RECORDS	9
CHAPTER 1.5: REGISTRATION OF FOOD BUSINESS ESTABLISHMENTS.....	10
CHAPTER 1.6: CROWN AND POLICE PREMISES.....	11
CHAPTER 1.7: FOOD INCIDENTS AND HAZARDS	14
SECTION 2: COMMUNICATION	16
CHAPTER 2.1: FOOD ALERTS.....	16
CHAPTER 2.2: AGENCY COMMUNICATIONS AND GUIDANCE	17
CHAPTER 2.3: INFORMATION TO BE SUPPLIED TO THE AGENCY.....	18
CHAPTER 2.4: LIAISON WITH OTHER MEMBER STATES	19
SECTION 3: GENERAL ENFORCEMENT	22
CHAPTER 3.1: APPROACH TO ENFORCEMENT	22
CHAPTER 3.2: IMPROVEMENT NOTICES	23
CHAPTER 3.3: PROHIBITION PROCEDURES	27
CHAPTER 3.4: SEIZURE AND DETENTION	39
CHAPTER 3.5: TEMPERATURE CONTROL REGULATIONS	43
CHAPTER 3.6: QUICK FROZEN FOODSTUFFS	48
CHAPTER 3.7: WASTE FOOD	60
CHAPTER 3.8: DISTANCE SELLING/MAIL ORDER	62
CHAPTER 3.9: BOTTLED WATERS	65
CHAPTER 3.10: IMPORT OF FOOD FROM THIRD COUNTRIES.....	68

SECTION 4: INSPECTIONS	69
CHAPTER 4.1: INSPECTIONS.....	69
CHAPTER 4.2: THE INSPECTION	70
CHAPTER 4.3: INSPECTION OF APPROVED ESTABLISHMENTS – ADDITIONAL REQUIREMENTS.....	72
CHAPTER 4.4: INSPECTION OF SHIPS AND AIRCRAFT	73
CHAPTER 4.5: ACTION FOLLOWING INSPECTION.....	80
SECTION 5: PRODUCT-SPECIFIC ESTABLISHMENTS	81
CHAPTER 5.1: APPROVAL OF PRODUCT-SPECIFIC ESTABLISHMENTS SUBJECT TO APPROVAL UNDER REGULATION 853/2004.....	81
CHAPTER 5.2: ENFORCEMENT OPTIONS IN PRODUCT-SPECIFIC PREMISES....	82
CHAPTER 5.3: MATTERS RELATING TO SHELLFISH	83
CHAPTER 5.4: MATTERS RELATING TO FRESH MEAT.....	84
SECTION 6: SAMPLING	85
SECTION 7: MONITORING	91
SECTION 8: ANNEXES	92
ANNEX 1: GLOSSARY OF TERMS.....	92
ANNEX 2: FSA GUIDANCE ON THE REQUIREMENTS OF FOOD HYGIENE LEGISLATION	94
ANNEX 3: FRESH MEAT / MEAT PRODUCTS / MEAT PREPARATIONS / ON FARM SLAUGHTER.....	142
ANNEX 4: SHELLFISH	147
ANNEX 5: FISHERY PRODUCTS	157
ANNEX 6: RAW MILK AND DAIRY PRODUCTS	168
ANNEX 7: EGG PRODUCTS AND LIQUID EGG	172
ANNEX 8: APPROVAL PROCESS	175
ANNEX 9: IMPORT OF FOOD FROM THIRD COUNTRIES.....	202
ANNEX 10: FOOD SAFETY MANAGEMENT PROCEDURES BASED ON HACCP PRINCIPLES	228

TABLE OF AMENDMENTS ISSUED

Amendment Number	Signed	Date
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Amendment No. 4	_____	_____
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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	_____	_____
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Please sign and date to confirm replacement of relevant pages with amendments issued by the Food Standards Agency.

PREFACE

This Practice Guidance is issued by the Food Standards Agency (the Agency) to assist Food Authorities with the discharge of their statutory duty to enforce relevant food law.

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

Food Authority officers authorised under Section 5(6) of the Food Safety Act 1990 to carry out duties under that Act and Regulations made under it are not simultaneously authorised to deal with food law under other legislation. Separate and specific authorisation under that other legislation is also required, for example, as interpreted in the Food Hygiene (England) Regulations 2005¹ and the Official Feed and Food Controls (England) Regulations 2005².

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

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

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

Attention is drawn to the guidance on the scope and conduct of official checks on establishments subject to approval under Regulation 853/2004³.

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

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

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

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

¹ SI 2005 No. xxxx

² SI 2005 No. xxxx

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

SECTION 1: ADMINISTRATION

CHAPTER 1.1: INTER-AUTHORITY MATTERS

1.1.1: Introduction

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

1.1.2: Service to Consumers

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

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

CHAPTER 1.2: QUALIFICATIONS AND EXPERIENCE

1.2.1: Introduction

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

1.2.2: Pooling Expertise

Food Authorities should consider identifying a pool of authorised officers within their local or regional liaison group, whose experience and qualifications encompass the range of activities contained in Regulation 853/2004 laying down specific rules for food of animal origin, for which they are responsible. Alternatively, for those food business operators 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.

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 RECORDS

1.4.1: Introduction

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

1.4.2: Data Protection

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

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

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

CHAPTER 1.5: REGISTRATION OF FOOD BUSINESS ESTABLISHMENTS

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

CHAPTER 1.6: CROWN AND POLICE PREMISES

1.6.1: Introduction

This Chapter deals with enforcement of food law in Crown and police premises.

1.6.2: Scope of Application of Food Law

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

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

The Code of Practice contains statutory guidance, which Food Authorities must follow regarding the enforcement of food law in Crown and police premises.

This non-statutory guidance concerns the approach to enforcement in Crown premises and in premises that are occupied by the police. It does not apply to premises that are occupied by the NHS or NHS Trusts since these are not Crown premises.

1.6.3: Conduct and Frequency of Inspections

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

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

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

1.6.4: Enforcement

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, by originating summons in the Queen's Bench Division of the High Court, for a declaration that any act or omission of

the Crown, which amounts to a contravention of the Food Safety Act 1990 or regulations made under the Act, is unlawful.

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

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

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

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

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

1.6.5: Position of Individual Civil or Government Servants

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

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

1.6.6: Statutory Notices

The service of a hygiene improvement or a hygiene 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.

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

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

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

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

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

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

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

1.6.7: Use of the Food Safety Act 1990

In the unlikely event that it is appropriate serve notices equivalent to those mentioned in paragraph 1.6.6 under the Food Safety Act 1990 in respect of food standards offences, consideration should be given to the guidance in paragraph 1.6.6 in this regard.

CHAPTER 1.7: FOOD INCIDENTS AND HAZARDS

1.7.1: Introduction

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

1.7.2: Information Received Locally Which May Indicate a Wider Problem

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

- Following microbiological examination or chemical analysis of samples submitted to a Food Examiner or Public Analyst;
- As a result of complaints from members of the public, either directly or through a third party, for example, the police, citizens' advice bureaux, etc;
- Through notifications from a manufacturing company, trade association, wholesaler, retailer, importer or caterer;
- Information from enforcement agencies in other countries;
- As a result of a notification from a GP of one or more cases of communicable diseases, including foodborne illness, or from the consultant in communicable disease control (CCDC), or the Health Protection Agency (HPA) Communicable Disease Surveillance Centre (CDSC), or in Scotland, the consultant in public health medicine (communicable disease/environmental health) (CPHM(CD/EH)), or The Scottish Centre for Infection and Environmental Health (SCIEH).

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 in the matter 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 in accordance with the Home Authority Principle.

1.7.3.3: Scientific Investigation of Food Complaint Samples

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

If the authorised officer considers that a food complaint sample should be analysed, it should be sent to the Public Analyst. If it should be microbiologically examined, it should be sent to a Food Examiner. If any other investigation is necessary, the food should be sent to somebody who is suitably qualified and able to give evidence in the event of a prosecution.

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

SECTION 2: COMMUNICATION

CHAPTER 2.1: FOOD ALERTS

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

CHAPTER 2.2: AGENCY COMMUNICATIONS AND GUIDANCE

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

CHAPTER 2.3: INFORMATION TO BE SUPPLIED TO THE AGENCY

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

CHAPTER 2.4: LIAISON WITH OTHER MEMBER STATES

2.4.1: Introduction

This Chapter deals with the administration of and the approach to the European liaison arrangements that are operated by the Agency.

2.4.2: The Role of the Agency

The Agency is responsible for ensuring that official controls in the UK are carried out in accordance with Regulation 882/2004. In relation to requirements concerning the exchange of information and provision of administrative assistance, the Agency will have a supervisory role. In order to determine whether routine exchanges have any policy implications, the Agency 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 Agency will also deal directly with matters falling under categories A and B (see Chapter 2.4 of the Code of Practice).

The Agency will be responsible for facilitating the transfer of information to and from EU Member States on routine food control matters. In respect of requests for assistance from other Member States, the Agency is responsible for ensuring that all the necessary information concerning compliance, or otherwise, with UK food law is provided without delay, except for information which cannot be released because it is the subject of legal proceedings.

2.4.3: The Role of Food Authorities

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

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

2.4.4: Enquiries from Member States

Requests for information or administrative assistance received by the Agency will be passed to the appropriate Home Authority for action. The subsequent response may be made either via the Agency and the appropriate liaison body or direct to the Enforcing Authority in the Member State concerned if appropriate. It would be helpful for monitoring purposes if, when Food Authorities are replying direct, that they copy in to any response to the other Member State.

2.4.5: Documentation

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

2.4.6: Freedom of Information

Some Member States have freedom of information legislation and the Directive requires them to declare the fact at the time of making a request or during any information exchanges. Before submitting information involving matters of professional or commercial secrecy, Food Authorities shall obtain confirmation from the Enforcing Authority that the information will not be disclosed to a third party. If this confirmation cannot be obtained Food Authorities should seek advice from the Agency. Food Authorities should also ensure that the information is really necessary and is relevant to the outcome of any investigation. If in doubt, they should seek advice from the Agency.

2.4.7: Use of Information in Criminal Proceedings

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

All EU Member States are parties to The European Convention on Mutual Assistance in Criminal Matters⁴. This Convention requires that requests for information to be used as evidence in criminal proceedings be transmitted through the relevant authority.

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

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

⁴ 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:

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

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

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

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

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

2.4.8: Non-compliance With Legislation

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

SECTION 3: GENERAL ENFORCEMENT

CHAPTER 3.1: APPROACH TO ENFORCEMENT

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

CHAPTER 3.2: IMPROVEMENT NOTICES

[DN: LACORS to update their guidance in this area]

3.2.1: Introduction

This Chapter deals with the use of hygiene improvement notices under Regulation 8 of the Food Hygiene (England) Regulations 2005, and the use of improvement notices under Section 10 of the Food Safety Act 1990 in connection with food standards issues.

3.2.2: The Enforcement Approach

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

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

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

3.2.3: Improvement Notices

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

Notices should normally be served either by delivery to the food business operator / food business proprietor in person, or by a postal or courier service that includes proof of posting or despatch and, ideally, proof of delivery.

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

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

Notices should normally be served either by delivery to the food business proprietor in person, or by a postal or courier service that includes proof of posting or despatch and, ideally, proof of delivery.

3.2.3.1: Drafting an Improvement Notice

It should be clear from the notice exactly what the recipient is required to do, and why. The notice should therefore be clearly drafted and easily understood.

As failure to comply with the requirements of an 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. The alternative of serving multiple notices, each with a different time limit, may be more appropriate where multiple contraventions are concerned.

Separate notices with separate time limits may also be easier to handle if there is an appeal. An appeal against a single notice concerning multiple contraventions would result in the suspension of the whole notice until the appeal had been dealt with.

Likewise, failure to comply with one or more items would be a failure to comply with the whole notice and constitute a single offence.

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

3.2.3.2: Improvement Notice Time Limits

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

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

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

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

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

3.2.3.3: Extension of Time

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

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

When deciding on a request for an extension of the time limit the officer should take into account:

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

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, enforcement of the notice should be deferred until the new time limit has expired. The operator / proprietor should be advised of the decision in writing and any new time limit confirmed.

3.2.3.4: Works of Equivalent Effect

Notices should make it clear that the Food Hygiene (England) Regulations 2005 / the Food Safety Act 1990 allows a food business operator / food business proprietor to carry out measures of at least equivalent effect to those specified in the 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.

3.2.3.5: Compliance

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

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

3.2.3.6: Appeals

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

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

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

3.2.3.7: Other Discussion With the Food Authority

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

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

If an operator / proprietor indicates that the requirements of an improvement notice are inconsistent with the interpretation or practice of other Food Authorities, the Food Authority should have regard to the views of the “home authority” as defined in the LACORS Home Authority Principle.

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

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

3.2.3.8: Other Guidance

Further guidance on the use and preparation of improvement notices has been issued by LACORS. **[DN: LACORS to update their guidance in this area]**

CHAPTER 3.3: PROHIBITION PROCEDURES

3.3.1: Introduction

This Chapter deals first with the use of hygiene prohibition procedures and remedial action procedures under Regulations 9, 10 and 11 respectively of the Food Hygiene (England) Regulations 2005 and the associated voluntary closure procedures. It then deals with the prohibition procedures of Section 11 and Section 12 of the Food Safety Act, the associated voluntary closure procedures and the prohibition of persons under Section 11 of the Act, in connection with food standards issues.

3.3.2: The Food Hygiene (England) Regulations 2005

3.3.2.1: Regulation 9 (Hygiene Prohibition Order) Procedures

A Magistrates Court may make a hygiene prohibition order under Regulation 9 of the Food Hygiene (England) Regulations 2005 to:

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

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

The Court will make an order if it considers that the premises, equipment, treatment and/or process fulfils the health risk condition as per Regulation 9(2).

The Court may also make an order prohibiting a food business operator from managing any food business.

3.3.2.2: Regulation 10 (Hygiene Emergency Prohibition) Procedures

An authorised officer may serve an emergency hygiene prohibition notice under Regulation 10 of the Food Hygiene (England) Regulations 2005 if the health risk condition is fulfilled in respect of a food business and there is an imminent risk of injury to health. The effect of the notice is to immediately close the premises, or prevent the use of equipment, or the use of a process or treatment. Unlike Regulation 9, these powers cannot be used against a person.

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

3.3.2.3: Regulation 11 (Remedial Action Notices)

See paragraph 5.2.3 of the Code of Practice.

3.3.3: The Food Safety Act 1990

3.3.3.1: Section 11 Procedures

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

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

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

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

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

3.3.3.2: Section 12 Procedures

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

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

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

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

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

3.3.4: “Health Risk Condition” / “Imminent Risk of Injury to Health”

Regulations 9 and 10 of the Food Hygiene (England) Regulations 2005 can only be used if the “health risk condition” is fulfilled. In respect of Regulation 9, there must be a risk of injury to health and in respect of Regulation 10 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 10 of the Food Hygiene (England) Regulations 2005 and Section 12 of the Food Safety Act 1990, the word “imminent” qualifies the word “risk”. There must always be an imminent risk of injury to health before a hygiene emergency prohibition notice or emergency prohibition notice can be served. It is the risk of injury that must be imminent. The injury itself may occur sometime in the future, but it is essential to show that it could occur for the action to succeed. Not everyone exposed to the risk of injury will actually suffer the injury. It is the exposure to the risk of injury that enables action to be taken.

Such circumstances may exist in relation to food hygiene if, for example, conditions in premises, or a defective process or treatment, carries a high risk of causing foodborne infection, e.g. cases of botulism associated with an ingredient of yoghurt.

Foods containing potentially harmful levels of pathogenic micro-organisms represent an imminent risk and should be seized or detained under Regulation 23 of the Food Hygiene (England) Regulations 2005 by using Section 9 of the Food Safety Act 1990. However, the process or treatment which exposed the food to this microbiological contamination should be dealt with under Regulation 10 of the Food Hygiene (England) Regulations 2005.

Such circumstances may exist in relation to food standards and use of the Food Safety Act 1990 if, for example:

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

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

The criteria for action still depend on the conditions in Regulation 9(2) of the Food Hygiene (England) Regulations 2005 and Section 11(2) of the Food Safety Act 1990 being met, i.e. that either the construction or condition of the

premises, or any equipment or the use of any process or treatment involves a risk of injury to health.

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

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

In the cases of Regulation 10 of the Food Hygiene (England) Regulations 2005 and Section 12(2) of the Food Safety Act 1990, the application is by the Food Authority and hence it bears the onus of proof and the persuasive burden. The necessary evidential requirements are respectively set out in Regulation 9(3) and (4) and Regulation 10(1) and (4) of the Food Hygiene (England) Regulations 2005 and Sections 11(3) and (4) and 12(1) and (4) of the Food Safety Act 1990.

Further guidance can be found in Paragraph 3.3.9.

3.3.5: 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 expertise⁵.

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

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

3.3.6: 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

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

business proprietor undertook to get a team of contract cleaners to improve the position during the night.

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

3.3.7: Issuing the Notice or Order

A hygiene emergency prohibition order, a hygiene prohibition order, an emergency prohibition order or a 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 emergency prohibition notice or order, a hygiene prohibition order, an emergency prohibition notice or order or a 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.

3.3.8: Methods of Serving the Notice or Order

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

The authorised officer may, if necessary, consult with the Justices' Clerk to see if it would be possible to serve the order before the proprietor leaves the Court.

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 of the business for information in advance of its formal service, but a hard copy must follow for it to be properly served.

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

Immediately the document has been legally served by one of the methods mentioned in Regulation 28 of the Food Hygiene (England) Regulations 2005 or Section 50 of the Food Safety Act 1990, the prohibition on the use of the premises, or equipment for the purposes of any food business, or a particular type of food business, or prohibition on a process or treatment, becomes effective under the order. The hygiene emergency prohibition notice or emergency prohibition notice then ceases to have effect. The start of the prohibition does not depend on the document being received.

3.3.9: Evidence Required

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

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

Although authorised officers do not need to be accompanied by a witness, there may be occasions when visual reports are of particular relevance and there would be benefits in matters being witnessed.

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

3.3.10: Prohibition Orders

During an inspection of premises prior to a Court hearing for an offence under processing or hygiene regulations, the authorised officer may discover that the matter(s) giving rise to the prosecution has either not been removed or has been removed but has recurred.

If the food business operator / food business proprietor is convicted, the Court's attention may be brought to the provisions of Regulation 9(1) of the Food Hygiene (England) Regulations 2005 or Section 11(1) of the Food Safety Act 1990 in order that the Court may consider making a hygiene prohibition order or prohibition order on the premises, process or equipment, thus ensuring that the risk to health is removed.

3.3.11: Prohibition of a Person

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

Circumstances where such action may be appropriate include repeated offences such as failure to clean, failure to maintain equipment, blatant disregard for health risks, or putting health at risk by knowingly using unfit food.

3.3.12: Application to the Court

Some Food Authorities have authorised officers under Section 223 of the Local Government Act 1972 to represent the Food Authority in proceedings before the Magistrates Court.

Where such an arrangement does not exist, the Food Authority should try to agree procedures. The Food Authority should discuss a detailed programme of formal action with its litigation solicitor and with the clerk of the local Magistrates Court and should clarify details of local Court practice to try and resolve potential difficulties of obtaining Court time at short notice. This could be initiated by informal contact with the Magistrates Clerk's Office to ensure that, if at all possible, applications for emergency prohibition orders are expedited.

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

3.3.13: 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 9(1) of the Food Hygiene (England) Regulations 2005 or Section 11(1) of the Food Safety Act so that a hygiene prohibition order or prohibition

order is to be considered, it is important that suitable evidence is gathered to produce to the Court.

3.3.14: Information to be Given to the Court

Information that the Court may require includes:

- The state of the premises or equipment, both at the time of the offence and at the time the premises were re-inspected prior to the hearing;
- Evidence that food business operator / food business proprietor had been involved in the commission of offences elsewhere, which tended to show weaknesses in management (the authorised officer may have to investigate to ascertain whether the operator / proprietor [or manager] 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.

Information on a trader's previous record may be held in the Office of Fair Trading's (OFT) Central Register of Convictions⁶, particularly if the trader operates from multiple sites in different Food Authority areas. Food Authorities are encouraged to use the register to discover relevant history when considering a prosecution or formal caution, and to notify the OFT of successful prosecutions and formal cautions so that they may be included in the Register.

3.3.15: Prohibition Orders / Notices and Hygiene Prohibition Orders / Notices

3.3.15.1: Affixing the Notice or Order on the Premises

Regulations 9 and 10 of the Food Hygiene (England) Regulations 2005 and Sections 11 and 12 of the Food Safety Act 1990 direct that as soon as practicable after the making of an order or the service of a notice, a copy of the order or notice should be affixed in a conspicuous position on the premises by the Food Authority.

The purpose of this is to inform the public, which includes anyone who may use the premises or equipment, that premises have been closed or a process or piece of equipment prohibited from being used.

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

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

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.

3.3.15.2: Unauthorised Removal or Defacement of Notices or Orders

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

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

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

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

Where an order has been removed or defaced the officer should start proceedings under Section 63(3) of the Magistrates Courts Act 1980 for disobedience to the Court's requirement that it should not be removed or defaced. Such proceedings can be started by making a complaint in writing to the Court, stating when the order was made, what its terms were and how a requirement of the order had been broken.

3.3.16: 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.

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 9(7) or 10(8) of the Food Hygiene (England) Regulations 2005, or Section 11(6) or 12(8) of the Food Safety Act 1990 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 9(7)(b) or 10(9)(b) of the Food Hygiene (England) Regulations 2005, or Section 11(7)(b) or Section 12(9)(b) of the Food Safety Act 1990 for the Food Authority to issue a notification of continuing risk to health as quickly as possible. The Food Authority must give reasons why it is not satisfied that the health risk condition has been removed.

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

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

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

3.3.17: 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 9(5) of the Food Hygiene (England) Regulations 2005 or Section 11(5) of the Food Safety Act 1990, respectively. A person who knowingly contravenes a hygiene emergency prohibition notice or order or an emergency prohibition notice or order is guilty of an offence under Regulation 10(5) or (6) of the Food Hygiene (England) Regulations 2005 or Section 12(5) or (6) of the Food Safety Act 1990, respectively.

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

If the authorised officer believes that there is sufficient evidence to show that the proprietor is unlikely to respond to a summons, application should be made for a warrant rather than a summons. The Court will decide if the circumstances justify this action and may ask the authorised officer for their

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

The Food Authority should make contingency arrangements with its legal department, so that in the event of the breach of a notice or order, there is no delay in making an application before the Court.

3.3.18: Appeals: Refusal of a Food Authority to Issue a Certificate That There Is No Longer a Risk to Health

Section 37 of the Food Safety Act allows anybody who is aggrieved by a decision of a Food Authority to refuse to issue a certificate that there is no longer a risk to health to appeal by way of a complaint to the Magistrates Court. The time limit for such an appeal is one month from the date when the Food Authority gave notice of their refusal to lift the prohibition.

The recipient of a notice of refusal should clearly understand their right of appeal. The notice should therefore include, or be accompanied by, details of the right of appeal and the name and address of the relevant Magistrates Court.

3.3.19: Compensation

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

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

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

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

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

- Obligation of the operator / proprietor to mitigate their own loss;

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

CHAPTER 3.4: SEIZURE AND DETENTION

3.4.1. Introduction

This Chapter concerns the use of the detention and seizure powers in food law.

3.4.2. When to Use Detention and Seizure Powers

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

An authorised officer who has reasonable grounds for suspecting that food does not satisfy food safety requirements may, under regulation 23 of the Food Hygiene (England) Regulations 2005, use Section 9 of the Food Safety Act 1990. This permits the service of a detention of food notice to prevent the use of the food for human consumption. Alternatively, if food does not satisfy food safety requirements for other than hygiene reasons, section 9 of the Food Safety Act 1990 should be used anyway. Subject to the reason for detention, the form of document given in Annex 7 of the Code of Practice or, in the Detention of Food (Prescribed Forms) Regulations 1990⁷ should be used.

In premises subject to Regulation 853/2004 laying down specific rules for food of animal origin, where a remedial action notice has been served on the food business operator under Regulation 11 of the Food Hygiene (England) Regulations 2005, food may be detained for the purposes of examination.

These detention powers should not, however, 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. Specific Powers of Seizure and Detention for County Council Food Authorities

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

- The Colours in Food Regulations 1995⁸
- The Sweeteners in Food Regulations 1995⁹
- The Kava Kava (England) Regulations 2002¹⁰
- The Food (Jelly Confectionery) (Emergency Control) (England) Regulations 2002¹¹
- The Contaminants in Food (England) Regulations 2004¹²

⁷ SI 1990 No. 2614

⁸ as amended, SI 1995 No.3124

⁹ as amended SI 1995 No. 2133

¹⁰ as amended SI 2002 No. 3169

¹¹ as amended SI 2002 No. 931

- The Genetically Modified Food (England) Regulations 2004¹³

3.4.4. 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 paragraph 3.4.8).

3.4.5. Seizure of Food

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

3.4.6. Notice of Seizure

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

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

Notification to the owner of the food may be by personal delivery, fax, telephone, e-mail, or other rapid means of communication.

This is especially important in cases of seizure, because of the right conferred by Section 9(5) of the Food Safety Act 1990 on any person who may be liable to prosecution for selling or producing unsafe food to attend before a Justice of the Peace, to be heard and to call witnesses.

¹² as amended, SI 2004 No.3062

¹³ SI 2004 No. 2335

3.4.7. Taking Action Without Inspecting

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

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

Information from another reliable source, e.g. another Food Authority, the HPA, the CCDC, or the Agency etc. may be sufficient to enable an authorised officer to act without inspecting.

Although an inspection of the food is not legally necessary in such situations, it may nonetheless be prudent, if only for identification purposes.

3.4.8. Dealing With Batches, Lots or Consignments of Food

Article 14(2) of Regulation 178/2002¹⁴ defines unsafe food and is relevant to both the Food Hygiene (England) Regulations 2005 and the Food Safety Act 1990. Section 8(2) of the Food Safety Act 1990 deals with food that fails to comply with food safety requirements, if it is unsafe within the meaning of Article 14(2) of Regulation 178/2002.

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

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

If a whole batch, lot or consignment is detained and it subsequently becomes clear that only part of the detained food is affected and needs to be seized, the remainder of the batch etc may be released. The compensation provisions should always be borne in mind if this course of action is used.

3.4.9. Voluntary Procedures

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

The fact that food had been condemned by a Justice of the Peace would be persuasive in any prosecution, but would not in itself necessarily establish an offence. It would still be necessary for a case to be proved beyond reasonable

¹⁴ 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

doubt. In this respect certificates of analysis or examination are of particular value.

CHAPTER 3.5: TEMPERATURE CONTROL REGULATIONS

3.5.1: Introduction

This Chapter provides guidance on the enforcement of Regulation 30/ Schedule 4 of the Food Hygiene (England) Regulations 2005. Where food is required to be kept at safe temperatures, but is not covered by the aforementioned Regulation, Annex II Chapter IV, (7) and Chapter IX, (5), (6) and (7) of Regulation 852/2004¹⁵ would apply, where appropriate. Other precise temperatures for foods of animal origin in certain situations are given in Regulation 853/2004.

3.5.2: General Approach to Temperature Checks

Stage 1 - Air Temperature Monitoring

Air temperature monitoring provides an indication of the performance of a refrigeration system over time, and a single reading at any one time will not necessarily be an indication of product temperature. Air temperature monitoring records are an indication of temperature history, including defrost cycles, door openings, breakdowns etc. They should be regarded as a guide to how a particular system is functioning.

Stage 2 – Between-pack Testing

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

It is important to ensure good thermal contact between the product and the probe when taking between-pack measurements. A total tolerance of +2.8°C (0.8°C as specified for instrument accuracy and 2°C for the limitation of the methodology) should be allowed. Care should be taken to allow time for the reading to stabilise, and to ensure that the temperature reading relates to the product, not the surrounding air, which can happen if the probe is not properly sandwiched between the packs. Testing should be conducted with the minimum of disturbance to the product or its temperature-controlled environment, particularly the airflow patterns in retail display cabinets. For products within an outer casing it will be necessary to open the casing and insert the temperature probe between packs.

Not all packs or packaging materials are suitable for between-pack testing. Irregularly shaped packs where good thermal contact is not possible, packaging materials that act as an insulator and products in cartons or bubble packs where large air spaces exist are all examples where a between-pack temperature measurement may not be sufficiently accurate to give an indication of product temperature. In such instances it may be necessary to proceed directly to a destructive temperature measurement.

¹⁵ Regulation (EC) No. 852/2004 on the hygiene of foodstuffs

Stage 3 - Product Testing (Destructive)

If a “stage 2” temperature measurement has not been possible, or there is reasonable doubt after a “stage 2” test about compliance with temperature requirements, it will be necessary to progress to destructive testing.

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

When a “stage 3” measurement is being carried out, insertion of the temperature probe into the food may render the food unsaleable. In such circumstances, the authorised officer should consider purchasing the food in question.

The selection of items to be tested is at the discretion of the officer. However, if “stage 2” testing has been carried out and there appears to be a breach of the relevant temperature requirements, it should not normally be necessary to select large numbers of items for “stage 3” testing.

In the first instance, items should be taken for “stage 3” testing from the warmest part of the refrigeration system. This can usually be identified using thermochromic (liquid crystal) strip temperature indicators. Although these do not give an accurate temperature reading, they can provide a useful guide to relative temperature distribution within a refrigeration system.

3.5.3: Taking Temperature Measurements

The temperature of a product should not be prejudiced by, for example, opening the doors in a vehicle too often or for too long; disturbing the air curtain in a chill cabinet, or removing the food from a refrigerated environment for long periods.

Any opened cases or cartons should be re-sealed and appropriately labelled or marked with the date and time of the inspection; the name of the person who opened it, and the name of the Food Authority. This is to show that the case or carton was opened for an official inspection and removes any suspicion of malicious tampering.

