

Food Safety Act 1990

Practice Guidance

FOOD SAFETY ACT PRACTICE GUIDANCE

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TABLE OF AMENDMENTS ISSUED

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

PREFACE

This guidance is issued by the Food Standards Agency to assist Food Authorities with the discharge of their statutory duty to enforce the Food Safety Act 1990 (the Act) and Regulations made under it.

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 1974, and directly under EC Regulations.

Food Authority officers authorised under Section 5 (6) of the Food Safety Act 1990 to carry out duties under that Act and Regulations made under it are not simultaneously authorised to deal with food law under other legislation.

Separate and specific authorisation under that other legislation is also required.

This Practice Guidance replaces all previous guidance issued by central Government on the Code of Practice, Regulations made under the Food Safety Act 1990, and other matters covered by this Practice Guidance.

Material in previous guidance has been reviewed and updated where necessary, and in some cases expanded to provide more detailed advice on key aspects of the Regulations and their enforcement.

The guidance has been specifically strengthened in several areas in response to 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 under product-specific hygiene Regulations, and in particular checks on raw materials, the use of commercial documents, and occupier controls over health marking.

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 Food Standards 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.

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 cover the full range of product-specific hygiene Regulations and 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 or contact the Information Commissioner.

CHAPTER 1.5: REGISTRATION OF FOOD BUSINESSES

1.5.1: Introduction

This Chapter deals with enforcement of the Food Premises (Registration) Regulations 1991 (the Regulations).

1.5.2: Food Premises Registration

The purpose of registration is to provide information for Food Authorities about food businesses in their area so that they can carry out their enforcement duties effectively.

The statutory form that businesses should use to register is part of the Regulations. Authorities may use a similar form containing all the information required by the statutory form.

There is no charge for registration and Food Authorities cannot refuse to register premises. Registration does not need periodic renewal.

Any new business has to apply to be registered at least 28 days before it opens.

The “registration authority” in England and Wales is the district council, metropolitan district council, London Borough Council, unitary authority and the City of London Corporation.

Moveable premises are registered with the authority in whose area they are normally kept or garaged. Port Health Authorities are registration authorities for premises for which they are the Food Authority under the Act.

The registration requirement does not apply to certain premises, which are not used for more than a few days or are not used regularly. Registration is required if premises are used for the purpose of a food business for 5 or more days (whether consecutive or not) in any 5 consecutive weeks. This rule also applies to any premises used by two or more food businesses.

The Regulations list certain specific exemptions. These include premises where crops are harvested but not processed, those used for egg production, those which are already registered or licensed for certain other food law purposes, stalls and vehicles which operate from premises which are already registered, or are exempt by virtue of being registered under other schemes.

Apart from the information that the Regulations require to be available to the public, authorities are required by the Regulations to keep the remaining information confidential.

Food Authorities should ensure that forms they receive relate to premises in their area and forward those that are received in error to the appropriate registration authority without delay.

The authority which received the form in error should inform the applicant that the form has been forwarded to the correct authority, giving the applicant the correct name and address for future reference.

The proprietor is responsible for ensuring the form has been properly completed. Where incomplete forms are received, the authority should assess the information so as to determine whether or not there is a need to contact the proprietor of the business concerned.

The authority should, wherever possible, contact the proprietor or person who has filled in the registration form if the missing information relates to the address of the premises, the name of the business or the type of premises, as this information is essential for the public record.

If a registration authority believes that the details submitted on the form are incorrect the authority should take all reasonable steps to verify the information before compiling their records, including contacting the proprietor of the food business or his representative if necessary.

Where incorrect details have been given, the authority should forward another form to the proprietor of the business for completion, stating where possible what was incorrect. The Regulations allow the registration authority to alter the register, but only after giving the proprietor 28 days' notice of their intention to do so and after considering any representations the proprietor may have made.

1.5.3: Supplementary Records

The Regulations require registration authorities to keep, as a supplementary record, that information supplied by the proprietor of a food business on the registration form, which is not available to the public. If a computer system is used for the register, the registration authority should ensure that the supplementary record is not publicly accessible.

When enforcement action is taken on any vehicle used for the purpose of a food business, the registration authority should record any identification mark (for example, a licence or container number) on the vehicle on the supplementary record, together with the type of action taken (for example, improvement notice, emergency prohibition notice). The information should be associated with the records for the premises at which the vehicle is usually kept.

1.5.4: Keeping the Register and Supplementary Record Up to Date

Updating the register and supplementary record should be an on-going process. Registration authorities should ensure that all changes notified to them by the proprietor of the food business are entered in the register and supplementary record within 28 days of receipt.

Registration authorities should evaluate information received from other sources which appears to require a change to an entry on the register. The authority should not alter the particulars without giving the proprietor of the business an opportunity to

make representations about the change and, where appropriate, should ask the proprietor to complete a new registration form to confirm the change. This is particularly important if there has been a change in the type of business carried on at the premises, which means the business now poses a greater potential risk to public health.

1.5.5: Access to the Register

Registration authorities are required by the Regulations to make the register available for inspection by the public at all reasonable times. It may be made available for inspection in hard copy or via a computer terminal.

CHAPTER 1.6: CROWN AND POLICE PREMISES

1.6.1: Introduction

This Chapter deals with enforcement of the Food Safety Act in Crown and police premises.