3.5.4: Tolerances

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

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

3.5.5: Checking and Calibration of Enforcement Measuring Thermometers etc

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

The record of such a check should be referenced to the instrument’s certificate of calibration and include serial numbers of the instrument and any interchangeable probes.

If a reference thermometer is not available, the sensor can be checked in a wet ice mixture. In this case, the system should be calibrated at 0°C. The temperature of wet ice from distilled water is 0°C. Drinking water with a salt content of 0.1% will only depress the melting point to -0.06°C. Therefore, in most cases drinking water can be used to make the ice for the checking procedure. Ice should be broken up into very small pieces, packed into a wide-necked vacuum flask, wetted with cold water and stirred. The sensor should be placed at the centre of the flask at a depth of at least 50mm and agitated frequently and the temperature read after three minutes when stabilised. The read-out instrument can be checked separately using calibration attachments at two or three different temperatures. The combination of checking the system at 0°C with that of checking the instrument should ensure accuracy at higher temperatures.

3.5.6: Pre-cooling of Instruments

The thermometer or other temperature measuring device and the penetration probe should be pre-cooled before being used to measure product temperature to ensure that instruments are as close as possible to the temperature of the product being measured. Pre-cooling reduces the likelihood of a rise in product temperature due to the temperature of the probe and the action of making the hole and can usually be done by leaving the instruments and probe in the same temperature controlled environment as the sample for about 10 minutes. Provided there is no significant rise in the temperature of the instrument or probe, subsequent measurements can be made after a much shorter pre-cooling period.

3.5.7: Preparation of Samples for Temperature Measurement

Only temperature measuring probes that are specifically designed for the purpose should be used to make a hole in the product. If the probe is not designed for this purpose a separate pre-cooled product penetration implement should be used. The diameter of the hole should provide a close fit to that of the probe and its depth will depend on the type of product being tested (as described below).

3.5.8: Measurement of Product Temperature

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

- (a) Where the product dimensions allow, insert the pre-cooled probe to a depth of at least 2.5cm from the nearest outside surface of the product.
- (b) Where (a) is not possible the probe should be inserted to a minimum depth from the surface of at least 3 times the diameter of the probe. With some products, because of their small size, greater care has to be taken to avoid excessive rises in product temperature from unnecessary handling of the sample.

Certain foods, because of their size or composition, cannot be penetrated satisfactorily to determine their internal temperature. In these cases, the internal temperature of the food package should be determined by insertion of a suitable pre-cooled sharp-stemmed probe to the centre of the pack to measure the temperature in contact with the food.

It may not always be possible to determine the internal product temperature accurately, especially of fragile or open-textured products. The temperature of such products should be measured by carefully removing the product from its packaging and firmly sandwiching a pre-cooled flat-headed probe between two items of product.

The temperature reading should not be recorded until it has stabilised.

3.5.9: Equipment Used for Chilled Product Temperature Measurement

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

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

A dry cell battery, not mains electricity, should power the measuring instrument. The instrument should incorporate a method of checking the battery voltage to indicate when replacement or re-charging is necessary. The design of the probe depends on the type of temperature measurement:

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

CHAPTER 3.6: QUICK FROZEN FOODSTUFFS

3.6.1: Introduction

This guidance gives informal, non-statutory advice to Food Authorities on checking temperatures and temperature monitoring systems when enforcing the Quick-frozen Foodstuffs Regulations 1990¹⁷ (the Regulations) as amended.

The Code of Practice requires authorised officers to adopt a staged approach to enforcement of the Regulations, and this is described in this Chapter.

A quick-freezing process can be regarded as any form of accelerated freezing such as blast freezing, plate freezing, liquid nitrogen freezing, etc.

3.6.2: Division of Enforcement Responsibility Between County and District Councils

Regulation 7.2 makes each Food Authority responsible for enforcement of the Regulations within its area. The Regulations are primarily concerned with the physical quality of food, which is generally the responsibility of the County Council Food Authorities. However, in the interests of efficiency it is expedient for District Council Food Authorities to be involved in certain aspects of the enforcement of the Regulations.

Parts of Schedule 1 of the Regulations are concerned specifically with the safety and quality of raw materials and the nature of the quick-freezing process. The conditions laid down concern both County and District Council Food Authorities who should liaise closely over the enforcement of these aspects of the Regulations. In particular they should liaise over the programme of inspections of premises where quick-frozen foodstuffs are processed and packaged. During such inspections the provisions concerning equipment used as required by Regulation 6 should also be enforced.

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

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

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

¹⁷ As amended, SI 1990 No. 2615

3.6.3: Temperature Requirements

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

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

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

3.6.4: Staged Approach to Enforcement

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

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

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

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

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

3.6.5: Air Temperature Checks

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

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

than air temperatures. Enforcement action should cease at this point if the air temperature check is satisfactory.

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

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

3.3.15.1: 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.

3.3.15.2: Air Temperature Checks: Transport

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

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

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

International transport of quick-frozen foodstuffs is sometimes achieved by conveying the product in insulated containers that have to be connected to

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

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

3.3.15.3: Air Temperature Checks: Retail Display Cabinets

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

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

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

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

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

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

3.6.6: Non-destructive Temperature Checks

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

Enforcement action should cease if the result of the non-destructive temperature check is satisfactory.

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

Not all packs or packaging materials are suitable for this type of measurement. Irregularly shaped packs where good thermal contact is not possible, packaging materials that act as an insulator and products in cartons or bubble packs where large air spaces exist are all examples where a non-destructive between-pack temperature measurement may not be sufficiently accurate to be indicative of product temperature. If the packaging of the food is not suitable for this type of measurement it may be necessary to proceed directly to a destructive temperature measurement.

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

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

Care should be taken to allow the reading to stabilise whilst ensuring that the temperature recorded is not that of the surrounding air, e.g. because the probe is not properly sandwiched between the packs. For products within an outer casing it will be necessary to open the casing and insert the temperature probe between packs.

3.6.7: Destructive Temperature Measurement

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

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

If internal product temperature measurement is to be undertaken, both the probe and the product penetration device should be pre-cooled. Only

temperature measuring probes that are specifically designed for the purpose should be used to make a hole in the sample.

In other cases a separate pre-cooled product penetration implement must be used. Pre-cooling minimises any local rise in product temperature due to the action of making the hole and can usually be done by leaving the instruments and probe in the same temperature controlled environment as the sample for about 10-15 minutes. Provided there is no significant rise in the temperature of the instrument or probe subsequent determinations can be made with a much shorter pre-cooling period.

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

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

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

3.6.8: Sampling

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

3.6.8.1: Sampling: Cold Stores

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

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

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

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

3.6.8.2: Sampling: Transport

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

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

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

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

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

"Choose four samples from amongst the following critical points:

- top and bottom of the consignment adjacent to the opening edge of doors,
- top rear corners of the consignment (at a point as far away from the refrigeration unit as possible),
- centre of the consignment,
- centre of the front surface of the consignment (as close as possible to the refrigeration unit),
- top and bottom corners of the front surface of the consignment (as close as possible to the return air [inlet] to the refrigeration unit)."

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

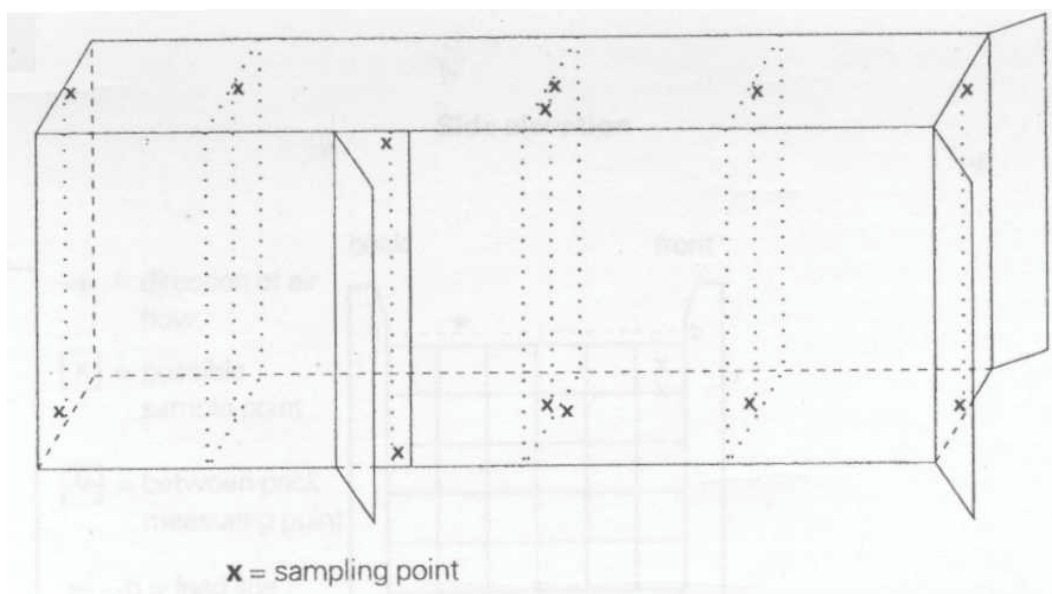


Figure 1. Sampling points for vehicles with more than one set of doors

3.6.8.3: Sampling: Retail Display Cabinets

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

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

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

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

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

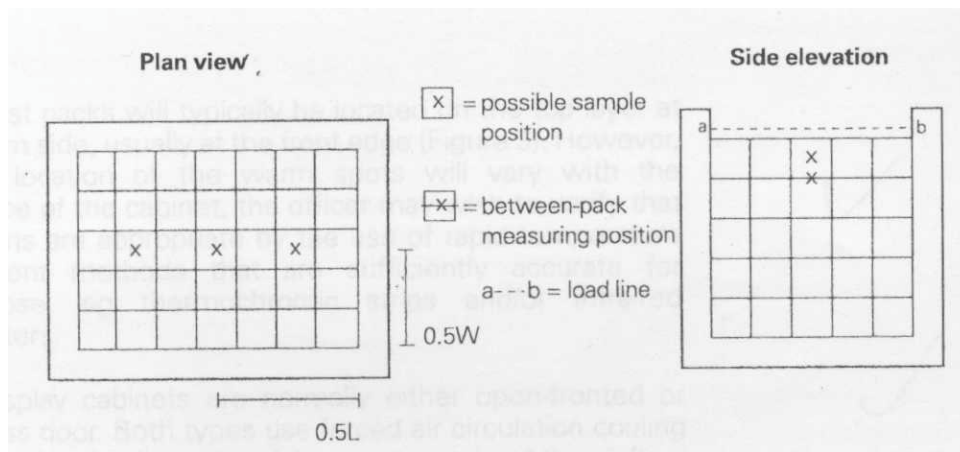


Figure 2. Horizontal cabinet – contact cooling

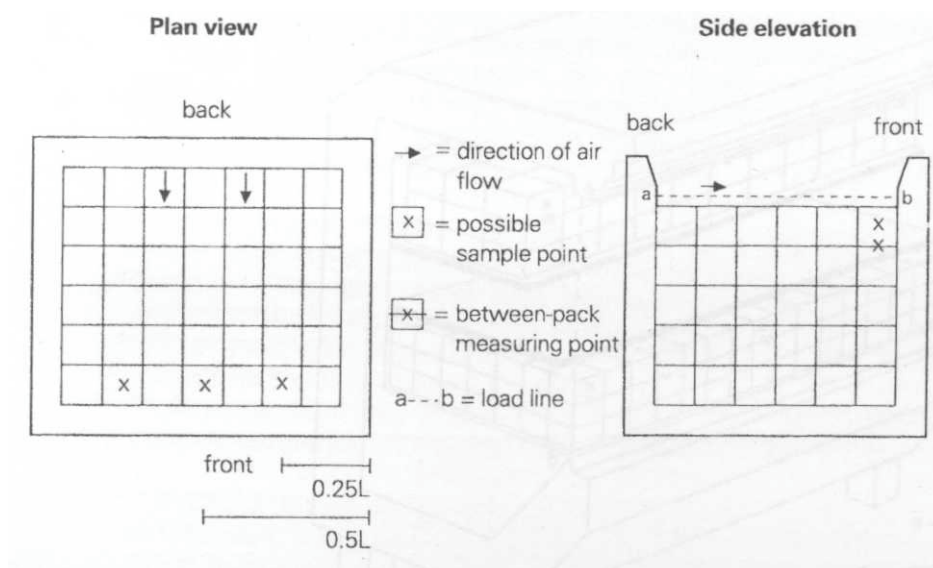


Figure 3. Horizontal cabinet – forced air circulation

Vertical display cabinets are normally either open-fronted or have a glass door. Both types use forced-air circulation cooling although design details vary and the exact pattern of the air flow will depend on the positioning of the fans. With open-fronted cabinets the warmest positions will generally be at the front of the top shelf (Figure 4). It is much more difficult to generalise the equivalent positions for glass door cabinets since the frequency of door openings and the length of time they are left open throughout the day will greatly affect the temperature of the food. Typically, packs closest to the door, which are exposed to radiant heat and furthest from the cooling source, will be the warmest (Figure 5). The use of rapid temperature measurement methods can aid the identification of "warm spots".

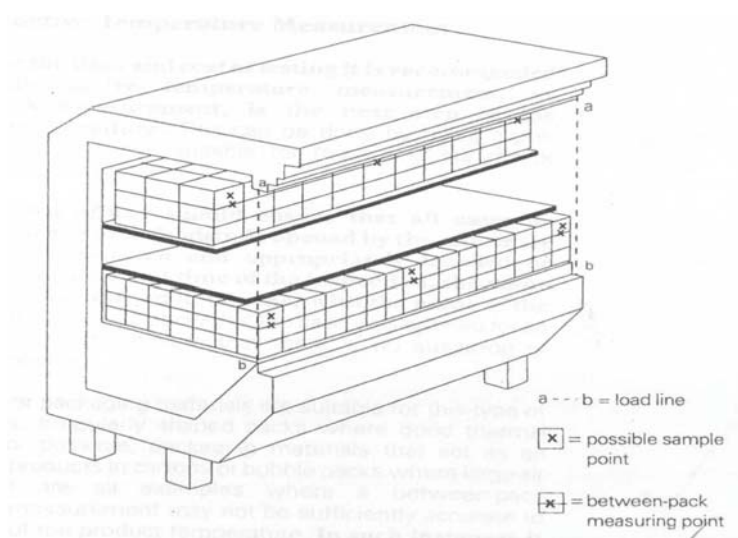


Figure 4. Open vertical cabinet

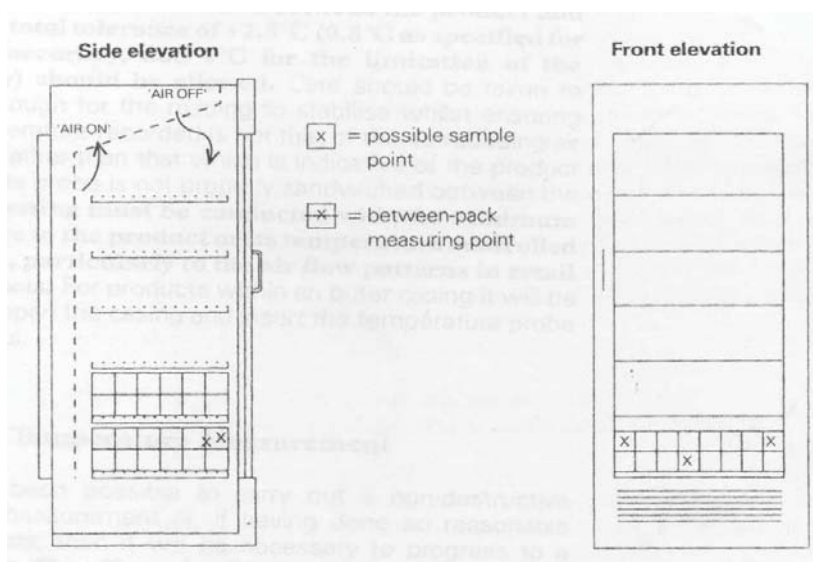


Figure 5. Vertical glass-fronted cabinet

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

3.6.9: 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 (eg green peas) cannot be drilled to determine their internal temperature. In these cases, the internal temperature of the food package should be determined by insertion of a suitable pre-cooled sharp-stemmed probe to the centre of the pack to measure the temperature in contact with the food.

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

3.6.10: Dealing with Food which is at a Higher Temperature than the Prescribed Frozen Temperature

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

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

3.6.11: General Specification for Temperature Measuring Instruments

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

Temperature measuring instruments that are used to gather evidence for a prosecution should be properly calibrated by a scientifically valid method and

have a current certificate of calibration. This may include the use of a calibration tank, provided the tank itself has a current certificate of calibration.

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

- (a) The response time should achieve 90% of the difference between the initial and final reading within three minutes;
- (b) The instrument (readout and probe) must have an accuracy of $\pm 0.5^{\circ}\text{C}$ within the measurement range -20°C to $+30^{\circ}\text{C}$;
- (c) The measuring accuracy must not be changed by more than 0.3°C during operation in the ambient temperature range -20°C to $+30^{\circ}\text{C}$;
- (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;
- (h) The temperature-sensitive part of the measuring device must be so designed as to ensure good thermal contact with the product;
- (i) The electrical equipment must be protected against undesirable effects due to the condensation of moisture.

CHAPTER 3.7: WASTE FOOD

3.7.1: Introduction

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

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

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

3.7.2: Inspection of Food Businesses

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

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

Checks should verify that threats to human or animal health which can arise from the illegal disposal of food waste, are effectively controlled by proper disposal in accordance with the requirements of the relevant legislation.

3.7.3: Major Investigations

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

The investigation of such cases may have serious resource implications for Food Authorities, both in terms of time and other resources. Nevertheless, it is vitally important that the very serious risks to human health and animal health that such cases may involve are brought to the attention of the relevant enforcement authority and investigated without delay, and that all necessary steps are taken to deal with them thoroughly.

The resources required may impact on a Food Authority’s ability to carry out its routine inspection and enforcement programme. If such circumstances arise, it is important that the Food Authority contacts the Food Standards Agency as soon as practicable.

The Agency and the Food Authority will then be able to discuss options, including whether support may be available, or whether the Food Authority’s

inspection programme should be re-prioritised to ensure that inspections of higher-risk premises are maintained.

CHAPTER 3.8: DISTANCE SELLING/MAIL ORDER

3.8.1: Introduction

This Chapter provides guidance to Food Authorities on the enforcement of food law in relation to the distance selling of food, and information on other generic legal requirements that relate to distance selling.

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

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

3.8.2: Location of the Seller

The ability of Food Authorities to enforce food law in relation to the distance selling of food depends on where the seller is based.

It is important to bear in mind that food bought via an internet website involves a sale via the world wide web, and that the seller could therefore be located anywhere in the world.

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

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

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

3.8.3: Location of the Buyer

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

3.8.4: Distance Selling of Food from the UK

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

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

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

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

Food Authorities should include an assessment of relevant food hygiene, safety, advertising, compositional, and labelling matters in programmed inspections of businesses involved in the distance selling of food from the UK in their areas.

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

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

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

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

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

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

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

3.8.6: Distance Selling of Food from Third Countries

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

¹⁸ SI 2003 No. 2075

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

3.8.7: Generic Distance Selling Legislation

Generic law regulating distance selling in the UK is set out in the Consumer Protection (Distance Selling) Regulations 2000¹⁹, which implement Council Directive 97/7/EC in the UK.

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

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

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

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

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

3.8.8: Other References

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

¹⁹ SI 2000 No. 2334

CHAPTER 3.9: BOTTLED WATERS

3.9.1: Introduction

This Chapter provides guidance to Food Authorities on enforcement of the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999²⁰ (the Regulations).

The Regulations were amended by The Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) (England) Regulations 2003²¹. Scotland, Wales and Northern Ireland have their own set of similar amending legislation.

The Regulations transpose into UK legislation the provisions of:

- Council Directive 80/777/EEC, as amended by Directive 96/70/EC, relating to natural mineral water and spring water;
- Council Directive 80/778/EEC covering spring waters and bottled waters, as amended by Council Directive 98/83/EC, relating to the quality of water for human consumption.

A further amendment, The Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) (England) Regulations 2004²² came into force on 5th April 2004. Scotland, Wales and Northern Ireland have their own set of similar amending Regulations.

These Regulations transpose into national legislation:

- Commission Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters.

3.9.2: Natural Mineral Waters

The Regulations require each UK natural mineral water source to be recognised by the Food Authority for the area in which the source is located.

Once recognition has been granted, the Food Authority is required to make periodic checks to ensure that the source remains free from all risk of pollution and that the composition of the water remains stable.

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

A list of recognised UK sources is available on the Agency's website at www.food.gov.uk/foodindustry/mineralwaters

²⁰ SI 1999 No. 1540

²¹ SI 2003 No. 666

²² SI 2004 No. 656

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

3.9.3: Recognition of Natural Mineral Waters

Applications for recognition of natural mineral waters in Great Britain are submitted in writing to the Food Authority. The Food Authority is required to assess all the information required by the Regulations.

Food Authorities must notify the Agency whenever they recognise a new natural mineral water, withdraw recognition, or approve a change in the name of the source or trade description of a natural mineral water.

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

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

3.9.4: Labelling of Natural Mineral Waters

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

3.9.5: Spring and Other Bottled Drinking Water

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

Spring water is normally extracted from a private water supply and is, therefore, also subject to the requirements of the Private Water Supplies Regulations 1991²³, which specify the frequency of local authority monitoring of a range of compositional and microbiological parameters.

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

3.9.6: Labelling of Spring and Other Bottled Water

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

²³ SI 1991 No. 2790

Bottled drinking waters are subject to the general labelling requirements of the Food Labelling Regulations 1996²⁴.

²⁴ as amended, SI 1996 No. 1499

CHAPTER 3.10: IMPORT OF FOOD FROM THIRD COUNTRIES

See Annex 9 of this guidance.

SECTION 4: INSPECTIONS

CHAPTER 4.1: INSPECTIONS

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

CHAPTER 4.2: THE INSPECTION

4.2.1: Introduction

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

4.2.2: Notice of Inspection

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

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

4.2.3: Co-ordination of Inspections

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

Wherever it is practicable and appropriate to do so, Food Authorities should co-ordinate inspections of food premises. The inspection team should include all the expertise necessary to inspect the premises in question and where appropriate further experts in particular fields of food technology²⁵.

4.2.4: Shellfish Identification Marks

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

²⁵ The Institute of Food Science and Technology maintains a list of experts in particular fields.

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

CHAPTER 4.3: INSPECTION OF APPROVED ESTABLISHMENTS – ADDITIONAL REQUIREMENTS

All relevant information is contained in the Code of Practice.

CHAPTER 4.4: INSPECTION OF SHIPS AND AIRCRAFT

4.4.1: Introduction

This Chapter supplements the information supplied in the corresponding Chapter in the Code of Practice to enable authorised officers to consider additional aspects relating to the inspection of ships and aircraft. It also provides inspection templates, which may be adapted, where appropriate, provided that the procedures outlined in the Code are not overlooked.

4.4.2: General

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

Examples include:

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

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

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

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

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

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 line or it could be a company hired to operate the food business. Authorised officers will need to establish who the operator / proprietor is in each case.

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

4.4.3: Catering Waste

The disposal of international catering waste to landfill is regulated by the Products of Animal Origin (Third Country Imports) (No. 4) Regulations 2004²⁶. DEFRA has identified significant risks to animal health if this waste is not dealt with effectively at landfill. Specific measures are needed to ensure that disease is not introduced into the UK from landfill sites, which receive this waste. A mechanism for suspending or amending the conditions of a landfill site approved to deal with such waste is in place, in the event that the conditions of approval are not observed.

4.4.4: Other Issues: Aircraft

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

Such reports, where available, should form part of the authorised officer’s initial checks. Authorised officers should also give consideration, where appropriate, to these Guidelines, which were first published in February 2003²⁷.

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

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

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

²⁶ SI 2004 No. 3388

²⁷ www.ifcanet.com/teams/foodsafety

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

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

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

4.4.5: Other Issues - Ships

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

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

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

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

Examples of relevant documentation:

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

4.4.6: Other References

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

4.4.7: Inspection Templates

Aircraft - Food Safety Inspection Report Form

Local Authority:

Airport:

Name of Authorised Officer:

Designation:

Tel. No:

Date of Inspection:

Time of Inspection

Flight No:

Airline Company or Airline operating the aircraft:

Address:

Airline Tel. No:

Airline Person interviewed/Designation:

Aircraft Reg. No:

Aircraft type:

Home Authority:

1. Date of previous inspection:
(if known)

2. Return catered: Yes/No

3. High risk foods served: Yes/No

4. Hazard Analysis
(✓ tick box if satisfactory)

☐

5. Training/Exclusion procedure ☐

6. Pest control

☐

7. Time/Temp control (outbound) ☐

8. Temp control (return catering)

☐

9. Cooking/Reheating ☐

10. Galley hygiene/storage areas

☐

11. Cleaning/Waste control ☐

12. Toilets

☐

13. Potable Water supply ☐

14. Airline sampling (food/water)

☐

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

Comments (including any samples procured)

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

Satisfactory Outcome

☐

Follow-up With Airline HQ/HA

☐

Prosecution ☐ Emergency Prohibition Notice ☐ Formal ☐
Detention/Seizure

Improvement Notice ☐ Letter to follow ☐ Verbal advice ☐
(not to cabin crew)

Signature of Officer

Signature of Person interviewed

Ships - Food Safety Inspection Report Form

Port Health Authority:

Name of Authorised Officer:

Address:

Telephone No:

Name of ship:

Type:

Home Port/Flag State:

Year of build:

Home Authority:

IMO or Official No:

Date/Time of Inspection:

Captain/Officer in Charge:

Owner/Agent:

Address of UK Owner/Agent:

Parts of vessel inspected:

Documents/Certificates scrutinised:

Hazard analysis:

Deratting/Deratting Exemption:

Temperature records:

Other pest control records:

Cleaning schedules:

Drinking water:

Other water:

Staff training records:

Other Records:

Garbage management plan:

Food samples taken:

Drinking water samples taken:

Drinking water quality monitoring/maintenance:

Other water:

Summary of Findings:

Satisfactory:

Verbal advice given:

Leaflets/advisory letter:

Letter to follow:

Notice to follow:

Person interviewed:

Officer's name:

Officer's signature:

If you require more information, please contact the inspecting officer on:

(TOP COPY OF THIS SELF-CARBONATING INSPECTION FORM AND A SELF-CARBONATING SECOND PAGE SHOULD BE AVAILABLE TO PROVIDE SPECIFIC DETAILS OF ANY DEFICIENCIES FOUND. THESE PAGES SHOULD BE LEFT WITH THE CAPTAIN)

CHAPTER 4.5: ACTION FOLLOWING INSPECTION

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

SECTION 5: PRODUCT-SPECIFIC ESTABLISHMENTS

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

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

CHAPTER 5.2: ENFORCEMENT OPTIONS IN PRODUCT-SPECIFIC PREMISES

All relevant material on enforcement options in product-specific premises is contained in the Code of Practice.

CHAPTER 5.3: MATTERS RELATING TO SHELLFISH

Relevant material on shellfish is contained in the Code of Practice and at Annex 7 of this guidance.

CHAPTER 5.4: MATTERS RELATING TO FRESH MEAT

Relevant material relating to fresh meat is contained in the Code of Practice and at Annex 3 of this guidance.

SECTION 6: SAMPLING²⁸

[DN: A draft Commission Regulation on microbiological criteria for foodstuffs is currently under discussion with a view to this Regulation coming into force on 1 January 2006. This part of the Code will be reconsidered after this Regulation has been finalised.]

6.1.1: Introduction

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

6.1.2: Procurement of Samples

The Food Hygiene (England) Regulations 2005 and the Food Safety Act 1990 allow samples to be procured either by “purchasing” or “taking”. The choice is at the discretion of the authorised officer, having regard to the policy of the Food Authority. Where the quantity or frequency of sampling gives rise to significant financial consequences for the owner of the food, the Food Authority should offer an ex-gratia payment if samples are not purchased. The officer should give the owner a receipt for, or a record of, all samples the officer has taken. If enforcement action is anticipated following microbiological examination or chemical analysis the sampling officer should purchase the sample.

6.1.3: Certificate by Public Analyst or Food Examiner

A Public Analyst or Food Examiner is required to analyse or examine samples as soon as practicable and, depending on local arrangements, to give the officer who submitted the sample a certificate specifying the result. Food Authorities should discuss with the Public Analyst or Food Examiner how these requirements are to be met, including the means by which results that indicate a significant risk to public health, or where legislative deadlines apply, such as water in poultry, can be notified without delay.

6.1.4: Avoiding Contamination

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

6.1.5: Samples for Analysis

6.1.5.1: Quantity of Samples for Analysis

²⁸ See also “Food Standards and Feeding Stuffs Sampling, Practical Guidance for Enforcement Officers” by the Food Standards Agency – published May 2004.

²⁹ SI 1990 No. 2463

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.

6.1.5.2: Containers for Samples for Analysis

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

The contained final parts should each be secured with a tamper evident seal and labelled, specifying the name of the food, the name of the officer, the name of the Food Authority, the place, date and time of sampling and an identification number. Where necessary, it should then be placed in a second container, such as a plastic bag, which should be sealed in such a way as to ensure that the sample cannot be tampered with. A copy of the food label if available and any other relevant details should be submitted to the Public Analyst with a final part.

6.1.5.3: Transport and Storage of Samples for Analysis³⁰

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 Government Chemist.

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

6.1.5.4: Samples which Present Difficulties in Dividing into Parts

An exception to division into three parts applies where the authorised officer is of the opinion that division of the sample is either not reasonably practicable, or is likely to impede proper analysis. Regulation 6(4) of the Regulations allows

³⁰ The Campden and Chorleywood Food Research Association publication "Guidelines for the preservation of official samples for analysis" includes further guidance.

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 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.

6.1.5.5: Certificates of Analysis

The owner of the food and any person who has received a final part and/or a notice in accordance with paragraph 6.1.7 of the Code of Practice is entitled, on request, to a copy of the certificate of analysis.

6.1.6: 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.

6.1.6.1: 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.

6.1.6.2: Handling of Samples for Examination

Full traceability in the taking and handling of the sample should be ensured, including the identity of those who have had dealings with the sample, and what they did with it. Samples of non-prepacked food, or from opened cans or packets of food, should be first placed in sterile, leak-proof containers or disposable sterile plastic bags. Disposable sterile plastic sampling bags should be sealed securely after filling, so that they cannot leak or become contaminated during normal handling. Advice should be sought from the Food Examiner in case of doubt. In any event, liaison with the Food Examiner before samples are submitted to the laboratory will ensure correct procedures are followed.

The samples, thus packaged, should be secured with a tamper evident seal and labelled, specifying:

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

Containers that may be easily damaged, or that cannot themselves be made tamper-evident, should then be placed in a second container, such as a plastic bag, which should be sealed in a such a way as to ensure that the sample cannot be tampered with. A copy of the food label, if available, and any other relevant details should be given to the Food Examiner, e.g. food handling techniques/storage methods observed in respect of the food sampled.

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

Officers should take steps to ensure that, as far as possible, samples for examination reach the laboratory in a condition microbiologically unchanged from that existing when the sample was taken. During sampling it is vital that the sample is not contaminated by the sampling officer. Appropriate action should be taken to avoid contamination of the sample and microbial growth or death during sampling, transport and storage. The temperature of transport should be monitored and recorded.

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

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

Such specimens should be collected as soon as possible after the onset of symptoms and submitted to the laboratory with relevant individual’s details included on the container and on any accompanying documentation.

It is important that faecal specimens are transported to the laboratory as soon as possible; some important pathogens may not survive the pH changes that occur in stool specimens which are not promptly delivered to the laboratory, even if transported in a refrigerated state. Liaison with the laboratory will help ensure that the specimens receive prompt attention on their arrival.

6.1.6.4: Continuity of Evidence

Food samples are normally dealt with in a food laboratory and faecal specimens in a clinical laboratory, operating independently of the Food Authority. Laboratory personnel may therefore need to be reminded of the possibility of legal action, the need to treat food samples and faecal specimens as evidence, and to ensure the continuity of such evidence.

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

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

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

Other laboratory personnel may also be required to give evidence as to the handling of food samples and faecal specimens and the testing and examination thereof in a criminal prosecution.

Full traceability in the laboratory therefore needs to be ensured, including recording the identity of everybody who has been involved in handling and examining the sample or specimen, and the action they took. Specifically there should be a system at the laboratory for logging the sample or specimen's arrival, and its storage, which should be secure. For food samples, the temperature of storage should be such as to minimise microbial change, and be monitored using calibrated thermometer or other similar device. Continuity preservation at the laboratory is vital so that there is certainty that the result relates to the sample/specimen submitted. There must be no possibility that the result could refer to a different sample or specimen. Neither must the results raise any doubt as to their reliability or the reliability or accuracy of laboratory procedures. An individual in the laboratory should be capable of

making a sworn statement and of providing sworn oral testimony on these points.

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

6.1.6.5: Request for Examination

The officer should ensure that all relevant information is passed to the Food Examiner with the sample to ensure that the sample is subjected to the most appropriate examination and to enable the Examiner to interpret the results.

6.1.6.6: Certificates of Examination

The owner of the food and any person who been notified in accordance with paragraph 6.1.12 of the Code of Practice should, on request, be given a copy of the certificate of examination.

SECTION 7: MONITORING

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

SECTION 8: ANNEXES

ANNEX 1: GLOSSARY OF TERMS

ABPO	Animal By-Products Order 1999
BSE	Bovine Spongiform Encephalopathy
CCDC	Consultant in Communicable Disease Control
CDSC	Communicable Disease Surveillance Centre
CEFAS	Centre for Environment, Fisheries & Aquaculture Science
CIEH	Chartered Institute of Environmental Health
CPHM (CD/EH)	Consultant in Public Health Medicine (communicable disease/environmental health)
DEFRA	Department 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
EU	European Union
FLEP	Food Law Enforcement Practitioners
Framework Agreement	Framework Agreement on Local Authority Food Law Enforcement
FVO	EU Food and Veterinary Office
HA	Home Authority
HACCP	Hazard Analysis Critical Control Points
HPA	Health Protection Agency
LACORS	Local Authorities Co-ordinators of Regulatory Services
MRM	Mechanically Recovered Meat
NAWAD	National Assembly for Wales Agriculture Department
OFT	Office of Fair Trading
OPOAO	other products of animal origin
REHIS	Royal Environmental Health Institute of Scotland
SCIEH	Scottish Centre for Infection and Environmental Health
SERAD	Scottish Executive Rural Affairs Department
SFI	Sea Fish Inspectorate
Seafish	Sea Fish Industry Authority
SFPA	Scottish Fish Protection Agency
SFSORB	Scottish Food Safety Officers' Registration Board

The Agency
TSE

UKAS
VMHA

The Food Standards Agency
Transmissible Spongiform
Encephalopathy
United Kingdom Accreditation Service
Veterinary Meat Hygiene Adviser

ANNEX 2: FSA GUIDANCE ON THE REQUIREMENTS OF FOOD HYGIENE LEGISLATION

[DN: This guidance provides an overview of the new EU Food Hygiene Regulations. It is based on guidance which was issued for consultation in October 2004 and is subject to amendments in the light of the comments received. Although aimed primarily at industry, this guidance provides a comprehensive overview of the EU Hygiene Regulations and will be a useful reference for Food Authorities].

A2.1: Introduction

1.1 From 1 January 2006 food hygiene legislation will be changing. Appendix 1 gives details of the relevant EU regulations and associated national legislation. The national regulations are needed to enforce the requirements of the EU regulations. They also contain some national provisions which the EU regulations require or allow us to make.

1.2 This guidance note explains the legal requirements food businesses have to comply with and should be read together with the EU and national legislation mentioned in Appendix 1.

1.3 While this guidance is not legally binding, it does nevertheless represent the considered views of the Agency and is issued under its statutory powers for the purpose of providing advice and information to food businesses about the new food hygiene rules. But only the courts can give a definitive view on the law.

1.4 In this guidance, references in the legislation are highlighted like this. Annex B gives details of other sources of advice and information which can help you to comply with the law.

A2.2: Background

2.1 The new legislation is needed to modernise, consolidate and simplify EU food hygiene legislation. It is intended to apply effective and proportionate controls throughout the food chain, from primary production to sale or supply to the final consumer. The legislation is also intended to focus controls on what is necessary for public health protection. It clarifies that it is the primary responsibility of food business operators to produce food safely.

2.2 The legislation brings together requirements for different types of foods which were previously covered under separate specific pieces of legislation. The new legislation has a number of provisions which apply in common to different foods. The type(s) of food you handle or sell will determine the with which requirements you have to comply.

2.3 In general terms, Regulations 852/2004 and 853/2004 lay down requirements for food business operators to comply with. Regulation 852/2004 applies to all food businesses (including those operating at the level of primary production). Regulation 853/2004 applies, in addition, to food businesses handling products of animal origin. Regulation 854/2004 lays down requirements for official controls on products of animal origin and therefore sets out what those enforcing the provisions have to do.

A2.3: Scope

Do I have to comply with the EU Regulations?

3.1 The EU Regulations lay down rules for food businesses and food business operators, as defined. If you do not meet the definitions, then the EU Regulations do not apply to you.

- "Food business" means any undertaking, whether for profit or not and whether public or private, carrying out any stage of production, processing and distribution of food."
- "Food business operator" means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control." (Article 3.2 and 3.3 of Regulation 178/2002).

A further indication of what is intended to be covered is found in recital 9 of Regulation 852/2004 which says:

- "...[the Community rules] should only apply to undertakings, the concept of which implies a certain continuity of activities and a certain degree of organisation."

3.2 The scope excludes activities such as the occasional preparation of food by individuals or groups for gatherings or for sale at charitable events or where for example hairdressers offer refreshments to their customers. Such activities would still be subject to the general legal requirements relating to placing unsafe food on the market contained in the Food Safety Act 1990.

3.3 Certain other activities are also excluded from the scope of the EU Regulations:

- a) primary production for private domestic use;
- b) the domestic preparation, handling or storage of food for private domestic consumption;
- c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer; and
- d) collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen. (Article 1(2) of Regulation 852/2004).

3.4 In the case of 3.3 c), these activities are subject to the general provisions of the Food Safety Act 1990 which would make it an offence to place unsafe food on the market. In the case of eggs supplied in accordance with c), the Ungraded Eggs (Hygiene) Regulations 1990 will also continue to apply. These Regulations prohibit the direct sale of cracked ungraded eggs by the producer to the consumer on his own farm, in a local public market or by door to door selling. In the case of 3.3 d) collection centres and tanneries supplying raw materials for gelatine or collagen production do nevertheless have to be approved by the local food authority and meet certain requirements

to prevent contamination. (Annex III, Section XIV, Chapter I (5) and Section XV, Chapter I (5) of Regulation 853/2004).

3.5 Appendix 3 contains a brief guide to whether the provisions of Regulation 852/2004 apply to you and your business. In working through this, you will need to consider all the activities you undertake. Annex D is a guide to whether the provisions of Regulation 853/2004 also apply. Again, you may need to work through this for all your activities to find out how your total business may be affected. Annex G summarises the provisions of the EU regulations and the national legislation which apply to different types of food business and highlights the most significant changes from existing legal requirements.

3.6 The EU Regulations use certain terms to describe activities subject to their provisions. These terms are not defined in the EU Regulations, but nevertheless have meaning in terms of those Regulations. Therefore, we cannot define them (and so give them a different meaning) in national legislation, nor can we offer an absolute definition of what they mean in guidance. We are, however, able to set out the way in which we consider the terms should be interpreted, in respect of different situations. These interpretations are set out in Annex H.

A2.4: Requirements of Regulation 852/2004

4.1 Under Regulation 852/2004, primary producers are subject to different requirements than are other types of food business. If you are a farmer, fisherman or a hunter of wild game then you are a 'primary producer'. The requirements covering primary production are described in Annex F. The provisions which apply to all other food businesses are discussed in more detail below.

A2.5: Registration

5.1 Food business operators must register their establishments (i.e. each separate unit of their food businesses, which includes game larders and collection centres) with the relevant competent authority. (Article 6 (2) of Regulation 852/2004) This does not apply to those establishments for which approval only is required (Article 6 (3) of Regulation 852/2004) (see paragraph 6 on approvals below).

5.2 Food business operators must register their establishments with the relevant competent authority and should do so at least 28 days before food operations commence. When registering, food business operators must provide the relevant competent authority with full details of the activities undertaken. A standard registration form, which should be completed for each establishment and submitted to the relevant competent authority, is attached at Annex I. Once their establishments are registered, food business operators must ensure that any changes to the details previously supplied e.g. a change of food business operator, a change to the food operations etc. are notified to the competent authority (Article 6 (2) of Regulation 852/2004). Such notifications should be made as soon as possible and in any event no later than 28 days after the change has happened.

5.3 Establishments in which a number of different activities are carried out may need to be registered in relation to certain activities and approved in relation to others. An example might be a dairy farm (registration) which also produces dairy products not for sale to the ultimate consumer (approval) and has a farm shop (registration) on the premises. A single registration can be submitted to cover the activities which require an establishment to be registered. Annex E contains a guide which will assist in determining whether registration and/or approval is required.

- If your establishment is already registered and there have been no changes since registration or since the last inspection visit by the competent authority, then you need take no further action to comply with this requirement.
- If you need to notify any changes, you should advise the relevant competent authority.
- If you are setting up a new business, you should complete a registration form (see Annex I) and submit this to the competent authority at least 28 days before food operations commence.

A2.6: Approval

6.1 Food business establishments that handle food of animal origin must, with some exceptions, be approved by the competent authority. Annex E contains a guide to whether an establishment needs approval. If your establishment needs approval, you do not need to register it as well. Approvals will replace current approvals and licences. If your establishment is already approved or licensed, it will need to be re-assessed for approval under the new Regulations. However you will be able to continue your business until such time as the enforcement authority carries out this reassessment. You need take no action until further information is sent to you at a later stage. If you are a new business, you will need to apply to the relevant enforcement authority for approval. Application forms will be available at a later stage.

6.2 If your business is:

- one that has only supplied wild game meat for the domestic market; or
- one that produced minced meat and meat preparations for the domestic market and has been registered with your local environmental health department, you will now need to be approved.

A2.7: Specific hygiene requirements

7.1 **Article 4 (2) of Regulation 852/2004** requires that you comply, as appropriate with the general hygiene requirements laid down in Annex II. For more guidance on what that means for your food business see guidance identified in Annex B. In addition, you may need to comply with the specific requirements of Regulation 853/2004 if you are producing products of animal origin (see Annexes D and G). Finally, there are specific additional provisions

contained in the national legislation listed in Annex A which may apply to you. These concern:

- bulk transport in sea-going vessels of liquid oils or fats and the bulk transport by sea of raw sugar (Regulation 29 and Schedule 3),
- temperature control requirements (Regulation 30 and Schedule 4)
- direct supply by the producer of small quantities of meat from poultry and lagomorphs slaughtered on the farm (Regulation 31 and Schedule 5) and
- restrictions on the sale of raw milk intended for direct human consumption (Regulation 32 and Schedule 6).

A2.8: Food Safety Management

8.1 With the exception of activities at the level of primary production, you are required to put in place procedures which manage food safety within your establishment. Article 5 (1) of Regulation 852/2004 requires that the procedure or procedures be based upon the HACCP (Hazard Analysis and Critical Control Point) principles set out in Article 5(2). The wording of the Article gives flexibility in that it requires that the procedures be based on those principles. It does not necessarily constrain you to implement a HACCP system, if this is not appropriate. More guidance on how to comply with this requirement can be found in the information listed in Annex B. Guidance materials for different food industry sectors are under development in the Agency, and such guidance for the catering sector is planned for 2005.

A2.9: Guides to good practice

Articles 7-9 of Regulation 852/2004 provide for the development of national or Community guides to good practice for hygiene and the application of HACCP principles. These Guides are to be developed by individual food sectors or, in the case of Community guides, the European Commission, in consultation with interested parties. Food business operators may use these guides, where developed, as an aid to compliance with their obligations under the food hygiene legislation. Enforcement authorities must take into account the use of such guides in the course of official control activities. Article 10(2)(d) of Regulation 852/2004 on official feed and food controls.

A2.10: Enforcement

[To be completed once comments from the consultation have been considered.]

APPENDICES

1. The Food Hygiene Regulations and other associated legislation.
2. Sources of advice and information.
3. Do the provisions of Regulation 852/2004 apply to me and my business?
4. Do the provisions of Regulation 853/2004 also apply to me and my business?
5. Does my establishment need approval?
6. Provisions applying to primary production
7. Summary guidance to what provisions apply to food businesses

8. FSA interpretation of terms used in the EU Regulations
9. Application form for registration of food establishments

Appendix 1: The Food Hygiene Regulations and Other Associated Legislation

1. The EU Regulations are:

- Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs;
- Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin; and
- Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption³¹.

They were published in the Official Journal of the European Union of 30 April 2004, L139. Corrected versions were published in the Official Journal Of the European Union of 25 June 2004, L226. Copies are obtainable from []

2. This legislation is applied in the UK by:

- [The Food Hygiene (England) Regulations 2005; SI 2005 No. xxxx]
- [The Food Hygiene (Scotland) Regulations 2005; SI 2005 No. xxxx]
- [The Food Hygiene (Wales) Regulations 2005; SI 2005 No. xxxx]
- [The Food Hygiene (Northern Ireland) Regulations 2005;

Copies are obtainable from []. These Regulations also lay down some national provisions for food businesses to comply with.

³¹ This has been amended by Regulation (EC) 882/2004 of the European Parliament and of the Council on official controls to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

3. The EU Regulations listed above use definitions laid down in:

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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.

This was published in the Official Journal of the European Union of 1 February 2002, L031. Copies are obtainable from []

Appendix 2: Applicability of Regulation 852/2004

1. Is my business a food business as defined? Art 3.2 of 178/2002 Yes ↓	No⇒	Hygiene legislation does not apply.
2. Is my business an undertaking, the concept of which implies a certain continuity of activities and a certain degree of organisation? Recital 9 of 852/2004 Yes ↓	No⇒	Hygiene legislation does not apply. <i>However, if you are making food other than for solely domestic use, you will need to comply with the general provisions of the Food Safety Act 1990.</i>
3. Does my business undertake primary production for private domestic use? Art 1(2)(a) of 852/2004 No ↓	Yes⇒	Hygiene legislation does not apply.
4. Does my business undertake the domestic preparation, handling or storage of fresh food for private domestic consumption? Art 1(2)(b) of 852/2004 No ↓	Yes⇒	Hygiene legislation does not apply.

5. Is my business a collection centre or tannery which falls within the definition of food business only because it handles raw material for the production of gelatine or collagen?

Art 1(2)(d) of 852/2004

No



6. Does my business supply small quantities³² of primary products directly to the final consumer or to local³³ retail establishments directly supplying the final consumer?

Art 1(2)(c) of 852/2004

No



852/2004 (at least) applies

National rules also apply. See Appendix 7, Sections A and B.

Yes⇒

Hygiene legislation does not apply.

However, you are required to be approved by your local food authority and meet certain requirements to prevent contamination. See paragraph 3.4.

Yes⇒

Rules under national law apply to the act of supply. See paragraph 3.4

³² For an interpretation of this term, see Appendix 8

³³ For an interpretation of this term, see Appendix 8

Appendix 3: Applicability of Regulation 853/2004

<p>1. Does my business manufacture food containing both products of plant origin and processed products of animal origin?</p> <p>Art 1(2) of 853/2004</p>	Yes⇒	<p>853/2004 does not apply to the production of that food. 852/2004 and national rules do apply. <i>However, processed products of animal origin used to prepare such food shall be obtained and handled in accordance with the requirements of 853/2004.</i></p> <p>Art 1(2) of 853/2004</p>
<p>No ↓</p> <p>2. Does my business produce and directly supply small quantities³⁴ of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat?</p> <p>Art 1(3)(d) of 853/2004</p>	Yes⇒	<p>853/2004 does not apply. 852/2004 and national rules do apply. See Annex G, Section C2.</p>
<p>No ↓</p> <p>3. Does my business undertake the hunting and supply of small quantities³⁵ of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer?</p> <p>Art 1(3)(e) of 853/2004</p>	Yes⇒	<p>853/2004 does not apply. 852/2004 and national rules do apply. See Annex F Section C.</p>

³⁴ For an interpretation of this term, see Appendix 8

³⁵ For an interpretation of this term, see Appendix 8

4. Does my business undertake the hunting and supply of quantities of wild game or wild game meat (other than “small quantities” – see the preceding question) directly to the final consumer or to local retail establishments directly supplying the final consumer?

Yes⇒

853/2004 does apply.
Annex III, Section IV of 853/2004

No
↓

5. Is my business a retail business **only** supplying food to the final consumer?

Yes⇒

853/2004 does not apply, except for certain conditions relating to live bivalve molluscs and fishery products.

Art 1(5)(a) of 853/2004

Annex III, Section VII (3) and Section VIII (2) of 853/2004

No
↓

6. Does my business carry out [retail] operations with a view to supplying food of animal origin to another establishment?

No⇒

853/2004 does not apply, except for certain conditions relating to live bivalve molluscs and fishery products.

Art 1(5)(b) of 853/2004

Annex III, Section VII (3) and Section VIII (2) of 853/2004

Yes
↓

7. Do these operations consist only of storage or transport?

Yes⇒

The specific temperature requirements (if any) laid down in Annex III of 853/2004 shall apply.

Art 1(5)(b)(i) of 853/2004

No
↓

8. Is the supply of food of animal origin from your retail establishment to other retail establishments only and is it a “marginal, localised and restricted activity”?³⁶

Art 1(5)(b)(ii) of 853/2004

No



853/2004 applies

Yes⇒

853/2004 does not apply.

³⁶ For an interpretation of these terms, see Appendix 8

Appendix 4: Establishments Subject to Approval under Regulation 853/2004

1. Does my business carry out activities to which <u>only</u> 852/2004 applies? Art 6 (3)(b) of 852/2004 No ↓	Yes⇒	Your establishment only needs to be registered as required by 852/2004. Article 6 (2) of 852/2004
2. Does my establishment handle products of animal origin for which requirements are laid down in Annex III of 853/2004? Art 4(2) of 853/2004 Yes ↓	No⇒	Your establishment only needs to be registered as required by 852/2004.
3. Does my establishment <u>only</u> carry out primary production? Art 4(2)(a) of 853/2004 No ↓	Yes⇒	Your establishment only needs to be registered as required by 852/2004.
4. Does my establishment <u>only</u> carry out transport operations? Art 4(2)(b) of 853/2004 No ↓	Yes⇒	Your establishment only needs to be registered as required by 852/2004.

5. Does my establishment only carry out the storage of products not requiring temperature-controlled storage conditions?

Art 4(2)(c) of 853/2004

No

↓

6. Does my establishment carry out retail operations only supplying food to the final consumer?

Art 4(2)(d) of 853/2004

No

↓

7. Does my establishment carry out operations with a view to supplying food of animal origin to another establishment?

Art 4(2)(d) and Art 1(5)(b) of 853/2004

Yes

↓

8. Do those operations consist only of storage or transport?

Art 4(2)(d) and Art 1(5)(b)(i) of 853/2004

No

↓

Yes⇒

Your establishment only needs to be registered as required by 852/2004.

Yes⇒

Your establishment only needs to be registered as required by 852/2004.

No⇒

Your establishment only needs to be registered as required by 852/2004.

Yes⇒

Your establishment only needs to be registered as required by 852/2004.

9. Is the supply of food of animal origin from my retail establishment to other retail establishments only and is it a “marginal, localised and restricted activity”?³⁷

Art 4(2)(d) and Art 1(5)(b)(ii) of 853/2004

No



Your establishment requires approval

Yes⇒

Your establishment only needs to be registered as required by 852/2004.

³⁷ For an interpretation of these terms, see Appendix 8

Appendix 5: Provisions Applying to Primary Production

1. The legislation lays down general and specific requirements for primary production of food. The relevant definitions are:

- "primary production" means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;" (Article 3(17) of Regulation 178/2002)
- "primary products" means products of primary production including products of the soil, of stock farming, of hunting and fishing;" (Article 2(1)(b) of Regulation 852/2004)

This includes farming (arable crops, livestock production, milk production, fish and shellfish farming), horticulture, hunting, fishing and the production and gathering of live bivalve molluscs and other shellfish. Many of these activities are only subject to the requirements of Regulation 852/2004. In some cases additional requirements are laid down in Regulation 853/2004. The guidance later in this Annex will take you through what provisions apply to different primary production activities.

2. If you are a primary producer undertaking food business activities other than primary production (e.g. if you have a farm shop or if you are manufacturing foods) then you need to comply with the relevant provisions of the legislation which apply to those activities.

3. All food business operators, including primary producers, are required to notify the competent authority of the establishments under its control with a view to those establishments being registered. However, the intention is to use information from existing Agriculture Department sources, e.g. census information and County/Parish/Holding (CPH) number data, to fulfil this requirement as far as is possible. The precise means of meeting this requirement is still being considered. If there are gaps in current information, it may mean that primary producers should inform the competent authorities of their existence and the nature of the operations.

4. Member States are required to apply and to enforce the legislation, including at the level of primary production. The intention is to develop a light-touch, practical and effective enforcement regime in consultation with Agriculture Departments and industry. There is no intention to introduce a new enforcement body for this purpose, but rather to use bodies already going on farm for other purposes to undertake this role. The detail of exactly what an enforcement regime will look like and who will undertake this role is still to be decided. This and the question of registration of primary production establishments will be consulted on further.

Appendix 6: Primary Production

A. AGRICULTURE AND HORTICULTURE

1. PRODUCTION/HARVESTING OF PLANT PRODUCTS

1. Does my business carry out an activity covered by the definition of “primary production” including “associated operations”?

Art 3.17 of 178/2002 and Annex I, Part A, I(1) of 852/2004

Yes



2. Does my business produce or harvest plant products?

No⇒

Go to 4.

Yes



3. Requirements:

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment
- c) Comply with the relevant hygiene provisions of Annex I, as follows:

Art 6(1) of 852/2004

Art 6(2) of 852/2004

Art 4(1) of 852/2004

Annex I, Part A, II(2),(3), (5) and (6), III(7) and (9) of 852/2004

2. FARMING OF LIVESTOCK (MEAT PRODUCTION)

4. Does my business produce animals (other than live bivalve molluscs or fish) for food production?

Yes



5. Does my business produce animals for meat production?

No⇒

Go to 15.

Yes



6. Does my business produce animals defined as “domestic ungulates”?

No⇒

Go to 8.

Annex I, 1.2 of 853/2004

Yes



7. Requirements:

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment
- c) Comply with the relevant hygiene provisions of Annex I, as follows:

Annex I, Part A, II(2),(3), (4) and (6), III(7) and (8) of 852/2004

- d) Comply, as required, with the requirements to supply food chain information
- e) Comply with the relevant hygiene provisions of Annex III, as follows:

Annex III, Section I, Chapter I and Chapter VI of 853/2004

Art 6(1) of 852/2004

Art 6(2) of 852/2004

Art 4(1) of 852/2004

Art 3(1) and Annex II,
Section III of 853/2004

Art 3(1) of 853/2004

8. Does my business produce animals defined as “poultry” or “lagomorphs”?

Annex I, 1.3 and 1.4 of 853/2004

Yes



9. Requirements:

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment
- c) Comply with the relevant hygiene provisions of Annex I, as follows:

Annex I, Part A, II(2),(3), (4) and (6), III(7) and (8) of 852/2004

- d) Comply, as required, with the requirements to supply food chain information
- e) Comply with the relevant hygiene provisions of Annex III, as follows:

Annex III, Section II, Chapter I and Chapter VI of 853/2004

Art 6(1) of 852/2004

Art 6(2) of 852/2004

Art 4(1) of 852/2004

Art 3(1) and Annex II,
Section III of 853/2004

Art 3(1) of 853/2004

No⇒

Go to 10.

10. Does my business produce animals defined as “farmed game”?

Annex I, 1.6 of 853/2004

Yes



11. Does my business produce even-toed farmed game mammals (*Cervidae* and *Suidae*)?

No⇒

Go to 13.

Yes



12. Requirements

As for 7 above. In addition the following may apply:

[Annex III, Section III, \(3\) and \(4\) of 853/2004](#)

13. Does my business produce farmed ratites?

Yes



14. Requirements

As for 9 above. In addition the following may apply:

[Annex III, Section III, \(3\) of 853/2004](#)

3. FARMING OF LIVESTOCK (DAIRY PRODUCTION)

15. Does my business keep farmed animals to produce milk with a view to placing it on the market as food?

No⇒

Go to 17.

Yes



16. Requirements:

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment
- c) Comply with the relevant hygiene provisions of Annex I, as follows:

Annex I, Part A, II(2),(3), (4) and (6), III(7) and (8) of 852/2004

- d) Comply with the relevant hygiene provisions of Annex III, as follows:

Annex III, Section IX, Chapter I [and Chapter II, as appropriate] of 853/2004

Art 6(1) of 852/2004

Art 6(2) of 852/2004

Art 4(1) of 852/2004

Art 3(1) of 853/2004

4. FARMING OF LIVESTOCK (EGG PRODUCTION)

17. Does my business keep farmed birds to produce eggs for direct human consumption or for the preparation of egg products for food?

No⇒

Go to 19.

Yes



18. Requirements:

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment
- c) Comply with the relevant hygiene provisions of Annex I, as follows:

Annex I, Part A, II(2),(3), (4) and (6), III(7) and (8) of 852/2004

- d) Comply with the relevant hygiene provisions of Annex III, as follows:

Annex III, Section X, Chapter I of 853/2004

Art 6(1) of 852/2004

Art 6(2) of 852/2004

Art 4(1) of 852/2004

Art 3(1) of 853/2004

B. FISHING AND AQUACULTURE

1. CULTIVATION AND GATHERING OF LIVE BIVALVE MOLLUSCS

19. Does my business cultivate or gather live bivalve molluscs?

No⇒

Go to 23.

Yes



20. Does my business operate a dispatch centre or a purification centre?

Yes⇒

Got to 22.

Annex I, 2.7 and 2.8 of 853/2004

No



21. Requirements

Operations that take place before live bivalve molluscs arrive at a dispatch or purification centre (including relaying) are primary production.

Annex III, Section VII
(4)(a) of 853/2004

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment
- c) Comply with the relevant hygiene provisions of Annex I as follows:

Art 6(1) of 852/2004
Art 6(2) of 852/2004
Art 4(1) of 852/2004

Annex I, Part A, II(2), (3), (4) and (6), III(7) and (8) of 852/2004

- d) Comply with the relevant hygiene provisions of Annex III as follows:

Art 3(1) of 853/2004

Annex III, Section VII, Chapter I (2)-(7), Chapter II, Chapter VIII(1) and Chapter IX, as appropriate, of 853/2004

22. Requirements

Operations that take place after live bivalve molluscs arrive at a dispatch or purification centre are not primary production

You have to:

- a) Co-operate with the competent authorities
- b) Have your establishment approved
- c) Comply with the relevant hygiene provisions of Annex II of 852/2004
- d) Comply with the relevant provisions of Annex III as follows:

Annex III, Section VII, Chapter I and Chapters III-IX of 853/2004

- e) (If a dispatch centre) apply an identification mark

- f) Put in place, implement and maintain a permanent procedure or procedures based on HACCP principles

Annex III, Section VII
(4)(b) of 853/2004

Art 6(1) of 852/2004
Art 4(2) of 853/2004
Art 4(2) of 852/2004

Art 3(1) of 853/2004

Art 5(1)(b), Annex II,
Section I and Annex
III, Section VII,
Chapter I(1) of
853/2004
Art 5(1) of 852/2004

2. FISHING AND FISH FARMING

23. Does your business catch, handle or process “fishery products” as defined?

Annex I, 3.1 of 853/2004

Yes



24. Does my business undertake any of the following activities in relation to fishery products?

- The farming, fishing and collection of live fishery products with a view to their being placed on the market;
- The following operations, if carried out on board fishing vessels: slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping;
- Also, the transport and storage of fishery products the nature of which has not been substantially altered, within fish farms on land; and,
- The transport of fishery products the nature of which has not been substantially altered, including live fishery products from the place of production to the first establishment of destination.

Annex III, Section VIII(4) of 853/2004

Yes



25. Does my business undertake the operations described in the definitions of “factory vessel” or “freezer vessel” on board such vessels, or do you otherwise process fishery products?

Annex I, 3.2 and 3.3 of 853/2004

No



No⇒

Go to 25.

Yes⇒

Go to 27.

26. Requirements

Fishing operations and associated activities, other than processing operations are primary production

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment (this includes a fishing vessel)
- c) Comply with the relevant provisions of Annex I as follows:

Annex I, Part A, II(2),(3),(4) and (6), III(7) and (8) of 852/2004

- d) Comply with the relevant hygiene provisions of Annex III as follows:

Annex III, Section VIII, Chapter I, I A and B, II(1) of 853/2004

Annex III, Section VIII
(3)(a) and (4) of
853/2004

Art 6(1) of 852/2004
Art 6(2) of 852/2004

Art 4(1) of 852/2004

Art 3(1) of 853/2004

27. Requirements

Processing operations, whether on vessel or on land, including the operation of wholesale and auction markets are not primary production.

You have to:

- a) Co-operate with the competent authorities
- b) Have your establishment (including a vessel) approved
- c) Comply with the relevant hygiene provisions of Annex II of 852/2004
- d) Comply with the relevant provisions of Annex III as follows:

Annex III, Section VIII ,as appropriate, of 853/2004

- e) Apply an identification mark

- f) Put in place, implement and maintain a permanent procedure or procedures based on HACCP principles

Annex III, Section VII
(4)(b) of 853/2004

Art 6(1) of 852/2004
Art 4(2) of 853/2004
Art 4(2) of 852/2004

Art 3(1) of 853/2004

Art 5(1)(b), Annex II,
Section I of 853/2004
Art 5(1) of 852/2004

B. HUNTING AND PROCESSING WILD GAME

1. The table below describes what elements of the various regulations apply to the hunting of wild game and its placing on the market. Further explanation is given in the paragraphs that follow.

WHAT APPLIES?	Regulation 852/2004	Regulation 853/2004	Regulation 854/2004
ACTIVITY			
1. Hunters shooting for own consumption	No Art 1(2)(a)	No Art 1(3)(c)	No
2. Hunters supplying small quantities direct to the final consumer or to local retailers (directly supplying the final consumer):			
a. Wild game (including gralloched deer, gutted small game)	No Art 1(2)(c) National rules apply. See paras 2-5 below	No Art 1(3)(c) National rules apply. See paras 2-5 below	No
b. Wild Game Meat	Yes Requirements A to E below.	No Art 1(3)(e) National rules apply. See paras 2-5 below	No
3. Hunters supplying wild game handling/ processing facilities	Yes Requirements A to E below.	Yes Requirements similar to WGMRs ³⁸ , but Annex III, Section IV adds procedures to be carried out by "trained person". Training must satisfy CA ³⁹ .	Yes OV ⁴⁰ to examine declaration delivered with carcase(s) and any other information provided by the hunter. Annex I, Section IV, Chapter 8 A paragraph (2)
4. Premises used for the production of Wild Game Birds	Yes Annex 1 applies. Premises to be registered. Art 6(2)	No	No
5. Game Larders/Collection Centres holding/handling primary products	Yes Annex I applies. Premises to be registered. Art 6(2)	No	No
6. Game Larders/Collection Centres holding/handling other than primary products.	Yes Classified as establishments to be registered. (Art 6(2) and Annex II, Ch I & III)	No	No

³⁸ Wild Game Meat (Hygiene and Inspection) Regulations 1995

³⁹ Competent Authority

⁴⁰ Official Veterinarian

7. Wild game-handling/processing establishment (any place where game meat is prepared for placing on the UK domestic or export market)	Yes Classified as establishments (Annex II, Ch I & III)	Yes Establishments to be approved. (Article 4(2)) Comply with Annex III, Section IV. Game must be presented to OV.	Yes
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2. The definition of primary production means that estates engaged in hunting activities are primary producers. "Primary production" excludes farmed animal production after slaughter, but not animals that are killed by hunters. Primary products exempted from Regulation 852/2004 by Art 1(2)(c) are unskinned/unplucked wild game that have only undergone any necessary gralloching, gutting or cutting in the field as a part of normal hunting practice.

3. Art 1.2(a) exempts from Regulation 852/2004 wild game primary products for private domestic use. Art 1.2(c) provides an exemption covering the direct supply by the producer (who can be the hunter) of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer. "Direct supply" must be understood in the light of recital 10 of Regulation 852/2004 and recital 11 of Regulation 853/2004, where the close relationship between the producer and the consumer is stated as the principle justification for the derogation. National rules are required to cover such activities which meet the objectives of Regulations 852/2004 and 853/2004 as appropriate. However, H1 Annex 1 applies to primary production even where that primary production leads to the supply of primary products exempted under Art 1.2(c).

4. These exemptions are repeated in Art 1(3)(c) of Regulation 853/2004. A further exemption in Art 1(3)(e) relates to hunters supplying small quantities etc. of wild game and wild game meat. Hunters supplying wild game meat exempted under Art 1(3)(e) will have to comply with Regulation 852/2004.

5. In summary, the requirements of the EU regulations will not apply to the supply of wild game primary products that can benefit from the small/final consumer/local exemption and that in those circumstances Regulation 852/2004 only will apply to the supply of wild game meat. Local authorities are responsible for undertaking official controls. In both cases of exemption, provisions under national law will be required that achieve the objectives of the EU regulations. These would be the controls in the Food Safety Act 1990 and the General Food Law Regulation (which applies from 1 January 2005) and controls covering labelling and record keeping in the Game Acts.

6. Regulation 852/2004 requirements

- A. Food safety management procedures based on HACCP principles, Art 5 (new).
- B. Registration of every food business establishment, Art 6.

- C. Competent Authority must encourage hunters' organisations to produce good hygiene and HACCP guide, Art 7 (new).
- D. Transport provisions, Annex I, Part A, I, 1.(c) and Annex II Ch IV.
- E. General and specific hygiene provisions, including re:
 - a) storage facilities (e.g. collection centres/game larders holding/handling primary products normally at place of production, but could be elsewhere on an Estate), Annex 1.
 - b) food premises (includes movable or temporary premises or private dwelling houses (Annex II, Chs I & 3) and food preparation rooms (Annex II Ch II). Would apply to any collection centre/game larder holding/handling other than primary products – although this unlikely given the limited purpose of such premises.

Appendix 7: Summary Guidance on what Provisions Apply to Food Businesses (Other than Primary Production)

(Appendix 6 provides guidance on what requirements apply to primary production)

In this Annex, references to the national Food Hygiene Regulations are to the specific regulations and the Schedules applying specific requirements to certain food businesses, rather than those parts of those Regulations applying the EU legislation.

A. RESTAURANTS, CATERERS AND SHOPS SELLING FOOD TO THE FINAL CONSUMER (including such operations carried out on board ships and aircraft)

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Registration
Annex II	General requirements for all food business operators

Regulation 853/2004

In general this regulation does not apply with the exception of the following:

- provisions relating to live bivalve molluscs and fishery products which apply to retail sales - Annex III, Section VII (3) and Section VIII (2)
- requirements for eggs that apply until sale to the consumer, e.g. eggs must be delivered within 21 days of lay – Annex III, Section X (1)-(3).

The Food Hygiene Regulations 2005

Regulation 30 and Schedule 4 Temperature control requirements

These national requirements are in addition to the general temperature control requirement in Annex II, Chapter IX (5)-(7) of Regulation 852/2004. The national requirements do not apply to food business operations on ships or aircraft.

Changed requirements

- Documented food safety management procedures based on HACCP principles (Article 5 of Regulation 852/2004)
- Those responsible for the development and maintenance of food safety management procedures to have received adequate training

**B OTHER FOOD BUSINESSES, PROCESSING OR HANDLING FOODS
ONLY SUBJECT TO REGULATION 852/2004**

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Registration
Annex II	General requirements for all food business operators

Regulation 853/2004

This Regulation does not in general apply. However, Article 1(2) has the effect of clarifying that food containing both products of plant origin and processed products of animal origin are subject only to the requirements of Regulation 852/2004. The processed products of animal origin used to prepare such food will need to comply with the requirements of Regulation 853/2004 (see below).

The Food Hygiene Regulations 2005

Regulation 29 and Schedule 3	Bulk transport in sea-going vessels of liquid oils and fats and the bulk transport by sea of raw sugar.
Regulation 30 and Schedule 4	Temperature control requirements

Changed requirements

- Documented food safety management procedures based on HACCP principles (Article 5 of Regulation 852/2004)
- Those responsible for the development and maintenance of food safety management procedures to have received adequate training
- Foods containing both products of plant origin and processed products of animal origin are subject only to Regulation 852/2004 requirements
- The national temperature control rules will extend to foods containing both products of plant origin and processed products of animal origin that are currently subject to product-specific temperature requirements and will fall within 852/2004 from 1 January 2006.

**C FOOD BUSINESSES PROCESSING OR HANDLING FOODS
SUBJECT TO REGULATION 854/2004**

In this section, the relevant provisions of Regulation 854/2004 are also listed. This Regulation concerns the way in which official controls are to be undertaken. As such, it does not describe the duties of food business operators (which are described in Regulations 852/2004 and 853/2004).

1. Meat of domestic ungulates

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Article 8	Special guarantees (where applicable)
Annex I	Definitions
Annex II	Section II Objectives of HACCP-based procedures (slaughterhouses only)
Annex II	Section III Food chain information (slaughterhouses only)
Annex III	Section I

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 5	Fresh meat (including health marking, Article 5(2))
Annex I	Fresh meat

Changed requirements

- Requirements apply irrespective of the throughput of a premises
- Provision of food chain information
- Change of terminology: “Licences” will be replaced by “Approvals”

2. Meat from poultry and lagomorphs⁴¹

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
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⁴¹ The direct supply by the producer of small quantities of meat from poultry and lagomorphs slaughtered on the farm is subject to the provisions of Regulation 852/2004 listed here and to Regulation 31 and Schedule 5 of the Food Hygiene Regulations 2005 only

Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Article 8	Special guarantees (where applicable)
Annex I	Definitions
Annex II	Section I Identification marking
Annex II	Section II Objectives of HACCP-based procedures (slaughterhouses only)
Annex II	Section III Food chain information (slaughterhouses only)
Annex III	Section II

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 5	Fresh meat
Annex I	Fresh meat

Changed requirements

- Requirements in general less prescriptive.
- Removal of 'low throughput' poultry meat plant concept, same requirements will apply to all plants irrespective of throughput.
- Use of company staff to carry out inspection activities, when they meet certain requirements.
- Greater possibility for on farm slaughter.
- Ostriches are now covered under farmed game. The provisions relating to poultry slaughterhouses and cutting plants will normally apply. However, producers will no longer be able to take advantage of any 'under 10,000 exemption' as allowed in existing the Poultry Meat Regulations related to on farm slaughter and processing of ostriches. Certain on farm slaughter activities will be permitted in the circumstances described in the Regulation.
- Change of terminology: "Licences" will be replaced by "Approvals"

3. Meat of farmed game

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section II Objectives of HACCP-based procedures (slaughterhouses only)
Annex II	Section III Food chain information (slaughterhouses only)
Annex III	Section III

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 5	Fresh meat (including health marking, Article 5(2))
Annex I	Fresh meat

Changed requirements

- In general, as for domestic ungulates
- Ostriches are now covered under farmed game. The provisions relating to poultry slaughterhouses and cutting plants will normally apply. However, producers will no longer be able to take advantage of any 'under 10,000 exemption' as allowed in existing the Poultry Meat Regulations related to on farm slaughter and processing of ostriches. Certain on farm slaughter activities will be permitted in the circumstances described in the Regulation.
- Change of terminology: "Licences" will be replaced by "Approvals"

4. Wild game meat

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
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Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex III	Section IV

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 5	Fresh meat (including health marking, Article 5(2))
Annex I	Fresh meat

Changed requirements

- Chilling of wild game within a reasonable period after killing. Active chilling not necessary where climatic conditions make this unnecessary
 - All wild game handling establishments will be approved and meet common hygiene standards irrespective as to whether meat is supplied for the domestic or international market.
 - Introduction of food safety management procedures based on HACCP principles (Article 5 of Regulation 852/2004)
 - Those responsible for the development and maintenance of food safety management procedures to have received adequate training
 - Requirement for certain hunters to be trained in health and hygiene
 - Hunting organisations to develop and implement training arrangements which satisfy the competent authority
 - Change of terminology: “Licences” will be replaced by “Approvals”
5. Minced meat, meat preparations and mechanically separated meat (MSM)

Regulation 852/2004

Article 4(2) Compliance with hygiene requirements

Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Article 8	Special guarantees (where applicable)
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section V

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

Changed requirements

- Manufacture of mechanically separated meat is brought within the scope of 'meat' legislation.
- All establishments will require approval; there will be no exemption from approval for establishments manufacturing for the national market only.
- Application of an identification mark to all production.
- Requirements, in general, less prescriptive.
- Removal of the 'industrial/non-industrial' production levels; the same requirements will apply to all plants irrespective of their production levels.

6. Meat products

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments

Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section VI

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

Changed requirements

- Requirements, in general, less prescriptive.
- Removal of the 'industrial/non-industrial' production levels, the same requirements will apply to all plants irrespective of their production levels.

7. Live bivalve molluscs

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section VII

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 6	Live bivalve molluscs
Annex II	Live bivalve molluscs

Changed requirements

- [To be added]

8. Fishery products

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section VIII

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 7	Fishery products
Annex III	Fishery products

Changed requirements

- [To be added]

9. Raw milk and dairy products

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking

Annex I	Definitions	
Annex II	Section I	Identification marking
Annex III	Section IX	

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 8	Raw milk and dairy products
Annex IV	Raw milk and dairy products

The Food Hygiene Regulations 2005

Regulation 32 and Schedule 6	Restrictions on the sale of raw milk intended for direct human consumption
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Changed requirements

- Raw milk from any animal showing individually a positive reaction to test for tuberculosis and brucella must no longer be used for human consumption. The milk from all other animals in the herd may continue to be used as long as it is heat treated.
- Removal of provisions contained in the Milk and Dairies (General) Regulations 1959 relating to heat treatment notices which were issued for herds which lost their disease free status or whose milk contained certain pathogens.
- Removal of the ban on the sale of thermised milk direct to the ultimate consumer.
- Removal of the specific requirements for the heat treatment of cream and ice cream.

10. Eggs and egg products

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking

Article 8	Special guarantees (where applicable)
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section X

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

Changed requirements

- [To be added]

11. Frogs' legs and snails

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section XI

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

Changed requirements

- [To be added]

12. Rendered animal fats and greaves

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section XII

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

Changed requirements

- Requirements, in general, less prescriptive.
- Requirement for approval.
- Application of an identification mark to all production.

13. Treated stomachs, bladders and intestines

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
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Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section XIII

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

Changed requirements

- Requirements, in general, less prescriptive.
- Requirement for approval.
- Application of an identification mark to all production.

14. Gelatine

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section XIV

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

Changed requirements

- Requirements, in general, less prescriptive.
- Requirement for approval.

15. Collagen

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section XV

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

Changed requirements

- Requirements, in general, less prescriptive.
- Requirement for approval.

Appendix 8: Food Standards Agency Interpretation of Terms used in the EU Regulations

Direct supply of small quantities of primary products (including wild game) to final consumer or local retail establishment.

(Article 1(2)(c) of Regulation 852/2004 and Article 1(3)(c) of Regulation 853/2004)

1. A meaningful interpretation of what constitutes a small quantity of various primary products will vary enormously from product to product, e.g. potatoes, strawberries, fish etc. For wild game it is suggested that a small quantity is under 10,000 small wild game and under 300 large wild game per year. The interpretation of “local” would be the same as for “localised”, see paragraph 4 b) below. In the case of raw cows’ milk for drinking, the quantity might be a few pints and not more than a single crate.

Direct supply to the final consumer, or local retail establishment, of small quantities of poultry and rabbits slaughtered on farm.

(Article 1(3)(d) of Regulation 853/2004)

2. We clarified during the negotiation of the legislation that the intention would be to continue to apply the approach given effect to in the Poultry Meat, Farmed Game Bird Meat and Rabbit Meat (Hygiene and Inspection) Regulations 1995 (as amended). Thus “small quantities” would be interpreted as **under 10,000 birds or rabbits per year reared and slaughtered on farm, as at present**. In addition we would interpret “small quantities” as including the output of those producers who are both members of an appropriate assurance scheme and who either dry pluck by hand or slaughter for up to 40 days per annum. The current provisions in respect of seasonal markets would also be considered to apply.

Direct supply to the final consumer, or local retail establishment, of small quantities of wild game meat.

(Article 1(3)(e) of Regulation 853/2004)

3. The intention would be to subject such supply to the general provisions of Regulation 852/2004 and not to apply any more specific rules. **The quantitative limit applied to such supplies would be under 10,000 small wild game and under 300 large wild game per year**. The interpretation of “local” would be the same as for “localised”, see paragraph 4 b) below.

Retail-to-Retail Supplies

4. In the Regulations the definition of ‘retail’ (written in from General Food Law (Regulation EC No. 178/2002)) includes ‘wholesale’. While the intention of Regulation 853/2004 is to exempt businesses retailing products of animal origin to the final consumer (i.e. the public), it is meant to apply to businesses that supply other businesses (e.g. caterers, pubs, restaurants,

other retailers). However, an exception applies when the operations consist only of storage or transport, or when the supply to other establishments is a “marginal, localised and restricted activity” when the more general requirements of 852/2004 would apply.

- **“marginal”**

‘Marginal’ is described in recital 13 of 853/2004 as only a small part of the establishment’s business. In this context, the supply of food of animal origin to other establishments will be treated as “marginal” for the purposes of Article 1.5(b)(ii) if it is a marginal part of the food business of the supplier.

Since Regulation 852/2004 will still apply to establishments exempted from Regulation 853/2004 and it is considered sufficient to control retail activities we consider that “marginal” should be interpreted as liberally as possible. However, we are constrained by its description in the recital as “only a small part of the business”. While the earlier consultation proposed proportions of between 50% and 30% of the business, we have come to the view that 25% of the business is the highest interpretation that can reasonably be placed on the term “marginal”. It is proposed that marginal is interpreted as being up to a quarter of the business’ turnover in terms of food.

- **“Local” / “localised”**

‘Localised’ is described in recital 13 of 853/2004 as in the immediate vicinity of the supplying establishment. It is proposed that “local” and “localised” be interpreted as ‘sales within the supplying establishment’s own county *plus* the greater of either the neighbouring county or counties or 30 miles/50 kilometres from the boundary of the supplying establishment’s county’. “County” would be interpreted here as meaning metropolitan or non-metropolitan counties in England and Wales as defined in the Local Government Act 1972 and London Government Act 1963⁴² (e.g. Greater London, North Yorkshire, Leicestershire, Powys), a local authority in Scotland, or an administrative county in Northern Ireland (e.g. Co. Fermanagh). This makes allowance for the imbalance between closely spaced urban authorities and widely spaced remote populations, as well as those on the boundaries or bordered by the sea.

- **“restricted”**

‘Restricted’ is described in recital 13 of 853/2004 as concerning only certain types of products or establishments which may be exempt under the ‘retail’ to ‘retail’ exemption in 853/2004. Having to list establishments and products was seen as bureaucratic and a potential barrier to trade and there are other legal requirements for traceability of food products. It is proposed that “restricted” be interpreted as specified product categories as

⁴² Except that the Isles of Scilly and the combined counties of Mid Glamorgan, South Glamorgan and West Glamorgan shall be regarded as one county each. For some larger authorities in Scotland a finite limit might be considered more appropriate.

referenced in 853/2004 (e.g. dairy products, collagen, minced meat) and establishment types (e.g. a butcher's shop, distribution centre).

“Food containing both products of plant origin and processed products of animal origin” (“Composite Products”)

Article 1(2) of Regulation 853/2004 states that the Regulation shall not apply to food containing both products of plant origin and processed products of animal origin. The most significant practical consequence of this exemption is that establishments making “composite products” (note: this term is not defined in law) would not be subject to approval under Regulation 853/2004. Regulation 852/2004 will apply to such establishments, although the products of animal origin used to prepare the composite products must have been obtained and handled in accordance with Regulation 853/2004.

In order to benefit from this exemption the food must, therefore, consist of both:

- (a) a processed product of animal origin, and
- (b) a product of plant origin.

Whether the product of animal origin is “processed” or not will depend on whether it meets the definition of “processed product” at Article 2 of Regulation 852/2004. Under that definition, a product is processed if it has been *substantially altered*. The definition of processing includes heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of these processes. Examples are also given of what does not constitute processing, and these include dividing, parting, severing, slicing, boning, mincing, skinning, grinding, cutting, cleaning, trimming, husking, milling, chilling, freezing and thawing.

Whether a food contains a product of plant origin is simply a matter of fact. There is no minimum amount of product of plant origin that the food must contain to be a “composite product”.

ANNEX 3: FRESH MEAT / MEAT PRODUCTS / MEAT PREPARATIONS / ON FARM SLAUGHTER

A.3.1: Introduction

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

[DN: A draft of the above Guide is out to public consultation for the period 9 May to 5 August 2005. The consultation is available on the Agency's website at <http://www.food.gov.uk/foodindustry/Consultations/ukwideconsults/foodsafetymeat2005>]

A.3.2: Enforcement in Meat Establishments

Where a process in a meat establishment requires control by an official veterinarian, all parts of the establishment processing meat will fall under the responsibility of the Meat Hygiene Service (MHS). Thus the MHS will be responsible for enforcement in all Meat Products, Minced Meat or Meat Preparations plants combined with a slaughterhouse or a cutting plant (correcting the current anomaly whereby meat products plants combined with cutting plants are subject to dual Food Authority/MHS enforcement). However, where an establishment handling meat also handles fishery or dairy products, Food Authorities will retain responsibility for these products for the time being.

Food Authorities will be responsible for enforcement in meat products, minced meat and meat preparations establishments not combined with a slaughterhouse, cutting plant or game handling establishment, and in establishments exempted from approval under Regulation 853/2004.

Currently, Food Authorities are responsible for enforcement in wild game processing facilities when the production is destined for the domestic market, while the MHS is responsible when the production is destined for export. Under the new Regulations, the same standard will apply to all "game handling establishments (currently called wild game processing facilities). All such premises will require veterinary control and will therefore be subject to MHS enforcement.

A.3.3: Approval of Establishments

The Agency will be responsible for approving establishments subject to veterinary control (i.e. slaughterhouses, cutting plants and game handling establishments) as well as any combined meat products, minced meat or meat preparations premises. Food Authorities will be responsible for approving non-combined meat products, minced meat and meat preparations establishments, or registering establishments exempted from approval.

A.3.4: Exemptions from Approval

[DN: This reflects current understanding, but is subject to further European Commission guidance].

A3.4.2: Cold Stores

The Agency interprets Regulation 853/2004 as exempting cold stores from approval in cases where storage is the only activity carried out at the premises in relation to food of animal origin (i.e. if additional activities such as cutting or processing are carried out, the exemption does not apply). The EU Commission has recently contested this interpretation, concluding that cold stores must be approved. The Agency is considering its position, but even if stand-alone cold stores were to require approval, they would be no requirement for veterinary control and responsibility for approval and enforcement would therefore pass from the Agency to Food Authorities.

A3.4.3: Wild Game

This Exemption is for hunters supplying small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.

It is proposed that the quantitative limit applied to such supplies should be under 10,000 small wild game and under 300 large wild game per year. The interpretation of “local” would be the same as for “localised”, see below.

The summary table in Appendix 9, Section B of Annex 2 of this guidance provides information on what elements of the various regulations apply to the hunting of wild game and its placing on the market.

A3.4.4: On farm slaughter and cutting of small quantities of poultry and lagomorphs

This exemption is for the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying the final consumer as fresh meat (Article 1(3)(d) of Regulation 853/2004). Article 1(4) goes on to say that the rules governing the persons and activities benefiting from this exemption (in addition to those set out in Regulation 852/2004) will be set out in national law. These national rules are set out in regulation 31 and Schedule 5 of the Food Hygiene (England) Regulations 2005.

A2.1: 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. “Small quantities” is not defined in the legislation, but the Agency

believes that the intention of the legislation is that producers such as the following should benefit from the exemption:

- producers annually slaughtering under 10,000 birds or lagomorphs;
- 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.

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

The limit of 10,000 birds or lagomorphs in the first category should not be applied absolutely. Annual fluctuations in slaughterings around the 10,000 level are acceptable provided that annual slaughterings are typically no more than 10,000. The limit of 10,000 should be applied to both poultry and lagomorphs slaughtered.

In judging whether an assurance scheme is appropriate, regard should be had as to whether the scheme has requirements that go beyond minimum legal requirements in relation to food safety and hygiene and whether it has independent verification arrangements. The Agency can advise in cases of doubt.

A2.2: 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 as fresh meat.

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 alternatively 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, and be supplied to the final consumer from those establishments as fresh meat. The retail establishments supplied must be *local*. Although “local” is not defined in the legislation, the Agency considers that local should be interpreted as meaning:

- the establishment’s own county *plus* the greater of either the neighbouring counties or 30 miles / 50 kilometres from the boundary of the establishment’s own county; or

- anywhere within the UK in the two weeks preceding Christmas or Easter or (for geese) Michaelmas.

A2.3: What rules apply?

Regulation 852/2004 applies to producers who benefit from this exemption. This includes, among other things, the requirement to maintain procedures based on the HACCP principles and to register the establishment with the Food Authority, as well as to comply with general hygiene and training requirements. In addition to this, the national rules in Schedule 5 to the Food Hygiene (England) Regulations 2005 apply. These set out rules on labelling and record keeping.

The labelling rules require that the meat bear a label or other marking clearly indicating the name and address of the farm where the bird or animal was slaughtered. This requirement is in addition to any labelling particulars required by the Food Labelling Regulations 1996.

The record keeping rule requires the producer to keep a record in adequate form to show the number of birds and the number of lagomorphs received into, and the amounts of fresh meat despatched from, the premises during each week. Such records, in order to be adequate, should at least record this information by species of animal slaughtered. The records should be retained for one year and be made available to an authorised officer of the Food Authority on request.

A3.4.5: Retail establishments (See also Appendix 8 of Annex 2 of this Guidance)

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

A major change as far as butchers are concerned is that, whereas the current definition of “*final consumer*” in the Meat Hygiene Regulations includes caterers, the definition in the new Regulations does not: “*final consumer*” is now defined as “*the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity*”, i.e. the public. This means that establishments supplying caterers will be considered to be supplying other establishments as opposed to supplying the final consumer. The Regulations will require establishments which cut meat for supply to other establishments to be approved as cutting plants and subject to veterinary control, unless that supply is on a marginal, localised and restricted basis. Catering butchers who supply all or most of their production to the catering trade will therefore in principle be subject to approval, as well as retail butchers supplying caterers and/or other establishments in excess of the marginal threshold.

A3.4.6: “Marginal, localised and restricted”

This exemption is outlined in Appendix 8 of Annex 2 of this guidance.

A3.4.7: “Composite” Products

This exemption is outlined in Appendix 8 of Annex 2 of this guidance.

ANNEX 4: SHELLFISH

A.4.1: Introduction

This Annex provides specific guidance to Food Authorities on the application and enforcement of the Shellfish (Live Bivalve Mollusc) aspects of Regulations 852/2004, 853/2004 and 854/2004.

A.4.2: Competent Authority

The Food Standards Agency is the UK central competent authority with lead responsibility for these Regulations. Food Authorities are responsible for enforcement of the Regulations at local level.

A.4.3: The Local Market Exemption

Regulation 853/2004 does not apply to the direct supply of small quantities of live bivalve molluscs to the final consumer or to local retail establishments directly supplying the final consumer. For live bivalve molluscs, a small amount is a total amount of not more than 25 tonnes of fishery products in a calendar year. The total amount may be made up of any species with the exception that the total amount shall not exceed the maximum amount for the following species:

A.4.4: Table

(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 this allowance it is still the responsibility of the harvester to ensure that the live bivalve molluscs meet the end product standards set down for placing them on the market. Any amount of the catch which include live bivalve molluscs must have originated from an 'A' class area, which designates the product as suitable for placing on the market with no further treatment required.

A.4.5: Heat Treatment

Live shellfish 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 shellfish up to the point where processing begins in an approved establishment. After that point they are considered to be fishery products.

The controls that must be exercised over any heat treatment process for bivalve molluscs from Class B or Class C areas are set out in Annex II, Section VII, Chapter II of Regulation 853/2004.

A.4.6: Shellfish Liaison Arrangements

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

It is essential for the effective enforcement of the Regulations that adjoining Food Authorities, including Port Health Authorities, in England and Wales maintain effective liaison arrangements.

All Food Authorities in England and Wales in areas in which there are commercial shellfish harvesting activities should maintain, participate in, and be represented at a local shellfish liaison group.

Each local shellfish liaison group should also include representatives of other relevant local and national organisations, including the Chief Fishery Officer of the local Sea Fisheries Committee, the Environment Agency, the DEFRA Sea Fisheries Inspectorate (SFI) and the Health Protection Agency (or a representative of the microbiology laboratory used by the Food Authorities if it is not an HPA laboratory).

Local shellfish liaison groups should consider holding periodic meetings with members of the local shellfish industry, particularly if there are difficulties over enforcement or interpretation of the Regulations.

The liaison group's functions should include:

- The identification of local relaying areas (if any) (working with the industry);
- Joint sampling plans to monitor the quality of shellfish from designated areas (and new production areas);
- Arrangements for the issue of movement documents;
- Arrangements for the making of Temporary Prohibition Orders covering waters from more than one Food Authority area;
- Arrangements for the detention/recall of shellfish affected by any Temporary Prohibition Order;
- Effective local notification procedures to advise interested parties of action taken under the Regulations (where such notification is required by the Regulations);
- Co-ordination of local monitoring procedures to ensure compliance with the requirements of the Regulations.

A.4.7: Notification of Production Areas and Relaying Areas

The Agency will supply a list of designated bivalve mollusc production and relaying areas to Food Authorities annually and, where necessary, additions and changes to the lists during the year.

Food Authorities should forward relevant details of designated production areas and approved relaying areas to members of the local shellfish industry, including harvesters, handlers, operators of dispatch and purification centres and other individuals and organisations likely to be substantially affected by the designation of bivalve mollusc production areas and approved relaying areas.

It may be necessary from time to time for the Agency to re-classify a bivalve mollusc production area. Relevant Food Authorities will be informed by the Agency whenever this is done. Food Authorities should forward all public information concerning the re-classification of production areas to members of the local shellfish industry as described above.

A.4.8: Monitoring of Registration Documents

Food Authorities should be aware of the commercial advantages of abusing the movement 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 movement 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 prescribed in Section VIII of Chapter V of Regulation 853/2004. On a cautionary note, it should be recognised that shellfish *E.coli* monitoring from any one production area may show significantly variable results, both temporally and spatially, due to environmental and other factors e.g. class C areas may occasionally yield single results <230 *E.coli*/100g (for this reason classifications are based on a time series of data rather than single results). Therefore a batch sample returning a single result that meets the requirements of a particular classification category should not be considered conclusive proof that the batch originated from the same class of production area.

Food Authorities will find that liaison with other statutory inspectorates e.g. SFI, the Scottish Fisheries Protection Agency (SFPA) and the local Sea Fisheries Committee is helpful in monitoring the harvesting of shellfish.

The movement document in respect of each batch of shellfish must be date stamped on delivery of the batch to a dispatch centre, purification centre, relaying area, or processing plant by the operator of the centre or area. Operators are required to retain movement documents for at least 12 months. Gatherers are also obliged to keep a copy of completed movement documents for the same period.

A.4.9: Sampling by Operators

Operators of approved purification / dispatch centres should also have adequate laboratory arrangements to ensure that the shellfish comply with the microbiological standards set out in Section VIII of Chapter V of Regulation 853/2004.

Officers should be aware that the Regulations do not prescribe a frequency for these microbiological tests.

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

A.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 Section VIII of Chapter V of Regulation 853/2004 must be recognised by the Food Authority. The laboratory may be directly associated with the approved centre, or may be a Health Protection Agency (HPA) Food Examiner, or any other appropriate laboratory.

However, recognition by the Food Authority will depend on the laboratory using methods for microbiological examination that are acceptable to Agency. The current recognised method is appended to the paper entitled “Modification of the standard method used in the United Kingdom for counting *Escherichia coli* in live bivalve molluscs”, published in Volume 1 of Communicable Disease and Public Health of 3 September 1998. Food Authorities may also wish to consider whether the laboratory is/should be accredited for the relevant method(s) and participates in a recognised external quality assurance scheme such as is run by the HPA.

A.4.11: Sampling of Live Bivalve Molluscs by Food Authorities

Sampling by Food Authorities should be aimed at verifying the results of tests carried out by producers and operators of centres. Test results that are inconsistent with those shown in the centre’s own records should be followed up by further investigations and tests.

A.4.12: Information on Standards to be applied

Information on the standards required by the Regulations may be found in a series of six operating manuals for the different types of purification system used in the UK and a further guidance document “Procedures to Minimise Risks to Food Safety in Bivalve Mollusc Purification” published by the Sea Fish Industry Authority (Seafish). These documents contain recommendations designed to help shellfish processors achieve high quality standards, as well as to comply with the requirements of the Directive. In some instances the guidance makes recommendations for good industry practice, which go

beyond the requirements of legislation. These documents are available on the Seafish Website www.seafish.org.

Food Authorities may refer to the guidelines to establish a consistent approach to the requirements of the Regulations but should avoid using, in support of formal enforcement action, those parts that are directed towards the achievement of good industry practice and high quality standards.

A.4.13: Molluscs and Other Shellfish Which Fail to Satisfy Requirements

Any live shellfish that have not been handled etc in accordance with the Regulations as failing to meet the requirements of the Regulations may be treated as failing to comply with Section 9 of the Food Safety Act 1990 and may be seized and taken before a Justice of the Peace to be condemned, implementing Directive 91/67/EEC on the animal health conditions governing the placing on the market of aquaculture animals and products.

A.4.14: Transfer of Seed Molluscs to Production Areas

Bivalve molluscs may be transferred from areas that are not designated as production areas for “growing on” within a production area of any Class. Such molluscs must be genuine “seed shellfish”. In fisheries regulated for conservation purposes under the Seafish (Conservation) Act 1967, transfers may only be carried out on approval of the holder of the Regulating Order for that fishery.

Transfers of “seed shellfish”, i.e. immature shellfish taken from an unclassified area, to be used to seed a classified production area are permitted, provided that they remain in the 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 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 Prohibition Orders

A Food Authority may make a temporary prohibition order to prohibit the collection of any live shellfish from a production area. An order may be made if the Food Authority is satisfied that the consumption of shellfish taken from the area is likely to cause a risk to public health. A temporary prohibition order will cease to have effect 28 days after the making of the order. Such an order might be considered appropriate where, for example, the designated mollusc production area was subject to sudden or accidental pollution which affected the quality of the production area. Temporary prohibition orders may also be appropriate where there is a local problem with chemical contamination or toxin producing plankton

There may also be circumstances when it would be appropriate for the Food Authority to consider seeking the opinion of appropriate experts such as the consultant in communicable disease control and consultant microbiologist at the HPA.

A.4.16: Live Shellfish Guidance Note for Food Authorities

CONSOLIDATED GUIDANCE NOTE FOR FOOD AUTHORITIES

LIVE SHELLFISH (BIVALVE MOLLUSCS)

INDEX

Approval of Establishments

1. When does a harvester or handler of shellfish need to consider becoming an approved dispatch centre?
2. May inland markets become dispatch centres?
3. Are separate approval numbers needed for dispatch and purification centres operating from the same site?
4. What locations are considered suitable for dispatch centres and purification centres?
5. Does the dispatch centre working area need to be physically identifiable from the purification centre working area, where both activities are carried out on the same premises?

Registration documents

6. Can a Food Authority issue registration documents to gatherers of shellfish in another Food Authority's area?

Identification Marking

7. If a dispatch centre is selling live shellfish to individual consumers on a retail basis, does the identification mark need to be applied to each sale?

Seed Shellfish

8. What is the minimum period of on growing of seed mussels before they can be harvested for human consumption?

CONSOLIDATED GUIDANCE NOTE FOR FOOD AUTHORITIES

LIVE SHELLFISH (BIVALVE MOLLUSCS)

Approval of Establishments

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

Regulation 853/2004, Annex 1(2) defines a dispatch centre as 'any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading and wrapping of live bivalve molluscs fit for human consumption.' All dispatch centres must be approved. As fishing vessels are considered primary production, fishing vessels do not need approval for washing and grading live bivalve molluscs at sea. Though fishing vessels will need to be registered.

The Regulation (853/2004/EC, Annex III, Section VII) requires all live bivalve molluscs destined to be placed on the market to enter the market via a dispatch centre. At the dispatch centre they are wrapped, health marked and sampled. The dispatch centre need not be on the shoreline but could be some distance away, even in another Member State.

2. May inland markets become dispatch centres?

Yes. The market would need to meet the approval conditions in the same way as other dispatch centres. Approval as a dispatch centre is not necessary to enable a market to unwrap parcels of live shellfish already sent from a dispatch centre and to split up the parcels for sale to retailers or consumers.

3. Are separate approval numbers needed for dispatch and purification centres operating from the same site?

No. Where both exist on the same premises then the same number should be used for the dispatch centre and for the purification centre. Different suffixes (D and PC) are no longer used to separately identify dispatch and depuration centres.

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

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

5. Does the dispatch centre working area need to be physically identifiable from the purification centre working area, when both activities are carried out on the same premises?

The need to separate clean from contaminated live shellfish would dictate this. It would also be in the interests of the business to have separate areas in the event of enforcement action on either the dispatch or purification centre. In small plants this is subject to a risk assessment by the Food Authority.

Registration documents

6. Can a Food Authority issue registration documents to gatherers of shellfish in another Food Authority's area?

Registration documents should generally be issued by the Food Authority with responsibility for the harvesting area. This ensures that up to date information about any public health issues relating to the harvesting area may be given to gatherers. However, a Food Authority may allow gatherers to apply to it for registration documents for gathering in another Food Authority's area. In these circumstances the two Food Authorities should liaise regarding the issue of the registration documents and ensure that arrangements operate effectively to assist industry and avoid abuse. Inter-authority arrangements of this kind should normally be restricted to adjoining Food Authorities.

Identification Marks

7. If a dispatch centre is selling live shellfish to individual consumers on a retail basis, does the identification mark need to be applied to each sale?

Regulation 853/2004 does not apply to retail. Under this regulation there is only a requirement for identification marks to accompany consignments of live shellfish prior to retail sale. After live shellfish are sold the retailer should retain a copy of the registration document for at least 12 months, or for as long as the competent authority requires. Therefore, where a dispatch centre is acting as a retailer, record keeping of the dispatch of batches of live shellfish through the retail outlet may suffice. The position is similar for live shellfish sold by mail order.

Seed Shellfish

8. What is the minimum period for on growing of seed mussels before they can be harvested for human consumption?

The minimum period for growing on genuine seed mussels should be six months.

A.4.17: Model Registration Document

LIVE SHELLFISH REGISTRATION DOCUMENT

Registration Document

No.....

Issued by:

Date of Issue:

Name of gatherer

Signature of gatherer

.....

Food Authority where shellfish landed

Address of gatherer

.....

Date of gathering

Location of production area
[described in as precise detail as
practicable] and, if live bivalve
molluscs, class of production area (A,
B* or C*)

.....

Name of shellfish species being moved
(common and scientific) and quantity of
shellfish being moved

Place of destination, including
(if applicable) approval number

.....

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

Relaying area

Duration of relaying

OR

Address of Purification Centre

.....

Date of Receipt

Place of Receipt

[Date of Signature]

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

ANNEX 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 agency is the UK central competent authority with lead responsibility for these Regulations.

Food Authorities are responsible for enforcement of the EU food hygiene Regulations at their regional 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 premises unless expressly indicated. They would however apply when operations are carried out to supply fishery products to other establishments.

Auctions and wholesale markets are required to have approval and should be inspected at regular intervals to check for compliance with hygiene and temperature requirements and subject to Regulation 853/2004 Annex III Section VIII Chapter II.

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

The Regulations do not apply the direct supply of small quantities of fishery products to the final consumer or to local retail establishments directly supplying the final consumer. For the purposes of fishery products (not including live bivalve molluscs) a small amount is a total amount of not more than 25 tonnes of fishery products in a calendar year. 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.5.5: Table

(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 the Regulations do not apply to this allowance it is still the responsibility of the harvester to ensure that these products meet the end product standards set down for placing these fishery products on the market. Any amount of the catch which include bivalve molluscs must have originated from an 'A' class area, which designates the product as suitable for placing on the market with no further treatment required.

A.5.6: Conditions During and After Landing

One of the public health and quality measures in the Regulations is periodic inspection and checks on the fitness for human consumption of fish at the time of landing or before the first sale. Where fishery products are sold at a market associated with the landings, these inspections should take place in that auction hall or wholesale market. It should not normally be necessary for any inspections to be carried out at the time of landing. An organoleptic examination of the fishery products would normally satisfy this requirement.

A Food Authority may authorise the transfer of fishery products from the landing (ex-quay) into containers for immediate delivery to an approved establishment or auction or wholesale market for the checks to be carried out there. Deferring the checks to be carried out later in an auction or wholesale market should not normally require any special arrangements with the receiving Food Authority.

Deferring checks to an approved establishment must, however, be subject to liaison and agreement with the receiving Food Authority, and have regard to the compliance record of the receiving establishment and confidence in its management. Authorisation of such deferred checks should be withdrawn if there is any suspicion of non-compliance with the requirements of the Regulations.

If an organoleptic examination of any product raises doubt as to the freshness of the product, the Food Authority may consider submitting the product for chemical analysis or microbiological examination.

With respect to the landing of fresh fish, checks required under the Regulations are without prejudice to other checks that may be required under EC marketing standards regulations by other statutory agencies.

Authorised officers should, where necessary, liaise with other statutory inspectors, e.g. the DEFRA Sea Fisheries Inspectorate, or the Scottish Fish Protection Agency (SFPA) to ensure that any enforcement action taken is appropriate

A.5.7: 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.

A.5.8: Fishery Products Guidance Note

GUIDANCE NOTE FOR FOOD AUTHORITIES

FISHERY PRODUCTS

INDEX

Approval of Establishments

1. What establishments need an approval number?
2. What is a retailer?
3. Who is the Final Consumer?
4. In what circumstances would auction or wholesale markets need to become establishments?
5. Should individual stalls in auction halls and wholesale markets, where heading and gutting of fish is carried out, be approved establishments?
6. Should retailers who also sell wholesale be approved establishments?
7. Are retailers engaged in preparation of fish covered by the Regulation?
8. Do cold stores need to be approved establishments, even though they are not involved in the handling and processing of fishery products?
9. Do cash and carries need to be approved?
10. Are sandwich makers covered by the Regulations and do they need to be approved establishments?
11. Do fishmongers who also smoke or process fish and, if applicable, supply fish vans, need to be approved establishments?
12. Are fishmongers who sell retail, but who keep fish live covered by the Regulations?
13. If a retail outlet only has upright or chest freezer cabinets, does it need to be approved to comply with the requirements laid down for cold stores?
14. Do premises storing only cans and jars of fishery products need to be approved?
15. Are airport caterers who supply fishery products to companies, which supply airlines, covered by the Regulations and do they need approval?

16. If a business has been approved under the Regulations and changes hands, does the new owner need to apply for approval and the business be reassessed?
17. If a business supplies a company or a contractor, who then supplies the final consumer would it be covered by the Regulations?

Conditions of Approval

18. Do all the requirements of Regulation 853/2004 in relation to fishery products apply to all fishery products establishments?
19. Could such facilities as wash basins and lavatories be communal to a number of establishments?
20. When the Regulations refer to temperature recording devices, does this mean that readings can be taken and logged manually?
21. Are communal filleting premises permissible?
22. The Regulations require that operations such as filleting and slicing must be carried out in a place other than that used for heading and gutting operations. How should this be interpreted?
23. Is there a list of approved detergents and similar substances for maintaining general conditions of hygiene in establishments and on equipment?

Fish Farms

24. Are fish farms covered by the Regulations?

Identification marks

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

Landings of fishery products

26. Do EHOs have to carry out histamine checks on other compounds listed in Regulation 854/2004 on all consignments of fish?
27. Do quaysides where fish are landed need to comply with the Regulations?

Approval of Establishments

1. What establishments need an approval number?

Article 6(2) of Regulation 852/2004 states that all food businesses shall notify the competent authority with a view to being registered however under Article 6(3)(b) food business operators shall ensure that all establishments requiring approval are approved when required Regulation 853/2004. Under Article 4 of Regulation 853/2004 establishments handling products of animal origin for which the Annex lays down requirements shall require approval by the competent authority. However, establishments carrying out 'primary production', 'transport or storage with temperature controls' or certain 'retail' activities are exempt from the requirements of the Regulation. 853/2004.

To decide whether a retail activity is, or is not exempt Article 1(5) of 853/2004 should be considered. The regulations will apply to retail when food operations are conducted with the purpose of supplying another establishment. However, if the retail operation consists of transport and storage only then they will not require approval. If the other establishment is in itself a retail operation then the regulations will not apply if this activity can be classified as local, marginal and restricted. In respect of these conditions food businesses claiming exemption must be considered on a case by case basis.

Fishery Products establishments carrying out the following will require approval:

- All fishery product establishments handling and processing live bivalve molluscs or fish.
- Fishery Products establishments that handle processed fish for storage only and where temperature controls are required.
- Auction and Wholesale Markets (see question below on retail) where handling and storage requires temperature control.
- Factory Vessels where fishery products are processed on board.
- Freezer Vessels

2. What is a retailer?

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

3. Who is the Final Consumer?

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

4. In what circumstances would auction or wholesale markets need to become establishments?

Under Article 2 (c) of Regulation 852/2004 an establishment is defined as 'any unit of a food business'. However, 852/2004 does not cover food business activities relating to 'primary production for private domestic use or any domestic preparation of food for domestic consumption'.

It is the case that wholesale outlets are included under the definition of retail in Regulation 178/2002 (see above). However, for wholesale units to fall within this definition they must be selling to the final consumer. When looking at the meaning of final consumer (see Q&A 3, above) it is apparent that it allows for wholesale units that could not be classified as retail, i.e. those that sell on for use in other food business operations or activities. Under these conditions auction or wholesale markets that do not sell primarily to the 'final consumer' cannot be considered retail. Therefore wholesale markets that supply to other food business operations or activities will need to be approved.

Under this definition fish auctions and units of wholesale markets are establishments and may require approval under the conditions as specified in the answer to question 1 above.

5. Should individual stalls in auction halls and wholesale markets, where heading and gutting of fish is carried out, be approved establishments?

Individual stalls in auction halls are classed as establishments and will need to meet the hygiene requirements of Regulation 852/2004, where appropriate. Regulation 853/2004 will only apply if the stall does not qualify for retail status (see Q&A 1, above). Should it be the case that the stall is not selling as a retail operation then it may still need to be subject to approval under Regulations 853/2004, especially if temperature controls are required. In addition to the allocation of an approval number to the wholesale market itself, Food Authorities may issue sub-approval numbers to individual units or groups of units within wholesale markets may. Each unit would be responsible for meeting the hygiene requirements.

6. Should retailers who also sell wholesale be approved establishments?

Retailers who also sell wholesale to those not considered to be the final consumer may fall within the scope of Regulation 853/2004 and may require approval (see Q&A 1, above).

7. Are retailers engaged in preparation of fish covered by the Regulation?

Yes, unless they are only selling prepared fish to the final consumer.

8. Do cold stores need to be approved establishments, even though they are not involved in the handling and processing of fishery products?

Yes, Only operations that conduct storage of fishery products without temperature control need not be approved.

9. Do cash and carries need to be approved?

Retail establishments, such as cash and carry outlets, are generally exempt from the requirements of Regulation 853/2004. However, where a cash and carry is not just selling to final consumers, but other food establishments as well, they will require approval if their sales to other establishments involve operations beyond transport or storage. If the other establishment is in itself a retail operation then the regulations will not apply if this activity can be classified as local, marginal and restricted. Cash and carry outlets claiming exemption under these conditions will therefore need to be considered on a case by case basis.

Where only transport and storage is carried out the temperature control conditions laid down in Annex III, Section VIII, Chapters VII and VIII of Regulation 853/2004 will still apply.

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

Sandwich makers, owing to the exemption for composite products in Article 1 of Regulation 853/2004, do not require approved status. However, the fishery product used to produce sandwiches should be obtained and handled in accordance with the requirements of Regulation 853/2004. Sandwich makers will still need to meet, where it is appropriate, the hygiene requirements of Regulation 852/2004.

11. Do fishmongers who also smoke or process fish and, if applicable, supply fish vans, need to be approved establishments?

Fishmongers that sell their own smoked or processed products, but only to the final consumer would not require approval under the Regulations. However, where appropriate, they will need to comply with Regulation 852/2004.

If a Fishmonger sells smoked or processed products to other establishments it will require approval under Regulation 853/2004, unless the other establishment is retail and the activity can be classified as local, marginal and restricted. Those fishmongers claiming exemption under these conditions will need to be considered on a case by case basis.

12. Are fishmongers who sell retail, but who keep fish live covered by the Regulations?

Regulation 853/2004 does not apply if they sell only to their final consumers.

13. If a retail outlet only has upright or chest freezer cabinets, does it need to be approved to comply with the requirements laid down for cold stores?

There is no need for the premises to be approved where the only storage activity with fishery products is in upright or chest freezer cabinets for display

for retail sale. However, where appropriate, they will need to comply with Regulation 852/2004.

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

No.

15. Are airport caterers who supply fishery products to companies, which supply airlines, covered by the Regulations and do they need approval?

If the airport caterers are supplying their fishery products by carrying out operations in relation to the fishery products beyond transport and storage then they will require approval. However, if the products they supply are composite products, like sandwiches, containing products of plant origin then Regulation 853/2004 would not apply and approval would not be required. In this situation the airport caterers would only have to ensure that the products of animal origin being used to prepare their food products is obtained and handled in accordance with Regulation 853/2004. Therefore the fishery products must originate from an approved establishment and the company would need to comply with Regulation 852/2004.

16. If a business has been approved under the Regulations and changes hands, does the new owner need to apply for approval and the business be reassessed?

Under the Regulations, an approval is in relation to the premises and not the business occupying the premises or the operator. So the new owner of the premises does not have to seek approval. However, the new owner is obliged to comply with any terms or limitations attached to the approval and with the general requirements of the Regulations. Where a new owner of a previously owned business changes the name or activities of that business the Food Authority must be informed and the premises re-assessed.

17. If a business supplies a company or a contractor, who then supplies the final consumer would it be covered by the Regulations?

Yes. The first business is not supplying its own final consumers.

Conditions of Approval

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

No. Under Regulation 852/2004 there are general conditions applicable to both businesses involved in primary production and those for manufacturing food businesses. However, the regulations indicate where separate conditions apply. Similarly under Regulation 853/2004 the different operations for establishments such as purification centres, fishing vessels, factory vessels and fishery product processing establishments.

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

Regulation 852/2004 covers the general hygiene requirements for food business establishment. With regards to wash basins and lavatories in, for example, wholesale markets, it is for the Food Authority to decide whether separate facilities, for different establishments, is in the public's health interest.

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

Regulation 852/2004 Annex II, Chapter I, stipulates that it should be possible to monitor and record temperatures at which foodstuffs are maintained. The Regulations do not stipulate that the recording of temperatures should be done automatically, which implies that manual recording is allowed. However, for freezer vessels or establishments on land where the freezing of fishery products is undertaken the requirement is that a temperature recording-device be installed.

See Regulation 853/2004 Annex III, Section VIII, Chapter one, I (C) – Requirements for Freezer Vessels and Chapter three, B Requirements for Frozen Products (on land).

21. Are communal filleting premises permissible?

The Regulations do not specify whether or not communal filleting premises are permissible. Provided that control arrangements are adequate, ensuring that filleting is carried out to avoid contamination or spoilage then communal filleting premises would not be precluded by the Regulations. However, a separate establishment for communal filleting is likely to require approval and meet the other hygiene requirements of the Regulations.

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

The main requirement under Regulation 853/2004 is to avoid contamination of fillets. There may be a number of ways in which this can be achieved, one of which is to separate operations by time rather than place. As long as the Food Authority are content that contamination of the fillets is prevented then this separation by time may be allowed. We would assume that filleting and slicing is carried out where necessary at a different time or a place other than that where heading and/or gutting is carried out.

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

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

Fish Farms

24. Are fish farms covered by the Regulations?

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

Identification marks

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

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

Landings of fishery products

26. Do Food Authorities have to carry out histamine checks?

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

Other checks are required under Annex III, Chapter II. Corresponding checks must also be carried out by food business operators.

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

There are no structural requirements for quays laid down in the regulations, however Annex II of Regulation 852/2004 does lay down general hygiene requirements for premises which will be applicable to auction and wholesale markets. Additionally handling practices for the unloading and landing of fish and some requirements relating to equipment are specified in Regulation 853/2004. Seafish Guidelines for Facilities and Equipment during Landing, Storage, Auction, and Dispatch from the Landing Area contains recommendations for quaysides.

- The proposed laboratory arrangements for the purpose of carrying out sampling in accordance with the Regulations;

- Documented cleaning schedules with details of any checks, including sampling, carried out by the occupier to establish the efficacy of proposed cleaning and disinfection methods;
- Documented maintenance schedules. These should specify the checks to be carried out and any reporting arrangements;
- Documented pest control arrangements, including copies of any contracts with external pest control companies;
- Details for calibrating and monitoring automatic temperature control equipment, where required by the Regulations;
- Proposed staff hygiene training programme, including records of training undertaken to date;
- Written company policy on staff illness and exclusion from work;
- Medical certificates for all staff;
- Details of traceability system, including checks on incoming raw materials, arrangements for controlling application of the health mark and correct use of commercial documentation. Details should include arrangements for documenting these procedures. It may also be appropriate to request examples of health marked labels;
- Emergency withdrawal procedure;
- Up to date list of suppliers;
- Up to date list of customers (National, EU, 3rd Country).

ANNEX 6: RAW MILK AND DAIRY PRODUCTS

A.6.1: Introduction

This Annex provides specific guidance to Food Authorities with regard to Raw Milk and Dairy Products. Separate Guidance to Food Authorities in England on Officially Tuberculosis Free Status and dairy hygiene legislation⁴³ has been circulated.

A.6.2: Enforcement

Food Authorities approve dairy establishments, and otherwise enforce the Regulations except in the cases listed below:

- Requirements in Regulation 5(1)(a) of the Food Hygiene (England) Regulations 2005 relating to the approval of production holdings and the subsequent supervision and inspection of approved production holdings (apart from animal health checks - see below). These are dealt with on behalf of the agency by the Dairy Hygiene Inspectorate (DHI) of the Rural Development Service in DEFRA. Separate guidelines are issued for enforcement of these requirements;
- Controls in Regulation 32 of the Food Hygiene (England) Regulations 2005 on the sale of raw cows' drinking milk, i.e. cows' milk that is supplied raw to the final consumer or to distributors, from farms direct to consumers, temporary guests or distributors and standards for such milk in Schedule 6. These are also dealt with by the DHI (the separate guidelines mentioned above also cover enforcement of these requirements);
- The Department of Environment, Food and Rural Affairs (Defra) is responsible for carrying out official tests for tuberculosis and brucellosis where appropriate.

Food business operators whose operations are both production holdings and processing establishments are approved by the agency as a production holding, and approved by the Food Authority as a dairy establishment.

Regulation 853/2004 covers the production and placing on the market of products of animal origin and, in respect of the dairy sector, will apply to premises engaged in:

- Production of raw milk (production holdings);
- Heat-treatment of milk (treatment establishments);
- Handling of dairy products, including manufacturing, preparing, processing, (including slicing and whipping), packaging, bottling, and wrapping or re-wrapping (processing establishments);

⁴³ Guidance to food Authorities in England on Officially Tuberculosis Free Status and Dairy Hygiene Legislation, as circulated under cover of CEHO letter ENF/E/05/014.

- Collection of raw milk (collection centres);
- Standardisation of fat content of raw milk (standardisation centres).

Treatment and processing establishments are not regarded as collection centres even if they collect raw milk.

Processing does not include cooling or freezing of raw milk, or placing of frozen milk in bags for transport to manufacturing businesses.

Storage depots and wholesalers, while not requiring approval, are subject to certain storage and transport provisions of the Regulations.

A.6.3: Food Business Operators Selling Raw Milk and Cream

Article 10(8) of Regulation 853/2004 allows member states to retain national rules on the retail sale of raw milk and cream. Food businesses that are on-farm processors of raw cows' drinking milk (i.e. those wrapping/packing/bottling raw milk) who sell such products exclusively direct to the final consumer (including from their own milk van and at Farmers Markets) are exempt from approval. However, such premises still need to meet the relevant requirements for processing establishments in Regulation 853/2004 and the relevant requirements of Regulation 852/2004.

Processors selling to cash and carries etc. or to other retail establishments or to distributors that are a separate business must be approved.

The restrictions on sales of raw cows' drinking milk in Schedule 6 of the Food Hygiene (England) Regulations 2005 are enforced by the DHI at farm level.

Food Authorities are responsible for enforcing the requirements of Schedule 6 of the Food Hygiene (England) Regulations 2005 in respect of sales of raw cows' drinking milk on milk delivery rounds and for enforcing the microbiological standards in respect of sales of raw ewes' and goats' drinking milk, which are still permitted at retail outlets. Distributors have to be registered with the Food Authority as food businesses.

A.6.4: Derogations

The Regulations provide for derogations to be given in a number of instances. Establishments with such derogations still need to be approved so that their products qualify for an EC health mark and can be traded with other Member States. Article 10(8) of Regulation 853/2004 covers derogations that Food Authorities may authorise, subject to there being no risks to product safety or public health. These include derogations for long maturing cheeses, retail sales of raw milk and raw cream.

A6.4.1: Long Maturing Cheeses

Under Article 10(8)(b) of Regulation 853/2004, derogations from certain requirements apply in the case of cheese with a maturing period of at least 60 days, which includes cheeses such as Cheddar and Stilton.

If a Food Authority is concerned about granting a derogation under the Regulations, they should try to resolve the matter through their local Food Liaison Group, or through LACORS in the absence of a consensus.

A.6.5: Testing for Residues, Raw Milk and Other Standards

Annex III, Section IX, Chapter I, Part III of Regulation 853/2004 requires that food business operators selling raw cows' drinking milk must ensure that checks are carried out to ensure that the raw cows' drinking milk meets the microbiological criteria set out in [Commission Regulation xxxx/2005 on microbiological criteria for foodstuffs]. The frequency sampling is two samples per month for plate count and one per month for somatic cell count. Food business operators shall also ensure that appropriate checks are made to ensure that antibiotic residues do not exceed the permitted levels in Annexes I and III of Regulation (EEC) No. 2377/99.

A.6.6: Hygiene Rules for Approval of Production Holdings

The requirements relating to the approval of production holdings are not enforced by Food Authorities in England.

A.6.7: 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.6.8: Health Requirements for Raw Milk Production

Food business operators are responsible for ensuring that the requirements of Regulation 853/2004, Annex III, Section IX, Chapter 1 are met through private veterinary inspections at regular intervals. The frequency of such inspections will be dependent on the individual circumstances. Such inspections can take place when a farmer's private veterinary surgeon is present for other purposes. Food business operators will need to keep evidence of such visits e.g. a receipt/invoice - and of any follow up action taken if problems occur - for checking by authorised officers. Purchasers (or processors) of raw milk are also required to ensure, e.g. through contracts, that checks have been carried out to assess compliance with relevant animal health standards. Immediate problems that may affect the safety of milk will normally be notified to Food Authorities by private veterinary surgeons or (more rarely) the State Veterinary Service. Longer-term issues arising from records could also be referred to Food Authorities. Where Food Authorities suspect that requirements are not

being complied with, or that follow up action has not been taken, they should raise the matter with the purchaser/processor, or in the case of producer/retailers of raw milk with the producer direct, and advise them to take appropriate advice e.g. from their private veterinary surgeon.

A.6.9: Criteria and Standards for Raw Milk

In the case of the standards laid down in Regulation 853/2004, Annex III, Section IX, Chapter III, Paragraph 3 for plate counts and somatic cell counts, the Regulations specify a minimum frequency of sampling by the food business operator or the purchaser. Authorised officers need to ensure that food business operators are carrying out the specified sampling programme. Authorised officers should check Food Business Operators' records, and when they have concerns about the test results, consider random official checks to satisfy themselves that the required standards are being met.

A.6.10: Temperature Requirements for Milk Used for the Manufacture of Dairy Products

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

A.6.11: Identification Marking for Raw Milk and Dairy Products: Derogations

There are two derogations in Regulation 853/2004, Annex III, Section IX, Chapter V for Raw Milk and Dairy Products. The identification mark can instead of indicating the approval code refer to where on the wrapping or packaging this information is indicated. The identification mark on reusable bottles may indicate only the initials of the consigning country and the number of the establishment.

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.

Also, Establishments processing eggs for use on the premises as ingredients in other foods that are produced on the same premises do not require approval if these are “composite products”. These are also exempt from the requirements of Regulation 853/2004 by virtue of Article 1(2).

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

A.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.

The Regulations do not cover egg products that are stored in separate establishments such as depots or warehouses outside approved egg products establishments. Such storage is covered by Regulation 852/2004.

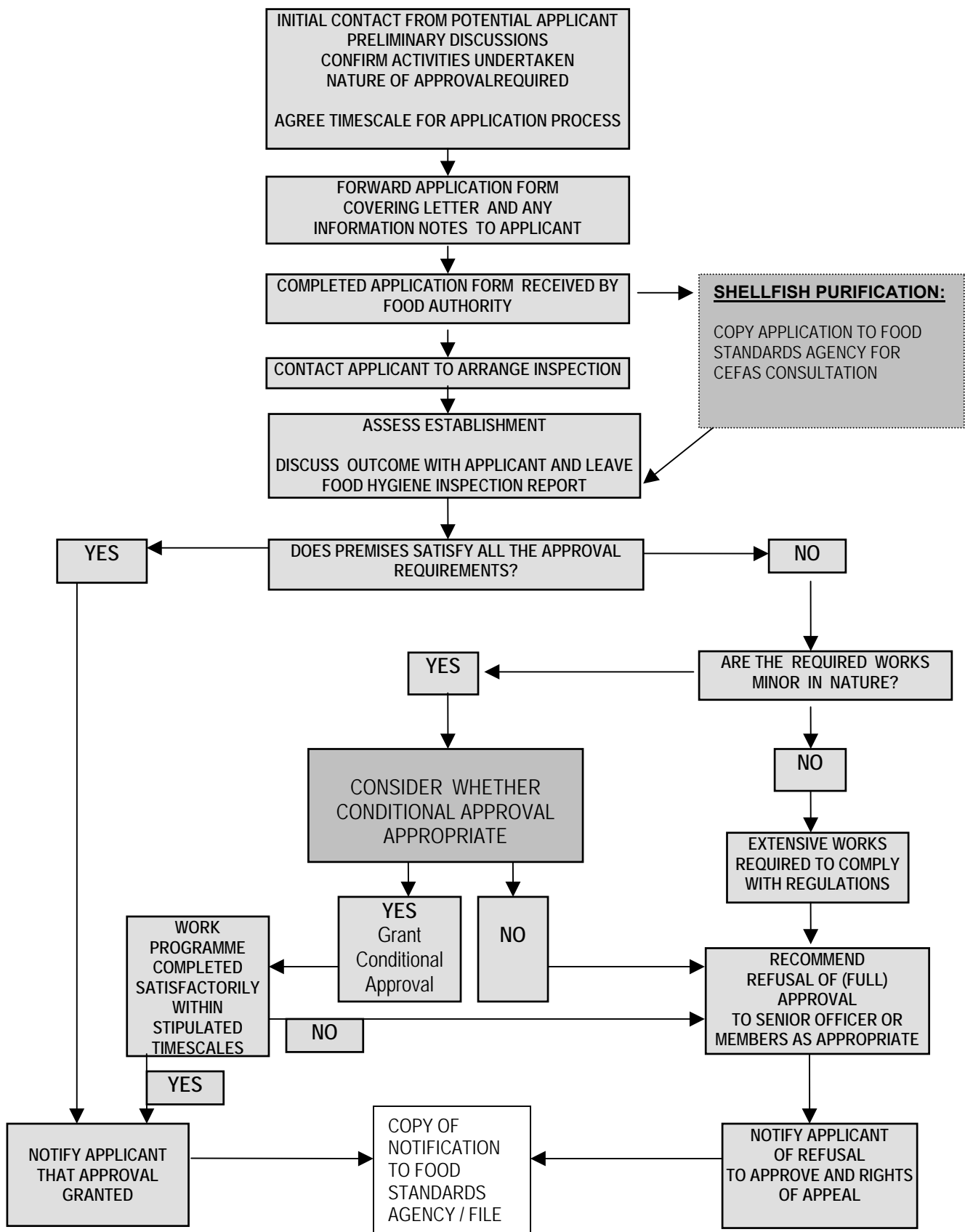
A.7.11: Egg Marketing

Egg packing centres, whether or not approved to produce liquid egg under the Regulations, are the responsibility of Defra in respect of egg quality and marketing regulations and are inspected by Egg Marketing Inspectors (EMIs).

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

ANNEX 8: APPROVAL PROCESS

Appendix 1: Flow Chart for Approval of Establishments



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

PART 1 – TYPE OF PRODUCT OF ANIMAL ORIGIN FOR WHICH APPROVAL IS SOUGHT

<input type="checkbox"/>	Minced Meat
<input type="checkbox"/>	Meat Preparations
<input type="checkbox"/>	Mechanically Separated Meat
<input type="checkbox"/>	Meat Products
<input type="checkbox"/>	Live Bivalve Molluscs (Shellfish)
<input type="checkbox"/>	Fishery Products
<input type="checkbox"/>	Dairy Products
<input type="checkbox"/>	Egg Products
<input type="checkbox"/>	Cold Store
<input type="checkbox"/>	Frogs' Legs / Snails
<input type="checkbox"/>	Gelatine
<input type="checkbox"/>	Collagen

Trading name

Full postal
Address

Postcode:

Name and full
Address of Food Business
Operator

Postcode:

Full names of managers of The Premises	1.	2.	3.
	Job titles	1.	2.

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

PART 4 – USE OF THE ESTABLISHMENT

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

<input type="checkbox"/>	Wholesale market
<input type="checkbox"/>	Manufacture
<input type="checkbox"/>	Other processing (please specify)
<input type="checkbox"/>	Packing
<input type="checkbox"/>	Storage
<input type="checkbox"/>	Distribution
<input type="checkbox"/>	Cash and carry / wholesale
<input type="checkbox"/>	Catering (preparation of food for consumption in the establishment)
<input type="checkbox"/>	Retail (direct sale to consumers or other customers)
<input type="checkbox"/>	Market stall or mobile vendor
<input type="checkbox"/>	Other (please specify)

PART 5 – TRANSPORT OF PRODUCTS FROM THE ESTABLISHMENT

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

<input type="checkbox"/>	Your own vehicle(s)
<input type="checkbox"/>	Contract / Private Haulier
<input type="checkbox"/>	Purchaser's own vehicle(s)
<input type="checkbox"/>	Other (please specify)

PART 6 – SUPPLY OF PRODUCTS FROM THE ESTABLISHMENT TO OTHER ESTABLISHMENTS

Which of the following will be supplied with products from the establishment (tick all that apply)?

<input type="checkbox"/>	Other businesses that manufacture or process food
<input type="checkbox"/>	Wholesale packers
<input type="checkbox"/>	Cold stores that are not part of the establishment to which this application relates
<input type="checkbox"/>	Warehouses that are not part of the establishment to which this application relates

<input type="checkbox"/>	Restaurants, hotels, canteens or similar catering businesses
<input type="checkbox"/>	Take-away businesses
<input type="checkbox"/>	Retail shops, supermarkets, stalls, or mobile vendors that you own
<input type="checkbox"/>	Retail shops, supermarkets, stalls, or mobile vendors that you do not own
<input type="checkbox"/>	Members of the public direct from the establishment to which this application relates
<input type="checkbox"/>	Other (please specify)

PART 7 – OTHER ACTIVITIES ON THE SAME SITE

Will any of the following activities be conducted on the same site as, or within, the establishment to which this application for approval relates?

	YES	NO	APPROVAL CODE
Slaughter, including pigs, sheep, cattle, poultry, game etc:	<input type="checkbox"/>	<input type="checkbox"/>	
Cutting fresh (including chilled and frozen) meat, poultry meat or game:	<input type="checkbox"/>	<input type="checkbox"/>	
Storage of fresh (including chilled and frozen) meat, poultry or game:	<input type="checkbox"/>	<input type="checkbox"/>	

PART 8 – INFORMATION AND DOCUMENTATION

The following information is required in order to process your application and should be sent with this application form if possible. Please indicate which information you are sending now (N.B. information that is not sent now will still be required before your application can be determined).

<input type="checkbox"/>	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
<input type="checkbox"/>	A description of the (proposed) establishment and equipment maintenance arrangements
<input type="checkbox"/>	A description of the (proposed) establishment, equipment, and transport cleaning arrangements
<input type="checkbox"/>	A description of the (proposed) waste collection and disposal arrangements
<input type="checkbox"/>	A description of the (proposed) water supply
<input type="checkbox"/>	A description of the (proposed) water supply quality testing arrangements
<input type="checkbox"/>	A description of the (proposed) arrangements for product testing
<input type="checkbox"/>	A description of the (proposed) pest control arrangements
<input type="checkbox"/>	A description of the (proposed) monitoring arrangements for staff health
<input type="checkbox"/>	A description of the (proposed) staff hygiene training arrangements
<input type="checkbox"/>	A description of the (proposed) arrangements for record keeping
<input type="checkbox"/>	A description of the (proposed) arrangements for applying the identification mark to product packaging or wrapping

PART 9 – ACTIVITIES / PRODUCTS TO BE HANDLED IN THE ESTABLISHMENT

Which of the following activities will be conducted in the establishment? Indicate by giving the approximate quantities to be handled in kilograms or litres per week (tick all that apply).

PART 9(1) – Minced Meat and Meat Preparations

<input type="checkbox"/>	Handling minced meat
<input type="checkbox"/>	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?	<input type="text"/>
---	----------------------

How many tonnes of meat preparations in total will be handled in the establishment per week on average?	<input type="text"/>
---	----------------------

PART 9(2) – Mechanically Separated Meat

Full Details of Activities

How many tonnes of mechanically separated meat in total will be handled in the establishment per week on average?	<input type="text"/>
---	----------------------

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?	<input type="text"/>
--	----------------------

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?	<input type="text"/>
--	----------------------

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 tonnes of Dairy Products will be handled in the establishment per week on average?	
--	--

PART 9(6) – Egg Products

Full Details of Activities and Specific Products Handled

--

How many litres of Egg Products will be handled in the establishment per week on average?	
--	--

PART 9(7) – 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 9(8) – 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(9) – Gelatine

Full Details of Activities

--

How many tonnes of gelatine in total will be handled in the establishment per week on average?	
--	--

PART 9(10) – Collagen

Full Details of Activities

--

How many tonnes of collagen in total will be handled in the establishment per week on average?	
--	--

PART 10 – APPLICATION

Name of applicant

--

Position in business

--

Name of contact

--

Position in business

--

Tel (incl. Dialling code)

--

Fax (incl. Dialling code)

--

E-mail

--

I hereby apply, on behalf of the business described in Part 2, for approval to use premises at the address specified in Part 2 for the purpose of handling products to which Regulation (EC) No. 853/2004 applies.

Signature

--

Date

.

Name in
BLOCK LETTERS

--

If you need any help or advice about how to complete this form, or about the products to which the Regulations relate, or the circumstances in which approval under the Regulations is required, please contact the officer named below.

When you have completed this form and collected the other information required, please send it to:

--

Contact Name:

Telephone:

Fax:

E-mail:

IMPORTANT

Please notify any changes to the details you have given on this form, by writing to the address shown.

Appendix 3: Food Authority Files

List of Contents

The following guidance is offered to Food Authorities in order to support and improve consistency in the content and structure of files produced for establishments which require formal approval.

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

Each file should contain:

- The application form;
- a plan or plans of the establishment indicating:
 - i. The layout of the establishment;
 - ii. The location of equipment;
 - iii. Work flows for each product line;
 - iv. Water distribution system within the establishment including all outlets and sampling points;
 - v. Drainage layout;
 - vi. Pest control - baiting and/or trapping points within the establishment and external areas;
- a synopsis of the establishment which briefly describes what type of establishment it is, products produced, volume of product, type of trade, number of employees, approval number and what it is approved for. This synopsis should be no more than one side of an A4 sheet;
- pre-approval inspection report;
- planned programme of works to achieve approval;
- approval notification document specifying:
 - i. Details of activities to which the approval relates;
 - ii. Approval number;
 - iii. Classification;
 - iv. Special hygiene direction(s);
 - v. Any derogations that have been granted;
 - vi. Any other conditions or limitations specified by the Food Authority;
 - vii. Any arrangements acceptable to the Food Authority;

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

- labels (printed, reprinted and use of) and commercial documents bearing the identification mark;

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

Appendix 4: Model Notification of Grant of Approval

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

To be completed by the Food Authority and sent to the applicant.

PART 1 – Name and address of applicant

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

Your application dated _____ for approval of your establishment which is subject to approval under Regulation (EC) No. 853/2004 has been approved in respect of the establishment or part(s) of the establishment shown in Part 3, and the scope of operations, activities and other matters set out in the relevant Parts of this document.

The approval code that has been allocated to this establishment is shown at the end of this document. It must be used, in the required format, and when required by the Regulations, on product labelling, packaging, and other documentation.

PART 3 – Trading name and address

Trading name of
establishment

Full postal address

Postcode:

This approval relates to:

- ☐ The whole of the establishment at this address.
- ☐ The following part(s) only of the establishment at this address:

PART 4 – Food Business Operator and Management

Name of applicant	<input type="text"/>
Position in business	<input type="text"/>
Name of contact	<input type="text"/>
Position in business	<input type="text"/>
Tel (Incl. Dialling code)	<input type="text"/>
Fax (incl. Dialling code)	<input type="text"/>
E-mail	<input type="text"/>

Name and full address
of Food Business
Operator

Postcode:

PART 5 – SCOPE OF APPROVAL

This approval authorises the handling of the following type(s) of product in the establishment shown in Part 3 of this document in respect of the specific activities and products detailed below:

- | | |
|--------------------------|--|
| <input type="checkbox"/> | Minced Meat |
| <input type="checkbox"/> | Meat Preparations |
| <input type="checkbox"/> | Mechanically Separated Meat |
| <input type="checkbox"/> | Meat Products |
| <input type="checkbox"/> | Live Bivalve Molluscs (Shellfish) |
| <input type="checkbox"/> | Fishery Products |
| <input type="checkbox"/> | Dairy Products |
| <input type="checkbox"/> | Egg Products |
| <input type="checkbox"/> | Cold Store |
| <input type="checkbox"/> | Frogs' Legs / Snails |
| <input type="checkbox"/> | Gelatine |
| <input type="checkbox"/> | Collagen |

Full Details of Activities and Specific Products Handled

--

The establishment shown at Part 3 has been granted the following derogations:

--

Approval Code:

--

Date 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.

Appendix 5: Model Notification of Refusal of Approval

Notification of REFUSAL to Grant Approval to a Food Business Establishment Subject to Approval under Regulation (EC) No. 853/2004

To be completed by the Food Authority and sent to the applicant.

PART 1 – Name and address of applicant

TO:	IMPORTANT You must not use any part of the establishment detailed in Part 3 for any purpose which would render the establishment subject to approval under Regulation 853/2004 unless this Food Authority has granted approval.	[Food Authority Logo]
-----	---	-----------------------

PART 2 – Notification of decision

Your application dated _____ for approval of your establishment which is subject to approval under Regulation (EC) No. 853/2004 has been **REFUSED** in respect of the establishment, or part of the establishment shown in Part 3 of this document.

The decision to refuse your application was made for the reason(s) set out in Part 4 of this document.

The establishment, or any part of it, must therefore not be used for any purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004 **UNLESS THIS FOOD AUTHORITY HAS GRANTED APPROVAL.**

Any person who is aggrieved by a decision of a Food Authority to refuse to grant an approval may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notice was served on you. You may wish to consult a legal adviser about the implications of this notice and your right of appeal against this Food Authority's decision on your application. The name and address of the Magistrates Court at which you should lodge your appeal is _____.

PART 3 – Trading name and address of the establishment

Trading name of premises

Full postal address

Postcode:

This refusal relates to:

- ☐ The whole of the establishment at this address.
- ☐ The following part(s) only of the establishment at this address:

PART 4 – Reasons for refusal

Your application for approval has been refused because you have failed to comply with the requirements of Regulation (EC) No. 853/2004 as indicated below.

The requirements of the Regulation that you have failed to comply with are:

Article No.	Requirement of the Regulation

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

Article No.	Details of non-compliance

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

Article No.	Measures needed to secure compliance

Signed:
Name:
Designation:
Date:

Name and address of Food
Authority:

Contact Name:

Telephone:

Fax:

E-mail:

IMPORTANT

You must not use any part of the establishment detailed in Part 3 for any purpose which would render the establishment subject to approval under Regulation 853/2004 unless this Food Authority has granted approval.

Appendix 6: Model Notification of Withdrawal of Approval / Conditional Approval

Notification of WITHDRAWAL of the [Approval / Conditional Approval] of a Food Business Establishment Subject to Approval under Regulation (EC) No. 853/2004

To be completed by the Food Authority and sent to the applicant, with a copy sent to the Food Standards Agency.

A separate notification must be completed for each approval that has been revoked in relation to this establishment.

PART 1 – Name and address of applicant

TO:	IMPORTANT With immediate effect, you must not use any part of the premises detailed in Part 4 for any activities that were subject to the approval that has been withdrawn, and you must not use the associated approval code on any product.	[Food Authority Logo]
-----	---	-----------------------

PART 2 – Notification of decision to withdraw [approval / conditional approval]

This is formal notification that the [approval / conditional approval] granted by this Food Authority (or by a predecessor Food Authority) on _____ in respect of the establishment shown in Part 4 of this document, which is subject to approval under Regulation 853/2004, to handle products of animal origin indicated in Part 3 of this document, has been **WITHDRAWN**. The decision to withdraw the [approval / conditional approval] was made for the reason(s) set out in Part 5 of this document.

You must therefore cease all activities that were the subject of the specified [approval / conditional approval], and you must not use the approval code _____ for any products, both with immediate effect.

Any person who is aggrieved by a decision of a Food Authority to withdraw an [approval / conditional approval] may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notification 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 to withdraw the approval. The name and address of the Magistrates Court at which you should lodge your appeal is _____.

If you are handling other products in the establishment that is subject to a different approval but with the same approval code as the code shown above, and that approval has not also been withdrawn, you must contact this Food Authority without delay. The name of the person you should contact is at the end of this notice.

PART 3 – Product(s) of animal origin for which [approval / conditional approval] has been **WITHDRAWN**

<input type="checkbox"/>	Minced Meat
<input type="checkbox"/>	Meat Preparations
<input type="checkbox"/>	Mechanically Separated Meat
<input type="checkbox"/>	Meat Products

- | | |
|--------------------------|-----------------------------------|
| <input type="checkbox"/> | Live Bivalve Molluscs (Shellfish) |
| <input type="checkbox"/> | Fishery Products |
| <input type="checkbox"/> | Dairy Products |
| <input type="checkbox"/> | Egg Products |
| <input type="checkbox"/> | Cold Store |
| <input type="checkbox"/> | Frogs' Legs / Snails |
| <input type="checkbox"/> | Gelatine |
| <input type="checkbox"/> | Collagen |

PART 4 – Trading name and address of the establishment

Trading name of
establishment

Full postal address

<input type="text"/> Postcode:

PART 5 – Reasons for withdrawal

The [approval / conditional approval] has been withdrawn because:

- | | |
|--------------------------|---|
| <input type="checkbox"/> | The activities for which the approval was granted are no longer being undertaken. |
| <input type="checkbox"/> | You have failed to comply with the requirements of the Regulation 853/2004 as identified below. |

The requirements of Regulation 853/2004 that you have failed to comply with are:

Article No.	Details of non-compliance

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

Article No.	Details of non-compliance

Signed:	<input type="text"/>
Name:	<input type="text"/>
Designation:	<input type="text"/>
Date:	<input type="text"/>

Name and address of Food Authority:

Contact Name:

Telephone:

Fax:

E-mail:

IMPORTANT

With immediate effect, you must not use any part of the establishment detailed in Part 4 for any activities that were subject to the approval that has been withdrawn, and you must not use the associated approval code on any product.

Appendix 7: Notification of Suspension of Approval

Notice of **SUSPENSION** of Approval of a Food Business Establishment Subject to Approval under Regulation (EC) No. 853/2004

To be completed by the Food Authority and sent to the proprietor, with a copy sent to the Food Standards Agency. A separate notification must be completed for each [approval / conditional approval] that has been suspended in relation to these premises.

PART 1 – Name and address of proprietor

TO:	IMPORTANT With immediate effect, you must not use any part of the establishment detailed in Part 4 for any activities that were subject to the approval that has been suspended, and you must not use the associated approval code on any product, until such time as the suspension is lifted.	[Food Authority Logo]
-----	---	-----------------------

PART 2 – Notice of decision to suspend [approval / conditional approval]

This is formal notice that the approval granted by this Food Authority (or by a predecessor Food Authority) on _____ in respect of the establishment shown in Part 4 of this document, which is subject to approval under Regulation 853/2004 to handle products of animal origin indicated in Part 3 of this document, has been **SUSPENDED**. The decision to suspend the [approval / conditional approval] was made for the reason(s) set out in Part 5 of this document

You must therefore cease all activities that were the subject of the specified approval, and you must not use the approval code _____ for any products, both with immediate effect, until such time as this Food Authority lifts the suspension.

Any person who is aggrieved by a decision of a Food Authority to suspend an approval may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notification 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 to suspend the approval. The name and address of the Magistrates Court at which you should lodge your appeal is _____.

If you are handling a product of animal origin in the establishment that is subject to a different approval but with the same approval code as the code shown above, and that approval has not also been suspended, you must contact this Food Authority without delay. The name of the person you should contact is at the end of this notice.

PART 3 – Product(s) of animal origin in respect of which approval has been **SUSPENDED**

- | | |
|--------------------------|-----------------------------------|
| <input type="checkbox"/> | Minced Meat |
| <input type="checkbox"/> | Meat Preparations |
| <input type="checkbox"/> | Mechanically Separated Meat |
| <input type="checkbox"/> | Meat Products |
| <input type="checkbox"/> | Live Bivalve Molluscs (Shellfish) |
| <input type="checkbox"/> | Fishery Products |

- ☐ Dairy Products
- ☐ Egg Products
- ☐ Cold Store
- ☐ Frogs' Legs / Snails
- ☐ Gelatine
- ☐ Collagen

PART 4 – Trading name and address of the establishment

Trading name of
establishment

Full postal address

Postcode:

PART 5 – Reasons for suspension

The approval has been suspended because:

- ☐ You have failed to comply with a notice (copy attached) served on you on under:
- ☐
- ☐

- ☐ You have failed to comply with the requirements of the Regulation 853/2004 as identified below.

The requirements of Regulation 853/2004 that you have failed to comply with are:

Article No.	Requirement of the Regulation

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

Article No.	Details of non-compliance

Signed:
Name:
Designation:
Date:

Name and address of Food
Authority:

Contact Name:

Telephone:

Fax:

E-mail:

IMPORTANT

With immediate effect, you must not use any part of the establishment detailed in Part 4 for any activities that were subject to the approval that has been suspended, and you must not use the associated approval code on any product, until such time as the suspension is lifted.

Appendix 8: Notification of Amendment to Approval

Notice of AMENDMENT of 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 occupier, with a copy sent to the Food Standards Agency. A separate notification must be completed for each approval that has been amended in relation to these premises.

PART 1 – Name and address of occupier

TO:	IMPORTANT With immediate effect, the Approval to use the establishment or part of the establishment detailed in Part 4 for activities that were subject to this Approval has been amended to the extent specified in Part 6 of this notice. You must therefore only use the establishment in accordance with the Approval as it has been amended, until such time as this notice has been lifted.	[Food Authority Logo]
-----	---	-----------------------

PART 2 – Notice of decision of Authorised Officer to amend an approval

This is formal notice that the [approval / conditional approval] granted by this Food Authority (or by a predecessor Food Authority) on to handle products of animal origin indicated in Part 3 of this notice in respect of the establishment subject to approval under Regulation 853/2004 shown in Part 4 of this notice, has been AMENDED to the extent specified in Part 5 of this notice.

The decision to amend the approval was made for the reason(s) set out in Part 4 of this notice, and will be withdrawn in writing as soon as the authorised officer is satisfied that the requirements set out in Part 5 have been completed.

If this notice requires you to implement additional systems or procedures, or to carry out any works, these requirements are necessary for the continued approval of your premises.

Any person who is aggrieved by a decision of a Food Authority to impose conditions on an approval may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notice was served on you. You may wish to consult a legal adviser about the implications of this notice and your right of appeal against the decision to impose new conditions on the approval. The name and address of the Magistrates Court at which you should lodge your appeal is .

PART 3 – Trading name and address of the establishment

Trading name of premises	
Full postal address	
	Postcode:

PART 4 – Reasons for amendment

The approval has been amended because:

--

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

Regulation No.	Requirement of the Regulations

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

Regulation No.	Details of non-compliance

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

Regulation No.	Measures needed to secure compliance

PART 5 – Amendment(s) to the approval that are imposed by this notice

- | | |
|--------------------------|---|
| <input type="checkbox"/> | The use of _____ is prohibited. |
| <input type="checkbox"/> | The use of the premises is prohibited. |
| <input type="checkbox"/> | The use of part of the premises, namely _____, is prohibited. |
| <input type="checkbox"/> | The use of the premises is subject to the following condition(s), namely _____. |
| <input type="checkbox"/> | The carrying out of _____ is prohibited. |
| <input type="checkbox"/> | The rate of operation of _____ is to be reduced so that _____. |
| <input type="checkbox"/> | The operation of _____ is to be stopped completely. |

Signed:	
Name:	
Designation:	
Date:	

Name and address of Food
Authority:

Contact Name:

Telephone:

Fax:

E-mail:

IMPORTANT

With immediate effect, the Approval to use the establishment or part of the establishment detailed in Part 4 for activities that were subject to this Approval has been amended to the extent specified in Part 6 of this notice. You must therefore only use the establishment in accordance with the Approval as it has been amended, until such time as this notice has been lifted.

Appendix 9: Notification of Refusal to Grant Full Approval to an Establishment which is Conditionally Approved

Notification of REFUSAL to Grant Full Approval to an Establishment subject to Approval under Regulation 853/2004, which is Conditionally Approved under Regulation 882/2004

To be completed by the Food Authority and sent to the applicant.

PART 1 – Name and address of applicant

TO:	IMPORTANT You must not use any part of the establishment detailed in Part 4 for any purpose which would render the establishment subject to approval under Regulation 853/2004 unless this Food Authority has granted approval.	[Food Authority Logo]
-----	---	-----------------------

PART 2 – Notification of decision

Your application dated _____ for approval of your establishment which is subject to approval under Regulation 853/2004 to handle products of animal origin indicated in Part 3 of this document has been **REFUSED** in respect of the establishment, or part of the establishment shown in Part 4 of this document.

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

The establishment, or any part of it, must therefore not be used for any purpose which would render it subject to approval Regulations 853/2004 **UNLESS THIS FOOD AUTHORITY HAS GRANTED APPROVAL.**

Any person who is aggrieved by a decision of a Food Authority to refuse to grant an approval may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notice was served on you. You may wish to consult a legal adviser about the implications of this notice and your right of appeal against this Food Authority's decision on your application. The name and address of the Magistrates Court at which you should lodge your appeal is _____.

PART 3 – Products of animal origin for which approval has been REFUSED

- | | |
|--------------------------|-----------------------------------|
| <input type="checkbox"/> | Minced Meat |
| <input type="checkbox"/> | Meat Preparations |
| <input type="checkbox"/> | Mechanically Separated Meat |
| <input type="checkbox"/> | Meat Products |
| <input type="checkbox"/> | Live Bivalve Molluscs (Shellfish) |
| <input type="checkbox"/> | Fishery Products |
| <input type="checkbox"/> | Dairy Products |

- ☐ Egg Products
- ☐ Cold Store
- ☐ Frogs' Legs / Snails
- ☐ Gelatine
- ☐ Collagen

PART 4 – Trading name and address of the establishment

Trading name of
establishment

Full postal address

 Postcode:

This refusal relates to:

- ☐ The whole of the establishment at this address.
- ☐ The following part(s) only of the establishment at this address:

PART 5 – Reasons for refusal

Your application for approval has been refused because you have failed to comply with the requirements of Regulation 853/2004 as indicated below.

The requirements of Regulation 853/2004 that you have failed to comply with are:

Article No.	Requirement of the Regulation

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

Article No.	Details of non-compliance

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

Article No.	Measures needed to secure compliance

Signed:	
Name:	
Designation:	
Date:	

Name and address of Food Authority:

Contact Name:

IMPORTANT

You must not use any part of the establishment detailed in Part 4 for any purpose which would render the establishment subject to approval under Regulation 853/2004 unless this Food Authority has granted approval.

ANNEX 9: IMPORT OF FOOD FROM THIRD COUNTRIES

CONTENTS

PAGE

A9.1: Introduction

Scope

A9.2: Status of this guidance

A9.3: The Official Feed and Food Controls (England) Regulations 2005

A9.4: Service planning

A9.5: Documented policies and procedures

A9.6: Authorisation

A9.7: Qualifications/experience of authorised officers

A9.8: Information

A9.9: Records

Identifying and recording food and feed importers

Records of consignments and examinations

Arrangements for points of entry without permanent local authority presence

A9.10: Reporting & Notification Arrangements

Nominated officer for imported food controls

Monitoring returns

Notification of food hazards or incidents

Notification of illegal imports of POAO

A9.11: Liaison

A9.12: Inland inspection of imported food

Deferred examinations

A9.13: Sampling of imported food

Considerations for sampling & Qualifications

A9.14: Food of non-animal origin (FNAO)

Identification

Prohibition

Examination

Deferred Examination

A9.15: Third Country Pre-Export Checks

A9.16: Charges

A9.17: Enforcement

Storage and destruction/disposal arrangements

Special Treatment

Re-dispatch,

Alternative Use

Voluntary Surrender & emergency controls.

A9.18: Specified (High Risk) Products

A9.19: Products of Animal Origin – Enforcement

Illegally introduced POAO

POAO dangerous to animal or public health

Detention of POAO inland

Reporting

A9.20: References

Appendix 1

Appendix 2

Appendix 3

A9.1: Introduction

1.1 All local authorities have responsibilities for certain aspects of imported food controls. The purpose of this guidance is to set out and assist local authorities in Great Britain on the level and type of activity to achieve effective and consistent enforcement on imported food. This document does not cover control activities at Border Inspection Posts, where central guidance produced by Defra is available¹. However, it does provide enforcement guidance for local authorities relating to illegally introduced Products of Animal Origin (POAO).

Scope

1.2 The scope of this guidance is for imported foods not of animal origin (FNAO) and for products of animal origin (POAO). It has been revised in the light of EU Regulation 882/2004 on Official Feed and Food Controls.

1.3 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 Great Britain from outside the European Union (“third countries”), and at the time of importation not in free circulation in the European Union; “point of entry” means a seaport, airport or international rail link at which imported food is introduced into the UK.

1.4 Local authorities (including Port Health Authorities) with a point of entry provide the first line of control on imported food to ensure it is safe and complies with EU and UK requirements. However, it is important that controls are also in place at Enhanced Remote Transit Sheds (ERTS), ships suppliers, international rail terminals and other premises inland as significant amounts of food of non-animal origin (FNAO) will not have been physically checked at points of entry and there is a possibility that POAO may have entered the UK illegally. Further details of the roles and responsibilities of Port Health Authorities, local authorities and other government agencies and departments can be found in the Food Standard Agency’s Local Authority Resource Pack on Imported Food Control².

1.5 This guidance incorporates relevant information from:

- Good practice guides contained in the Syniad/APHA/FSA Benchmarking study into the port health function involving port health participants from seaports, LACORS and other Government Departments³
- The Food Standards Agency’s Local Authority Resource Pack on Imported Food Control provided to food authority delegates at national update training seminars².

1.6 This guidance includes summaries of some statutory provisions, however, these are indicative and for general guidance only. Where references are made to legislation which extends to England only, the equivalent Welsh and Scottish legislation is detailed in Annex 2.

A9.2: Status of this Guidance

2.1 This document should be considered as centrally issued guidance for the purpose of the Framework Agreement on Local Authority Food Law Enforcement (the latest version is available on the Agency's website⁴. Amendments have been made to the Standard in the Framework Agreement to clarify its application to imported food control (Amendment issued in June 2004).

2.2 This guidance should also be read in conjunction with the Food Safety Act 1990 Code of Practice, which has been reviewed and re-issued under Regulation 24 of the Food Hygiene (England) Regulations 2005 , and Regulation 6 of the Official Feed and Food Controls (England) Regulations 2005 in light of the Official Feed and Food Controls (EU) Regulation 882/2004. The Code of Practice will also provide direction and guidance on the local authority approach to enforcement.

A9.3: The Official Feed and Food Controls (England) Regulations 2005

3.1 The Official Feed and Food Controls (England) Regulations 2005, gives effect to Regulation (EC) 882/2004 in England only.

3.2 The scope of The Official Feed and Food Controls (England) Regulations 2005 is for foods not already covered by Directive 97/78/EC (POAO Veterinary Checks regime) and also includes food and feed at all stages within the food chain. It also includes materials and articles in contact with food as well as cleaning and maintenance products and processes, and pesticides. This guidance will cover food controls only – animal feed is subject to separate enforcement guidance issued by the Food Standards Agency.

3.3 For information, Annex 1 of this guidance displays the main import controls introduced FNAO by the Official Feed and Food Control (EU) Regulation (882/2004) and The Official Feed and Food Controls (England) Regulations 2005, and provides some comparison with the previous controls in the Imported Food Regulations 1997 (IFRs), which they replace. This Annex will not be included in the final guidance and is for consultation purposes only.

A9.4: Service Planning

4.1 The Framework Agreement on Local Authority Food Law Enforcement includes service planning guidance. Section 2.3 of the framework ("Scope of the food service") and Section 2.4 ("Demands on the food service") provide for local authorities to set out the scope of the responsibilities and service provided and to describe any external factors that may impact on their service. Where relevant, local authorities should include in these sections imported food responsibilities and the control arrangements in place.

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

A9.5: Documented Policies and Procedures

5.1 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.

5.2 Procedures relating to examination of imported food including deferred examinations under The Official Feed and Food Controls (England) Regulations 2005 (detailed under Section 14.12), cover both food safety and food standard issues.

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

A9.6: Authorisation

6.1 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.

6.2 For food safety and food standards matters this should include authorisation under the Food Safety Act 1990 and under hygiene and processing Regulations issued under it, including any relevant contaminants legislation.

6.3 Officers should also be authorised to enforce relevant regulations issued under the European Communities Act 1972 (e.g. The General Food Regulations 2004). The European Communities Act does not however contain any enforcement powers and its primary function is to provide a mechanism by which Regulations can be enacted. Powers of enforcement for Regulations made under the Act are usually contained in the Regulations themselves, therefore the Agency's view is that all Regulations relevant to imported food control should specifically be referred to in authorisation documents, including officers' credentials. As such these should, for example, include:

- The Products of Animal Origin (Import and Export) Regulations 1996 as amended,
- The Products of Animal Origin (Third Country Imports) (England) Regulations 2005.

Note: the definition of "local authority" for enforcement purposes does not currently include County Councils.

- Emergency Control Regulations e.g. The Food (Hot Chilli and Hot Chilli Products) (Emergency Control) (England) (Amendment) Regulations 2004, and
- The Official Feed and Food Controls (England) Regulations 2005.

6.4 General advice on the authorisation of officers has been developed by LACORS.⁵ Local Authorities may also wish to consult their own legal advisors on this matter.

A9.7: Qualifications/experience of authorised officers

7.1 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 Safety Act 1990 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.

7.2 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 Agency's Local Authority Resource Pack on Imported Food Control²; or
- (c) Other relevant training of an equivalent content eg in-house training or cascade training relating to (a) & (b) above.

A9.8: Information

8.1 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 lines.
- 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 BIPS¹⁸.
- Equipment available for carrying out inspections and sampling of imported food.
- Details of appointed and specialist laboratories for analysis and/or examination of samples that are able to provide an appropriate service for sample analysis (in particular relation to the time-scale of analysis and issue of results).
- Health and safety requirements.
- Security requirements.

8.2 Local authorities with a point of entry, ERTS or international rail terminals should establish routine local liaison and communication with relevant local organisations for the purpose of general exchange of information on food imports and for the effective handling of incidents. These contacts could include, where appropriate:

- HMRC (Her Majesty's Revenue and Customs) including anti-smuggling and Convention On International Trade in Endangered Species (CITES) teams,
- The State Veterinary Service (SVS),
- The Health Protection Agency in England, or Scottish Centre for Infection and Environmental Health in Scotland or the National Public Health Service for Wales,
- The Horticultural Marketing Inspectorate and Plant Health & Seeds Inspectorate (Defra) in England and Wales or the Horticultural and Marketing Unit (Scottish Executive Environment and Rural Affairs Department) in Scotland,
- Port operator; import agents; Transit Shed \ ERTS operators,
- Maritime and Coastguard Agency (MCA),
- Neighbouring local authorities, particularly for joint boards and ports, which fall under the jurisdiction of more than one local authority, including County Councils for certain Trading Standards responsibilities, and
- The Medicines & Health Care products Regulatory Agency (MHRA).

Contact details and information on the roles and responsibilities of relevant central government departments and other organisations can be found in the Food Standards Agency's Local Authority Resource Pack on Imported Food Control²

8.3 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.

A9.9: Records

Identifying and recording food importers

9.1 All local authorities should ensure that food premises and traders in their district (outside and within port areas) which import food are identified and recorded in premises/trader databases and included in inspection programmes as appropriate.

9.2 Completed food premises registration forms can be used to assist identification of food premises as importers, so far as the Food Premises (Registration) Regulations 1991 (as amended) and The Food Hygiene (England) Regulations 2005 provide for this.

9.3 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 The Official Feed and Food Controls (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.

9.4 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 proprietors and other local government departments as part of routine programmed activities.

Records of consignments and examinations

9.5 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 information on the checks made to determine compliance with legal requirements. The level of information recorded about food examinations (including examinations undertaken at ERTS or international rail terminals) and deferred examinations should provide consignment traceability and permit effective internal monitoring. This information should include any identifying reference for the consignment examined, country of origin, information on the nature of the food and the checks carried out and, where any enforcement action or sampling has been undertaken, the details of the agent and/or consignor/consignee.

Arrangements for points of entry without permanent local authority presence

9.6 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.

9.7 The purpose of these arrangements is to provide local authorities with updated information on food being imported. This will enable risk-based judgements to be made on the targeting of enforcement action and to ensure that emergency controls or restrictions on certain foods are being enforced. This includes at the designated point of entry, and requirements relating to documentary checks and associated statutory sampling (further details on risk-based checks can be found in Section 14).

A9.10: Reporting and Notification Arrangements

Nominated officer for imported food controls

10.1 Every local authority with a point of entry should appoint a nominated officer with the necessary competency in imported food control to be a point of contact with the Food Standards Agency on imported food matters. The details of the nominated officer or changes to the nominated officer should be notified to the Agency's Imported Food Division or in Scotland, FSA Scotland, and in Wales, FSA Wales⁶.

Monitoring Returns

10.2 All local authorities should complete relevant enforcement monitoring returns to the Food Standards Agency and should ensure that the returns are an accurate reflection of their imported food control activity.

10.3 In April 2005 the Food Standards Agency wrote to all local authorities seeking baseline data on imported food law enforcement activity, to be used as a measure for the Government's initiative to achieve a 'step change' in local authority delivery and co-ordination of imported food controls. In order for the Agency to monitor imported food control work, authorities should comply with future requests for such data.

10.4 Local authorities should also supply any other information reasonably requested by the Food Standards Agency. 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 public health issues or emerging National Control Plans and annual reports provided for in Articles 42 and 44 of The Official Feed and Food (EU) Regulation 882/2004.

Notification of Food Hazards or Incidents

10.5 All local authorities should send details of any imports rejected where there is a direct or indirect risk to health to the Agency's Food Incident Branch⁷ 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.

10.6 In addition, with regard to testing for residues of veterinary medicines in Annex IV of EU Regulation 2377/90, as amended (such as nitrofurans and chloramphenicol) or those not approved for use, details of ALL positive results should be sent to the Incident Branch using the RASFF notification form. Where available, copies of the health certificate and the airway bill or bill of lading should also be forwarded to the Incident Branch at:

Donna.Stephenson-Baah@foodstandards.gsi.gov.uk or
Sinead.Johnson@foodstandards.gsi.gov.uk

10.7 Guidance on completing the RASFF notification form has already been provided to local authorities. A copy of the notification template can be found on the Agency's website⁸.

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

10.8 All local authorities should notify the Agency of a serious localised incident or a wider problem under the Food Alert System as soon as a decision has been taken that one has occurred, using the appropriate contact details and reporting arrangements set out in the Food Safety Act 1990 Code(s) of Practice and any subsequent documents.

Notification of illegal imports of POAO

10.9 A notification should be made to Her Majesty's Revenue and Customs (HMRC) on the INTEL form whenever illegally imported POAO are seized. Further details are contained in Section 19 of this guidance.

A9.11: Liaison

11.1 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, the local authority at the point of entry should be informed to help target their future surveillance activities.

11.2 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.

11.3 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, as labelling legislation cannot be enforced at time of import.
- Where examination under The Official Feed and Food Controls (England) Regulations 2005 has been deferred.
- Where unsatisfactory test results are received for samples taken for routine surveillance and as such the consignment has been released from the port.
- Where analysis indicates that nuts are not suitable for human consumption but are referred for feed use.

11.4 This is reliant on the full co-operation of inland authorities. Wherever possible, inland authorities should agree to assist with these referrals and respond as appropriate without undue delay and provide feedback to the local authority at the point of entry on the outcome. To assist this process a suggested pro-forma for this purpose is available on the Agency's website⁹. Records of such referrals and details of any action taken should be maintained by authorities.

11.5 It may also be necessary for the Food Standards Agency to refer matters concerning illegally imported POAO to inland authorities. This information will normally be received from HMRC where they have intercepted illegal imports destined for commercial premises. Local authorities should respond to these referrals without undue delay and where requested provide feedback directly to HMRC. Authorities should maintain records of action taken.

A9.12: Inland Inspection of Imported Food

12.1 Local authority procedures should ensure food (including imported food) examination forms part of food premises inspections.

12.2 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.

12.3 The Official Feed and Food Controls (England) Regulations 2005 also include semi-finished products, materials and articles in contact with food, pesticides, and labelling issues.

12.4 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.

12.5 In addition to assessing fitness for consumption, reasonable steps should be taken to check the legality of the importation of any POAO and FNAO from a third country. The Food Standard Agency's Local Authority Resource Pack on Imported Food Control provides detailed advice on points to consider when investigating the legitimacy of imports. The Agency's website¹⁰ and Schedule 5 of The Official Feed and Food Controls (England) Regulations 2005 provides the types of food imports and countries of origin which are prohibited or restricted, as well as links to other relevant sites.

Deferred Examination of FNAO – inland controls

12.6 The Official Feed and Food Controls (England) Regulations 2005 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 international rail terminal or at any other place of destination in the UK. Further guidance on this is given in Section 14.12.

12.7 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.

12.8 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.

A9.13: Sampling of Imported Food

Considerations for sampling

13.1 In addition, routine sampling considerations, for local authority sampling programmes for surveillance and enforcement purposes should be influenced by any statutory requirements for sampling laid down in European Commission Decisions or Emergency Control Regulations (usually this will occur at a point of entry), any agreed LACORS/Food Standards Agency sampling programmes, any sampling required following a Food Alert or RASFF notification, and any EU, LACORS, regional liaison group, local or other sampling survey information (this may include newly placed imported foods where no other sampling activity is known).

13.2 Specified Products (high risk) commodities as listed in the Schedule 5 of The Official Feed and Food Controls (England) Regulations 2005 should be detained until the enforcement authority receives the results or as stated in the implementing rules.

13.3 Local authorities should also take into account local priorities 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.

13.4 Local authorities should take into account any specific central guidance on sampling or other matters set out by the Agency or Defra (Scottish Executive Environment and Rural Affairs Department (SEERAD) in Scotland, National Assembly for Wales Agriculture Department (NAWAD) in Wales), or LACORS.

Qualifications/experience/training of officers carrying out sampling

13.5 Samples for microbiological examination or chemical analysis should be taken by authorised officers, having been properly trained in the appropriate techniques, 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 Safety Act 1990 Code of Practice.

13.6 Local authorities should ensure that officers carrying out sampling for the official control of contaminants in foodstuffs, are also competent in sampling methods prescribed in Commission legislation (Regulation 466/2001/EC) implemented by The Contaminants in Food (England) Regulations 2004 (as amended) and any relevant Food Standards Agency and APHA guidance.

A9.14: Food of Non-Animal Origin (FNAO)

14.1 This section applies to local authorities with a point of entry, checks undertaken at ERTS or international rail terminals, and deferred examinations under The Official Feed and Food Controls (England) Regulations 2005.

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

Identification

14.3 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 correct status of food imports.

14.4 Local authorities overseeing airports, ERTS and international rail terminals should set up, implement and maintain documented procedures on the arrangements in place to identify imported food.

14.5 This might include:

- Liaison with HMRC regarding food imported directly from third countries or via other Member States or ports under T1 arrangements;
- 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.

Prohibition

14.6 It is an offence for any person to import a product that does not comply with food law as set out in Regulation 22 of The Official Feed and Food Controls (England) Regulations 2005. This prohibition applies to products being imported either direct from a third country or from a third country through another EU Member State.

Examination

14.7 Imported food should be subjected to risk based food safety and, where appropriate, food standards checks. These may consist of at least systematic documentary checks, random identity checks and where appropriate physical checks. Physical checks might include: checks on the means of transport, checks on the packaging, checks on the temperature controls, organoleptic testing, and chemical or microbiological examination. Such checks may also depend on the guarantees that the competent authority of the third country has given. The arrangements and follow up actions should be set out in relevant service policies and procedures.

14.8 Physical checks should be carried out under appropriate conditions 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.

14.9 Where an authorised officer reasonably requires facilities and assistance to carry out checks on a product, the importer may be asked to provide these. An authorised officer may require that physical checks take place at a specified place when necessary for such examination, for example in circumstances where it is not practical to undertake a particular check at the point of entry.

14.10 Checks should be informed by:

- Statutory requirements for documentary checks and associated sampling laid down in any legislation listed in The Official Feed and Food Controls (England) Regulations 2005, Schedule 5, European Commission Decisions and Emergency Control Regulations,
- The risk associated with different types of food safety issues,
- Knowledge of the product e.g. new or unusual,
- Any requirements following a Food Alert or RASFF notification,
- The history of compliance for the product, country of origin and exporter/importer,
- The controls that the food business importing the food has carried out,
- Any guarantees that the competent authority of the third country of origin has given,
- 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 HMRC or the port operator who may have concerns about a consignment.

14.11 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 wish to ensure relevant port operators, local HMRC, or agents/importers are aware of any restrictions. Arrangements should also be in place to deal with any such consignments which may arrive at the point of entry.

14.12 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.

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

Deferred Examinations of FNAO

14.14 The Official Feed and Food Controls (England) Regulations 2005 allows for the examination of consignments of FNAO to be deferred and undertaken by the food authority covering the ERTS or international rail terminal or at any other place of destination in the UK. Deferred examinations may be appropriate where, for example, it is considered unnecessarily destructive to open the consignment at the point of entry.

14.15 Either the local authority covering the point of entry or the importer can request deferred examination. However, the decision rests with the local authority covering the point of entry. In coming to their decision they need to liaise with the receiving authority to ensure that appropriate checks will be carried out and deferral should therefore be based on co-operation and agreement between authorities.

14.16 Given the requirements for Specified Products to be imported through designated points of entry, any such foods should be allowed deferred examination in exceptional circumstances only. For example, there may be overriding health and safety considerations. In all cases high risk food should be subject to relevant document and identity checks before being deferred for physical checks

14.17 When any examination is deferred, the importer should be required to provide a written undertaking that the consignment has been sealed and will not be opened until it reaches its specified destination. 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.

14.18 Deferred examinations under The Official Feed and Food Controls (England) Regulations 2005 should be carried out in accordance with Regulation 21 of the Regulations, as outlined above.

A9.15: Third Country Pre-Export Checks

15.1 The Official Feed and Food Controls (EU) Regulation 882/2004 allow for the Commission to grant that certain third countries reduced import checks on certain imported FNAO. Details of relevant products and third countries will be notified to local authorities, as appropriate. 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, and an official certificate would be required to accompany such consignments.

15.2 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.

A9.16: Charges

16.1 EU Regulation 882/2004 includes a framework for financing of official controls. In essence, this requires mandatory fees in some sectors with an option for Member States to impose fees in others. The provisions, in general, do not apply until 1 January 2007. For 'high risk' FNAO imports, mandatory fees *may* be introduced by means of implementing rules when these products are identified at Community level. This may possibly be before 1 January 2007 but is dependent on the Commission putting forward proposals. If mandatory fees are not established, the Member States may use the optional provisions of the Regulation to introduce charging from 1 January 2007 if they wish. The optional provision may also be used to introduce charges for other FNAO ('low risk') import inspections. The FSA is currently considering what options are available to apply the new financing framework and will consult with stakeholders in due course.

A9.17: Enforcement

17.1 Where, for the purpose of examination at points of entry, or deferred examination at ERTS, international rail terminals or other place of destination, an authorised officer considers that a consignment needs to be inspected to confirm compliance, the product may be detained pending the results of any examination associated with the official controls.

17.2 Where an authorised officer has detained a food consignment, they should notify in writing the person importing the food or any person in possession of the food who is entitled to be in possession of it. The notification should specify that the food should not be removed from the place stated, until the officer's examination of the food has been completed. The person on whom any notification is given should be informed in writing by the authorised officer of any relevant appeal provisions at that time.

17.3 The Official Feed and Food Controls (EU) Regulation 882/2004 does not specify a time limit for examination and investigation of consignments. However, such examinations should be expedited as quickly as practicable, and /or detention periods such as to avoid unreasonable disruption to the trade.

17.4 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.

17.5 If it appears to an authorised officer upon inspection or examination of food, that a batch, lot or consignment of food fails to comply with food safety requirements (Food Safety Act 1990 Section 8 as amended), Regulation 30 of The Official Feed and Food Controls (England) Regulations 2005 allows 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

17.6 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 shall allow 60 days for a decision by the responsible person. Where the official control allows for re-dispatch, if after a 60 day period re-dispatch does not take place, the consignment should be destroyed, unless delay is justified.

17.7 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.

17.8 A consignment should only be re-dispatched outside the EU where 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 that it is willing to accept the consignment. The consignment should be officially detained pending re-dispatch.

17.9 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.

17.10 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.

17.11 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 Safety Act 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 signing the receipt.

17.12 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.

17.13 Officers should have regard to The Official Feed and Food Controls (England) Regulations 2005, The Contaminants in Food (England) (Amendment) Regulations 2005 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.

17.14 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.

A9.18: Specified (High Risk) Products

18.1 The Official Feed and Food Controls (EC) Regulation 882/2004 provides that the Commission may issue a list of Specified Products. These will be foods of non-animal origin that, on the basis of known or emerging risk, should be subject to increased import controls at the point of entry. The frequency and nature of such checks will be specified by the Commission under the procedures in Article 15(5) of the Regulation or in specific emergency provisions. The enhanced controls provided for by these arrangements include; prior notification, import through designated ports only, and specified documentary and physical checks at points of entry.

18.2 Local authorities will be advised of any relevant emergency provisions, and when such a list and additions to the list are issued. Details will also be published on the Agency's website and amendments made to Schedule 5 of The Official Feed and Food Controls (England) Regulations 2005.

18.3 The Food Standards Agency would implement the requirements for products on the list by means of a declaration under The Official Feed and Food Controls (England) Regulations 2005. This is in order that measures for Specified Products can be applied in a similar manner to that for emergency measures for POAO under Regulation 59 of the Products of Animal Origin (Third Country Imports) (England) Regulations.

18.4 Ports will be designated by the Food Standards Agency on the basis that they have the necessary facilities and/ or arrangements in place to ensure required checks can be carried out effectively, hygienically and safely.

18.5 Where the designation of a point of entry has been withdrawn by the Agency in relation to a certain Specified Product, and the relevant authority notified in writing of the fact, the food can no longer be imported through that point of entry from the time that the written notification was received.

18.6 Relevant amendments will be made to Schedule 4 of the Regulations at the first available opportunity. However, importers should be advised to check

with the local authority at the relevant port or the Food Standards Agency website before importing a Specified Product.

18.7 Food operators are required to pre-notify the local authority at the point of entry of the nature and arrival of any Specified Products. No time period is specified for this process, however, the prior notification may be in electronic form and at least one language should be in English.

18.8 It is an offence for any person to import a Specified Product from third countries:

- other than at a designated point of entry,
- which is non-conforming,
- without providing prior notification,
- without presenting the product (or ensuring it is presented) and any required documents to an authorised officer at the designated point of entry.

18.9 Where a Specified Product is not; presented for official controls, imported through a designated point of entry, or pre-notified to the authority in accordance with the Regulations, it should be recalled and / or detained until it is either destroyed or re-dispatched outside the EU.

A9.19: Products of Animal Origin - Enforcement

Illegally introduced POAO

19.1 POAO should be imported in accordance with the Products of Animal Origin (Third Country Imports) (England) Regulations 2005. 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 checks at the BIP have been evaded.

19.2 HMRC became responsible in April 2003 for detecting smuggled POAO in Customs controlled areas including ERTS. However, local authorities still have responsibilities relating to goods presented at Border Inspection Posts and also inland where officers come across illegal POAO in the course of their routine enforcement activities (MHS are responsible for illegal POAO found at premises under their control). Defra have produced guidance clarifying the roles and responsibilities, including relevant contact details, of enforcement agencies involved in the control of illegal imports of POAO¹³. The Food Standards Agency has also produced Enforcement Guidance on Illegal Meat for Enforcement Officers¹⁷.

19.3 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.

19.4 Where an authorised officer, in the course of their duties, comes across POAO at premises under Customs control i.e. in a port area or an ERTS, which they have reason to believe has been illegally introduced, they should notify HMRC and issue a detention notice under Regulation 16(4) of the POAO (Third Country Imports)(England) Regulations 2005.

19.5 Where illegal imports of POAO are found inland in an area/premises outside customs control, the local authority has responsibility for the enforcement action. Where an authorised officer is satisfied that a POAO has been illegally introduced, they should serve a notice under Regulation 24 of the POAO (Third Country Imports) (England) Regulations 2005 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.

POAO Presenting a Risk to Public or Animal Health

19.6 Where an authorised officer, either at a port of entry or inland, considers that a consignment or product from a third country presents a risk to animal or public health, they should serve a notice under Regulation 25 of the POAO (Third Country Imports) (England) Regulations 2005 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.

Detention of POAO inland

19.7 Where an officer wishes to detain any POAO inland in order to investigate further to establish its safety or compliance, voluntary co-operation could be sought in the first instance. In situations where this is not possible or is inappropriate due to risk, there is a provision under Regulation 8 of the POAO (Third Country Imports) (England) Regulations 2005 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.

19.8 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.

19.9 Regulation 16 covers consignments posing a risk to health or illegal consignments. Under 16(3), where an authorised officer has reasonable grounds for believing that any POAO does not comply with animal or public health conditions relating to import into Great Britain or the European Community, a Notice may be served to prohibit the movement of the consignment. Regulation 16(4) provides that a notice should then be served ordering the destruction of the goods, or public and animal health considerations permitting, use of the goods for other purposes as may be specified in the notice, including returning them (with the authorisation of the competent authority of the country of origin) to their country of origin. If the consignment fails to comply with legislation due to an irregularity in documentation only, the notice shall grant the consignor a period of seven days to produce the correct documentation before action is taken (Regulation 16(5)).

Reporting

19.10 A notification to HMRC on the INTEL form 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) (England) Regulations 2005.

A9.20: References

Email: imported.food@foodstandards.gsi.gov.uk

Tel: 020 7276 8018

This guidance can be found on the FSA's website at::

<http://www.food.gov.uk/foodindustry/guidancenotes/foodguid/importedfoodcontrols>

¹ For information and guidance on international trade in animal products see Defra's website www.defra.gov.uk/animalh/int-trde/default.htm.

² Food Standards Agency Imported Food Control Resource Pack (available on the Agency's website www.food.gov.uk). (V4 2005 at time of printing)

³ Benchmarking the Port Health Function, The Syniad Benchmarking Centre (martin.goodman@wlg.gov.uk)

⁴ www.food.gov.uk/enforcement/frameagree/

⁵ Local Authority Delegated Powers, Authorisation of Officers and Use of Credentials, LACORS .

⁶ Imported Food Division – Tel. 020 7276 8018 , fax 020 7276 8024, email imported.food@foodstandards.gsi.gov.uk

⁷ Food Incidents Branch – Tel. 020 7276 8448, fax 020 7276 8446, email sinead.johnson@foodstandards.gsi.gov.uk or donna.stephenson-baah@foodstandards.gsi.gov.uk

⁸ www.food.gov.uk/multimedia/worddocs/section11proformas.doc.

⁹ www.food.gov.uk/multimedia/worddocs/referralsproforma.doc.

¹⁰ www.food.gov.uk/enforcement/imports/

¹¹ www.food.gov.uk/multimedia/pdfs/foodstuff_controls.pdf

¹² This document was introduced on 1 March 2004 and is standardised throughout EU Member States. The predecessor of the CVED was the Certificate of Veterinary Checks (CVC).

¹³ Enforcement guidance for anti-smuggling activity against illegal imports of meat and other products of animal origin. For further information, contact andy.green@defra.gsi.gov.uk, or phone 020 7904 8233.

¹⁴ <http://ilaps.defra.gov.uk>. Food authorities without user names and passwords should contact richard.j.stuckey@defra.gsi.gov.uk to be allocated these.

¹⁵ www.defra.gov.uk/animalh/bse/animal-health/paptseguide.pdf

¹⁶ Blank

¹⁷ Food Standards Agency Illegal Meat. Enforcement Guidance for Local Authority officers in England July 2004. This can be found at:
<http://www.food.gov.uk/foodindustry/guidancenotes/meatregsguid/illegalmeatguidance>

¹⁸ The BIP Manual. Published by DEFRA. Available at:
<http://www.defra.gov.uk/animalh/int-trde/prod-im/bipmanual.pdf>
[Issue 6, January 2005 at the time of consultation].

Appendix 1: Differences between the Imported Food Regulations 1997 and the EU Official Feed and Food Controls Regulation (882/2004) / the Official Feed and Food Controls (England) Regulations 2005

Regulation 882/2004 (see articles) / The Official Feed and Food Controls (England) Regulations 2005	Imported Food Regulations (IFRs) 1997 [DN: It is anticipated that these Regulations will be revoked as part of the exercise to implement Regulation (EU) 882/2004 on Official Controls of Feed and Food. The Regulation applying to imports of FNAO will apply from the 1 st January 2006, following public consultation].
Applies to imports as well as all stages of food & feed chain	Only applied at time of import
Products may be detained until results of official controls obtained – examination/Analysis to be conducted as soon as practicable (Article 18)	6 days allowed for detention for examination (excluding weekends and public holidays)
Importer may be requested to provide such facilities/assistance as may be reasonably needed for import checks (Regulation 28)	Importer may be requested to provide such facilities as may be reasonably needed for import checks
Examination includes systematic documentary check, identity check and as appropriate physical check (Article 16)	Products can be examined, including sampling, at PHA discretion
Import controls may be deferred to enforcement authority at destination at PHA discretion (Regulation 21)	Import controls may be deferred to enforcement authority at destination at PHA discretion
PHA may require that checks take place at a specified place (Regulation 28)	Not specified
Prohibits the import of non conforming products (Regulation 22)	Prohibits import of food which fails to comply with food safety requirements or be unsound or unwholesome
Non-compliant products can be detained and destroyed, subject to special treatment, re-despatch or to appropriate measures other than those originally intended at PHA discretion. (Article 19)	Non-compliant products can be detained and destroyed (under provisions of section 9 of the Food Safety Act 1990), or re-exported or used for purposes other than human consumption at PHA discretion
Goods deemed injurious to health or	EU measure

unsafe should be destroyed or subject to measure necessary to protect health (Article 19)	
<ul style="list-style-type: none"> Provision for sampling and analysis (Regulations 35 and 36) 	Provides for sampling and analysis
<ul style="list-style-type: none"> Additional import controls may apply for products listed by the European Commission as high risk (i.e. specified products) under Article 15(5) of the EU OFFC Regulation. 	Specified products measures are EU
Specified Products may only be imported through designated points of entry (Article 17) (FSA will designate such ports)	Any port under IFRs, but some EU emergency control measures specify ports
Prohibits import of a Specified Product at any port other than a designated port (Regulation 24)	Any port under IFRs, but some EU emergency control measures specify ports
Prohibits import of a non-conforming Specified Product (Regulation 25)	No specified products measures
Requires pre-notification for Specified Products in advance of import (Article 17)	No pre-notification required
Prohibits import of Specified Product unless prior notification of arrival (one language should be English and may be by electronic form) (Regulation 26).	No pre-notification required
Requires importer to present a Specified Product and any required documents to PHA at designated port (Regulation 27)	No specified products measures

Appendix 2: 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 Customs & Excise.
Consignment	Consignments can consist of one type of product, or a number of different types of products, which is covered by the same health certificate and/or airway bill or bill of lading. See legal definition in POAO Regs.
ERTS	Enhanced Remote Transit Shed. Customs approved warehouse facilities where imported goods are held in temporary storage under Customs control. They are intended to facilitate entry of goods for Customs purposes and may be some distance from the seaport or airport, so may therefore fall under the jurisdiction of another local authority. May be referred to as “temporary storage facilities”.
Feeding stuffs	Term used in Legislation on feed mixes for farm animals wild animal feed (e.g. bird feed) and pet food
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.
Joint board	Port Health Authorities may be a stand-alone organisation managed by a Joint Board of Members from a two or more local authorities who each part fund the PHA
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 Customs & Excise. T1 signifies that the goods are not in Free Circulation i.e. they are subject to Customs control

ANNEX 10: FOOD SAFETY MANAGEMENT PROCEDURES BASED ON HACCP PRINCIPLES

A10.1: Introduction

Article 5 of Regulation 852/2004, requires food business operators (other than those carrying out primary production) 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 trade bodies.

A10.2: Approach To Enforcement

Enforcement should continue to be graduated and educative.

Food premises that present a clear and imminent danger to public health should have formal enforcement action taken against them for 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 for 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 comprises 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 enforcement activity can be used. This is a graduated approach.

A10.3: Flexibility

Regulation 852/2004 does 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 business operators 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:*

- *questioning to obtain assurance that the person responsible for food safety understands significant hazards and has them under control,*
- *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 small (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 practice and understands it. Documentation and record keeping may not be necessary.

[DN: Further guidance on flexibility is expected from the Commission. The key points are likely to be:

- Flexibility applies to all food businesses
- The manager of a business should be trained in developing and maintaining a food safety management system proportionate to their business, and not simply trained in HACCP principles
- Training should be proportionate and reflect the flexibility guidance and that 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 in place of training courses, attendance at a formal training event is not necessary.
- Incident recording is an appropriate and proportionate form of record keeping in many businesses
- Corrective actions should 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 and less developed businesses.

The 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 – and that this can be achieved by substituting in a simplified but effective way some or more of the seven principles. This is clarified in the further Commission guidance on flexibility. Similarly, the terminology or ‘jargon’ of HACCP need not be used, and may be confusing to some businesses.

	<p>Identify any hazards that must be prevented eliminated or reduced;</p> <p>Mapping Hazard Analysis with tools such as flow-charts may not be suitable for all businesses. It is sufficient that the business has thought about its activities in a structured way. The effect of the analysis and the procedures produced should be to ensure that safe food is always produced.</p> <p>The traditional HACCP approach of controlling some hazards through pre-requisite programmes of Good Hygienic Practice and others through the HACCP system may not be appropriate, particularly in small businesses where it is not readily understood. Whatever the format of the guidance, the business must be managing all significant hazards including those traditionally controlled through Good Hygienic Practice. In practice, <i>for enforcement, this means:</i></p> <ul style="list-style-type: none"> • <i>Seeing some evidence that the person responsible for food safety has thought about their business and identified significant hazards and knows how to control them – for some businesses it may be appropriate to follow standard advice from the FSA, trade bodies etc.</i>
	<p>Identify the critical control points (CCPs) at the steps at which control is essential; and Establish critical limits at CCPs;</p> <p>Critical control points and their limits may not always be helpful ways of thinking about food safety for small businesses and they may instead identify generic controls - like thorough cooking, together with the ways of ensuring they know this has happened.</p> <p>The legislation is flexible in stating the requirement that establishing a critical limit does not always imply that a numerical value must be fixed. This is in particular the case where monitoring procedures are based on visual observation, for example a businesses may rely on sensory information such as colour change, juices running clear 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 enforcers, <i>in practice, this means:</i></p> <ul style="list-style-type: none"> • <i>Seeing some evidence that the business is following procedures that include steps where the significant hazards are controlled – for many businesses it may be appropriate to follow standard advice.</i> •
	<p>Establish procedures to monitor the CCPs;</p> <p>Management of food safety through the procedures detailed above will need to be demonstrated. This can be shown in many ways. In some larger businesses this may be achieved by monitoring 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</p>

	<p>followed. It will be important to establish that if the procedures are followed, safe food will result.</p> <p>Monitoring may in many cases be a purely sensory exercise, for example a regular visual verification of the temperature of cooling facilities, or a colour change. For enforcers, <i>in practice, this means:</i></p> <ul style="list-style-type: none"> • <i>Seeing some evidence that the business is monitoring their procedures, either using physical checks such as noting temperatures or via sensory checks such as noting that a stew or sauce is bubbling. The person responsible for food safety should be able to explain the chosen method of monitoring.</i>
	<p>Establish corrective actions to be taken if a CCP is not under control;</p> <p>It is also important that the business knows what to do when things go wrong – the corrective action that needs to be taken. For enforcement, <i>in practice, this means:</i></p> <ul style="list-style-type: none"> • <i>Questioning the person responsible for food safety management to ensure adequate supervision of staff and equipment so as to assure that procedures are being followed and safe food produced, and that when things go wrong appropriate action is taken.</i>
	<p>Establish procedures to verify whether the above procedures are working effectively;</p> <p>The business will need to demonstrate that its procedures are verified and reviewed and kept up to date, and that changes to menus, types of foods and cooking methods, and new equipment are reflected. In larger businesses, verification is often achieved by third parties, but for smaller businesses it is sufficient that the business carries out periodic reviews of its procedures and methods, and takes account of good practice and safe methods. For enforcement, <i>in practice, this means:</i></p> <ul style="list-style-type: none"> • <i>Seeing evidence that the procedures in a business are reviewed to ensure they continue to represent good practice and reflect changes in the business</i>
	<p>Establish documents and records to demonstrate the effective application of the above measures.</p> <p>Documentation and record keeping are particularly onerous for smaller businesses and the new legislation is clear that this should be well balanced and limited to what is essential with regard to food safety. Records should include the corrective action that has been taken. For enforcement, <i>in practice, this means:</i></p> <ul style="list-style-type: none"> • <i>Seeing documentation that is up to date and describes the main procedures or methods used in the business to control the most important hazards, and</i>

	<ul style="list-style-type: none"> • <i>Seeing some periodic records that represents evidence that these procedures were followed, this does not have to record every monitoring and supervisory activity</i> • <i>For simple small businesses following good hygienic practice guides, documentation and record keeping may not be necessary.</i>
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A10.4: Role of Food Authorities

The legislation will require the industry to raise its standards to that already achieved by the best businesses. The flexibility means that all food businesses should be able to comply.

[Until the legislation is in force, enforcers should try to persuade businesses to take a forward look. To some extent this will depend on the availability of guidance, and it is likely that only the keen businesses will make progress.]

The FSA is working to produce appropriate guidance for the industry and to influence the provision of vocational and other training. These are likely to be available by late 2005. Training for local authority Environmental Health Practitioners on how to deliver and audit guidance will be made available from July 2005.

In accordance with the legislation, businesses are required to implement appropriate food safety management procedures. Different support models have been developed and are appropriate for different types of business. Proper implementation of the appropriate support model will constitute compliance with Article 5 of Regulation 852/2004.

nce the legislation is in force, the same educative and graduated approach will be expected.] Businesses should either have in place or be seen to be making progress toward having effective food safety management systems. Enforcement officers should try to educate and give businesses an understanding about what is required. For these new regulations, and for businesses that are not a threat to public health, it is expected that formal enforcement action should only be taken where: the business:

- The business has been given reasonable opportunity to implement food safety management,
- Appropriate training is available if needed, and
- Appropriate guidance for the business is available.

The graduated approach should seek to educate businesses and improve their standards in realisable steps. Guidance material should be broken down in such a way that the enforcer and business can agree that by their next visit, so much progress should have been made. The FSA advice, 'Safer food, better business', is broken down into the 4Cs (cooking, cleaning, chilling & cross-contamination) and it may be appropriate to set a business one of these 'Cs' at a time. Other guidance

material can also be divided into 'chunks' like this. Where fundamental skills are missing, enforcers should point businesses at sources of the competencies – guidance materials, books, courses etc. Enforcers should look to the business to make reasonable progress through the material and make appropriate changes in their practices before the graduated approach progresses from education to more formal infraction methods.

A food safety management system should give assurance that the business knows how to produce safe food, has procedures in place that assure this, and repeatedly does produce safe food. Whether a business has an effective food safety management system in place is a judgement for enforcement officers. *In practice, this means:*

- *Judging whether the business would continue to produce food safely if things went wrong – staff absences, unexpected demand etc.*

Food Law Practice Guidance

TABLE OF CONTENTS

TABLE OF AMENDMENTS ISSUED	4
PREFACE.....	5
SECTION 1: ADMINISTRATION	6
CHAPTER 1.1: INTER-AUTHORITY MATTERS.....	6
1.1.1: Introduction	6
1.1.2: Service to Consumers	6
CHAPTER 1.2: QUALIFICATIONS AND EXPERIENCE	7
1.2.1: Introduction	7
1.2.2: Pooling Expertise	7
CHAPTER 1.3: CONFLICTS OF INTEREST.....	8
CHAPTER 1.4: FOOD BUSINESS RECORDS	9
1.4.1: Introduction	9
1.4.2: Data Protection	9
CHAPTER 1.5: REGISTRATION OF FOOD BUSINESS ESTABLISHMENTS	10
CHAPTER 1.6: CROWN AND POLICE PREMISES	11
1.6.1: Introduction	11
1.6.2: Scope of Application of Food Law	11
1.6.3: Conduct and Frequency of Inspections	11
1.6.4: Enforcement.....	11
1.6.5: Position of Individual Civil or Government Servants.....	12
1.6.6: Statutory Notices.....	12
1.6.7: Use of the Food Safety Act 1990	13
CHAPTER 1.7: FOOD INCIDENTS AND HAZARDS	14
1.7.1: Introduction	14
1.7.2: Information Received Locally Which May Indicate a Wider Problem	14
1.7.3: Guidance on Food Complaints	14
1.7.3.1: Notification of Food Complaints	14
1.7.3.2: Involvement of Other Food Authorities.....	15
1.7.3.3: Scientific Investigation of Food Complaint Samples	15
SECTION 2: COMMUNICATION.....	16
CHAPTER 2.1: FOOD ALERTS.....	16
CHAPTER 2.2: AGENCY COMMUNICATIONS AND GUIDANCE	17
CHAPTER 2.3: INFORMATION TO BE SUPPLIED TO THE AGENCY	18
CHAPTER 2.4: LIAISON WITH OTHER MEMBER STATES.....	19
2.4.1: Introduction	19
2.4.2: The Role of the Agency.....	19
2.4.3: The Role of Food Authorities	19
2.4.4: Enquiries from Member States	20
2.4.5: Documentation	20
2.4.6: Freedom of Information.....	20
2.4.7: Use of Information in Criminal Proceedings.....	20
2.4.8: Non-compliance With Legislation.....	21

SECTION 3: GENERAL ENFORCEMENT22

CHAPTER 3.1: APPROACH TO ENFORCEMENT	22
CHAPTER 3.2: IMPROVEMENT NOTICES	23
3.2.1: Introduction	23
3.2.2: The Enforcement Approach	23
3.2.3: Improvement Notices	23
3.2.3.1: Drafting an Improvement Notice	24
3.2.3.2: Improvement Notice Time Limits.....	24
3.2.3.3: Extension of Time.....	25
3.2.3.4: Works of Equivalent Effect	25
3.2.3.5: Compliance	26
3.2.3.6: Appeals.....	26
3.2.3.7: Other Discussion With the Food Authority	26
3.2.3.8: Other Guidance	26
CHAPTER 3.3: PROHIBITION PROCEDURES	27
3.3.1: Introduction	27
3.3.2: The Food Hygiene (England) Regulations 2005.....	27
3.3.2.1: Regulation 9 (Hygiene Prohibition Order) Procedures.....	27
3.3.2.2: Regulation 10 (Hygiene Emergency Prohibition) Procedures.....	27
3.3.2.3: Regulation 11 (Remedial Action Notices)	28
3.3.3: The Food Safety Act 1990	28
3.3.3.1: Section 11 Procedures	28
3.3.3.2: Section 12 Procedures.....	28
3.3.4: "Health Risk Condition" / "Imminent Risk of Injury to Health"	29
3.3.5: Seeking Additional Advice.....	30
3.3.6: Deferring Immediate Action.....	30
3.3.7: Issuing the Notice or Order	31
3.3.8: Methods of Serving the Notice or Order	31
3.3.9: Evidence Required	32
3.3.10: Prohibition Orders	32
3.3.11: Prohibition of a Person.....	32
3.3.12: Application to the Court.....	33
3.3.13: Action to be Taken Prior to the Hearing.....	33
3.3.14: Information to be Given to the Court.....	34
3.3.15: Prohibition Orders / Notices and Hygiene Prohibition.....	34
Orders / Notices.....	34
3.3.15.1: Affixing the Notice or Order on the Premises	34
3.3.15.2: Unauthorised Removal or Defacement of Notices or Orders.....	35
3.3.16: Lifting the Notice or Order	35
3.3.17: Breach of a Notice or Order	36
3.3.18: Appeals: Refusal of a Food Authority to Issue a Certificate That There Is No Longer a Risk to Health	37
3.3.19: Compensation	37
CHAPTER 3.4: SEIZURE AND DETENTION.....	39
3.4.1. Introduction	39
3.4.2. When to Use Detention and Seizure Powers.....	39
3.4.3. Specific Powers of Seizure and Detention for County Council	39
Food Authorities.....	39
3.4.4. Detention of Food.....	40
3.4.5. Seizure of Food.....	40
3.4.6. Notice of Seizure.....	40
3.4.7. Taking Action Without Inspecting.....	41
3.4.8. Dealing With Batches, Lots or Consignments of Food	41
3.4.9. Voluntary Procedures.....	41
CHAPTER 3.5: TEMPERATURE CONTROL REGULATIONS	43
3.5.1: Introduction	43
3.5.2: General Approach to Temperature Checks	43
3.5.3: Taking Temperature Measurements.....	44

3.5.4:	Tolerances.....	44
3.5.5:	Checking and Calibration of Enforcement Measuring Thermometers etc	45
3.5.6:	Pre-cooling of Instruments	45
3.5.7:	Preparation of Samples for Temperature Measurement	45
3.5.8:	Measurement of Product Temperature	46
3.5.9:	Equipment Used for Chilled Product Temperature Measurement.....	46
CHAPTER 3.6: QUICK FROZEN FOODSTUFFS		48
3.6.1:	Introduction	48
3.6.2:	Division of Enforcement Responsibility Between County and District Councils	48
3.6.3:	Temperature Requirements	49
3.6.4:	Staged Approach to Enforcement.....	49
3.6.5:	Air Temperature Checks	49
3.3.15.1:	Air Temperature Checks: Cold Stores.....	50
3.3.15.2:	Air Temperature Checks: Transport.....	50
3.3.15.3:	Air Temperature Checks: Retail Display Cabinets	51
3.6.6:	Non-destructive Temperature Checks	51
3.6.7:	Destructive Temperature Measurement	52
3.6.8:	Sampling	53
3.6.8.1:	Sampling: Cold Stores.....	53
3.6.8.2:	Sampling: Transport.....	54
3.6.8.3:	Sampling: Retail Display Cabinets.....	55
3.6.9:	Procedure for Product Temperature Measurement	57
3.6.10:	Dealing with Food which is at a Higher Temperature than the Prescribed Frozen Temperature	58
3.6.11:	General Specification for Temperature Measuring	58
	Instruments	58
CHAPTER 3.7: WASTE FOOD		60
3.7.1:	Introduction	60
3.7.2:	Inspection of Food Businesses	60
3.7.3:	Major Investigations	60
CHAPTER 3.8: DISTANCE SELLING/MAIL ORDER.....		62
3.8.1:	Introduction	62
3.8.2:	Location of the Seller	62
3.8.3:	Location of the Buyer	62
3.8.4:	Distance Selling of Food from the UK.....	62
3.8.5:	Distance Selling of Food from the EU (Outside the UK).....	63
3.8.6:	Distance Selling of Food from Third Countries	63
3.8.7:	Generic Distance Selling Legislation	64
3.8.8:	Other References	64
CHAPTER 3.9: BOTTLED WATERS		65
3.9.1:	Introduction	65
3.9.2:	Natural Mineral Waters	65
3.9.3:	Recognition of Natural Mineral Waters	66
3.9.4:	Labelling of Natural Mineral Waters.....	66
3.9.5:	Spring and Other Bottled Drinking Water.....	66
3.9.6:	Labelling of Spring and Other Bottled Water	66
CHAPTER 3.10: IMPORT OF FOOD FROM THIRD COUNTRIES		68
SECTION 4: INSPECTIONS.....		69
CHAPTER 4.1: INSPECTIONS.....		69
CHAPTER 4.2: THE INSPECTION.....		70
4.2.1:	Introduction	70
4.2.2:	Notice of Inspection.....	70
4.2.3:	Co-ordination of Inspections	70
4.2.4:	Shellfish Identification Marks	70

CHAPTER 4.3: INSPECTION OF APPROVED ESTABLISHMENTS – ADDITIONAL REQUIREMENTS	72
CHAPTER 4.4: INSPECTION OF SHIPS AND AIRCRAFT	73
4.4.1: Introduction	73
4.4.2: General.....	73
4.4.3: Catering Waste	74
4.4.4: Other Issues: Aircraft	74
4.4.5: Other Issues - Ships.....	75
4.4.6: Other References.....	76
4.4.7: Inspection Templates.....	77
CHAPTER 4.5: ACTION FOLLOWING INSPECTION	80
SECTION 5: PRODUCT-SPECIFIC ESTABLISHMENTS	81
CHAPTER 5.1: APPROVAL OF PRODUCT-SPECIFIC ESTABLISHMENTS SUBJECT TO APPROVAL UNDER REGULATION 853/2004	81
CHAPTER 5.2: ENFORCEMENT OPTIONS IN PRODUCT-SPECIFIC PREMISES.....	82
CHAPTER 5.3: MATTERS RELATING TO SHELLFISH.....	83
CHAPTER 5.4: MATTERS RELATING TO FRESH MEAT	84
SECTION 6: SAMPLING	85
6.1.1: Introduction	85
6.1.2: Procurement of Samples.....	85
6.1.3: Certificate by Public Analyst or Food Examiner.....	85
6.1.4: Avoiding Contamination	85
6.1.5: Samples for Analysis.....	85
6.1.5.1: Quantity of Samples for Analysis.....	85
6.1.5.2: Containers for Samples for Analysis.....	86
6.1.5.3: Transport and Storage of Samples for Analysis	86
6.1.5.4: Samples which Present Difficulties in Dividing into Parts	86
6.1.5.5: Certificates of Analysis.....	87
6.1.6: Samples for Examination	87
6.1.6.1: Quantity of Samples for Examination.....	87
6.1.6.2: Handling of Samples for Examination	87
6.1.6.3: Handling, Transport and Storage of Faecal Specimens for Examination	88
6.1.6.4: Continuity of Evidence.....	89
6.1.6.5: Request for Examination	90
6.1.6.6: Certificates of Examination.....	90
SECTION 7: MONITORING.....	91
SECTION 8: ANNEXES.....	92
ANNEX 1: GLOSSARY OF TERMS	92
ANNEX 2: FSA GUIDANCE ON THE REQUIREMENTS OF FOOD HYGIENE LEGISLATION	94
A2.1: Introduction	94
A2.2: Background.....	94
A2.3: Scope.....	95
A2.4: Requirements of Regulation 852/2004	96
A2.5: Registration.....	96
A2.6: Approval.....	97
A2.7: Specific hygiene requirements.....	97
A2.8: Food Safety Management.....	98
A2.9: Guides to good practice	98
A2.10: Enforcement.....	98
Appendix 1: The Food Hygiene Regulations and Other Associated Legislation.....	100

Appendix 2: Applicability of Regulation 852/2004	102
Appendix 3: Applicability of Regulation 853/2004	104
Appendix 4: Establishments Subject to Approval under Regulation 853/2004	107
Appendix 5: Provisions Applying to Primary Production	110
Appendix 6: Primary Production	111
Appendix 7: Summary Guidance on what Provisions Apply to Food Businesses (Other than Primary Production)	125
Appendix 8: Food Standards Agency Interpretation of Terms used in the EU Regulations	139
ANNEX 3: FRESH MEAT / MEAT PRODUCTS / MEAT PREPARATIONS / ON FARM SLAUGHTER	142
A.3.1: Introduction	142
A.3.2: Enforcement in Meat Establishments	142
A.3.3: Approval of Establishments	142
A.3.4: Exemptions from Approval	143
A3.4.2: Cold Stores	143
A3.4.3: Wild Game	143
A3.4.4: On farm slaughter and cutting of small quantities of poultry and lagomorphs	143
A2.1: Which producers benefit from this exemption?	143
A2.2: Where can the meat be sold?	144
A2.3: What rules apply?	145
A3.4.5: Retail establishments (See also Appendix 8 of Annex 2 of this Guidance)	145
A3.4.6: "Marginal, localised and restricted"	145
This exemption is outlined in Appendix 8 of Annex 2 of this guidance	145
A3.4.7: "Composite" Products	146
ANNEX 4: SHELLFISH	147
A.4.1: Introduction	147
A.4.2: Competent Authority	147
A.4.3: The Local Market Exemption	147
A.4.4: Table	147
A.4.5: Heat Treatment	147
A.4.6: Shellfish Liaison Arrangements	148
A.4.7: Notification of Production Areas and Relaying Areas	149
A.4.8: Monitoring of Registration Documents	149
A.4.9: Sampling by Operators	150
A.4.10: Laboratories Used in Connection with Dispatch or Purification Centres	150
A.4.11: Sampling of Live Bivalve Molluscs by Food Authorities	150
A.4.12: Information on Standards to be applied	150
A.4.13: Molluscs and Other Shellfish Which Fail to Satisfy Requirements	151
A.4.14: Transfer of Seed Molluscs to Production Areas	151
A.4.15: Temporary Prohibition Orders	151
A.4.16: Live Shellfish Guidance Note for Food Authorities	153
A.4.17: Model Registration Document	156
ANNEX 5: FISHERY PRODUCTS	157
A.5.1: Introduction	157
A.5.2: Competent Authority	157
A.5.3: Scope of Approval	157
A.5.4: Direct supply of small quantity of Fish.	157
A.5.5: Table	157
A.5.6: Conditions During and After Landing	158
A.5.7: Information on Standards to be applied	158
A.5.8: Fishery Products Guidance Note	159
ANNEX 6: RAW MILK AND DAIRY PRODUCTS	168
A.6.1: Introduction	168
A.6.2: Enforcement	168
A.6.3: Food Business Operators Selling Raw Milk and Cream	169
A.6.4: Derogations	169
A6.4.1: Long Maturing Cheeses	169
A.6.5: Testing for Residues, Raw Milk and Other Standards	170
A.6.6: Hygiene Rules for Approval of Production Holdings	170
A.6.7: Reusable Containers	170

A.6.8: Health Requirements for Raw Milk Production	170
A.6.9: Criteria and Standards for Raw Milk	171
A.6.10: Temperature Requirements for Milk Used for the Manufacture of Dairy Products	171
A.6.11: Identification Marking for Raw Milk and Dairy Products: Derogations	171
ANNEX 7: EGG PRODUCTS AND LIQUID EGG	172
A.7.1: Introduction	172
A.7.2: Scope of the Regulations	172
A.7.3: Types of Approved Premises	172
A.7.4: Dirty Eggs	173
A.7.5: Centrifuging or Crushing	173
A.7.6: Identification Marking	173
A.7.7: Pasteurisation and Heat Treatment	173
A.7.8: Analytical Specifications	174
A.7.9: Temperature Control	174
A.7.10: Storage and Transport	174
A.7.11: Egg Marketing	174
ANNEX 8: APPROVAL PROCESS	175
Appendix 1: Flow Chart for Approval of Establishments	175
Appendix 2: Model Application for Approval	177
Appendix 3: Food Authority Files	183
Appendix 4: Model Notification of Grant of Approval	185
Appendix 5: Model Notification of Refusal of Approval	188
Appendix 6: Model Notification of Withdrawal of Approval / Conditional Approval	190
Appendix 7: Notification of Suspension of Approval	193
Appendix 8: Notification of Amendment to Approval	196
Appendix 9: Notification of Refusal to Grant Full Approval to an Establishment which is Conditionally Approved	199
ANNEX 9: IMPORT OF FOOD FROM THIRD COUNTRIES	202
A9.1: Introduction	204
Scope	204
A9.2: Status of this Guidance	205
A9.3: The Official Feed and Food Controls (England) Regulations 2005	205
A9.4: Service Planning	205
A9.5: Documented Policies and Procedures	206
A9.6: Authorisation	206
A9.7: Qualifications/experience of authorised officers	207
A9.8: Information	207
A9.9: Records	208
Identifying and recording food importers	208
Records of consignments and examinations	209
Arrangements for points of entry without permanent local authority presence	209
A9.10: Reporting and Notification Arrangements	209
Nominated officer for imported food controls	209
Monitoring Returns	209
Notification of Food Hazards or Incidents	210
Notification of illegal imports of POAO	210
A9.11: Liaison	211
A9.12: Inland Inspection of Imported Food	212
Deferred Examination of FNAO – inland controls	212
A9.13: Sampling of Imported Food	212
Considerations for sampling	213
Qualifications/experience/training of officers carrying out sampling	213
A9.14: Food of Non-Animal Origin (FNAO)	213
Identification	214
Prohibition	214
Examination	214
Deferred Examinations of FNAO	216
A9.15: Third Country Pre-Export Checks	216
A9.16: Charges	217
A9.17: Enforcement	217
A9.18: Specified (High Risk) Products	219

A9.19: Products of Animal Origin - Enforcement.....	220
Illegally introduced POAO	220
POAO Presenting a Risk to Public or Animal Health.....	221
Detention of POAO inland.....	221
Reporting.....	222
A9.20: References	222
ANNEX 10: FOOD SAFETY MANAGEMENT PROCEDURES BASED ON HACCP PRINCIPLES ..	228
A10.1: Introduction	228
A10.2: Approach To Enforcement	228
A10.3: Flexibility.....	228
A10.4: Role of Food Authorities.....	232