1.6.2: Scope of Application of the Act

The Food Safety Act extends to police premises, most Crown premises (subject to the exemptions listed 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 Act 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 on the enforcement of the Act 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 hygiene 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

The Act does not allow the Crown to be prosecuted.

Section 54(2) of the Act 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 food safety legislation, is unlawful.

The identity of the proprietor of the food business concerned should be carefully considered if the question of action under Section 54(2) arises.

Contract caterers operating on Crown premises can be prosecuted as they are not subject to this exemption. It is only where the proprietor of the business is the Crown itself that a prosecution cannot be taken. 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 and Section 54 action against the Crown may be appropriate.

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 office of a non-Departmental Government body.

1.6.5: Position of Individual Civil or Government Servants

Although the Crown is immune from prosecution, 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 Sections 7, 8, 9, 14 or 15 of the Act or Regulations or Orders having effect under the Act 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 an improvement or emergency prohibition notice does not itself make the recipient criminally liable. Such notices may therefore be served on the Crown where it is the proprietor of the food business concerned.

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

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

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

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

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

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

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

CHAPTER 1.7: FOOD INCIDENTS AND HAZARDS

1.7.1: Introduction

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

1.7.2: Information Received Locally Which May Indicate a Wider Problem

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

- following microbiological examination or chemical analysis of samples submitted to a Food Examiner or Public Analyst;
- as a result of complaints from members of the public, either directly or through a third party, for example, the police, citizens' advice bureaux etc;
- through notifications from a manufacturing company, trade association, wholesaler, retailer, importer or caterer;
- information from enforcement agencies in other countries;
- as a result of a notification from a GP of one or more cases of communicable diseases, including foodborne illness, or from the consultant in communicable disease control (CCDC), or the 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 food 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, the advice of the Public Analyst and/or Food Examiner should be sought, who will be able to advise on the form of scientific investigation which may be appropriate, particularly since some will require a combination of analysis and examination.

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: FOOD STANDARDS AGENCY COMMUNICATIONS AND GUIDANCE

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

CHAPTER 2.3: INFORMATION TO BE SUPPLIED TO THE FOOD STANDARDS AGENCY

All relevant material on information to be supplied to the Food Standards 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 single European liaison arrangements that are operated by Local Authorities Co-ordinators of Regulatory Services (LACORS) on behalf of the Food Standards Agency.

2.4.2: The Additional Food Control Measures Directive

Article 6 of the Additional Food Control Measures Directive (93/99EEC) states:

“The competent authorities of the Member States shall afford each other administrative assistance in all supervisory procedures in connection with legal provisions and quality standards applicable to foodstuffs and in all proceedings for infringements of the law applicable to foodstuffs.

To facilitate this administrative assistance each Member State shall designate a single liaison body. It shall be for the body designated by the Member State to liaise as appropriate with the liaison bodies of other Member States. The role of the bodies shall be to assist and co-ordinate communication and, in particular, the transmission and reception of requests for assistance.”

This chapter is concerned only with the provision of administrative assistance and exchange of information on routine food control matters.

2.4.3: The Role of the Food Standards Agency

The Food Standards Agency is responsible for the implementation of the Additional Food Control Measures Directive 93/99/EEC in the UK.

In relation to requirements concerning the exchange of information and provision of administrative assistance, the Food Standards Agency will have a supervisory role. In order to determine whether routine exchanges have any policy implications, the Food Standards 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 Food Standards Agency will also deal directly with matters falling under categories A and B (see Chapter 2.4 of the Code of Practice).

2.4.4: The Role of LACORS

The Food Standards Agency has designated LACORS as the UK liaison body to provide administrative assistance on routine food control matters under the Directive.

LACORS 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, LACORS 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.

2.4.5: 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.

2.4.6: Enquiries from Members States

Requests for information or administrative assistance received by LACORS will be passed to the appropriate Home Authority for action. The subsequent response may be made either via LACORS 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 LACORS into any response to the other Member State.

2.4.7: Documentation

Food Authorities should provide original documents, but where this is not possible the Directive allows copies of documents to be transmitted.

2.4.8: 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

LACORS. 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 LACORS.

2.4.9: 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 Matters¹. 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 LACORS so that they can fulfil their role as the UK single liaison body.

The UK Central Authority address is:

Home Office
UK Central Authority
Judicial Co-operation Unit
50 Queen Anne’s Gate
London
SW1H 9AT.

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.

Neither local authorities nor Food Authorities are “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.

¹ UN 1963, 472:185,6841

2.4.10: 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 LACORS who in turn will report to the Food Standards Agency. The Agency will decide whether the Commission should be notified.

SECTION 3: GENERAL ENFORCEMENT

CHAPTER 3.1: APPROACH TO ENFORCEMENT

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

CHAPTER 3.2: IMPROVEMENT NOTICES

3.2.1: Introduction

This Chapter deals with the use of improvement notices under Section 10 of the Food Safety Act 1990.

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 an 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 Act requires an improvement notice to be served on the proprietor of a food business. It is not always possible to identify the proprietor, however, and Section 59(2) of the Act therefore allows the notice to be addressed to the “owner” and left at the premises if the proprietor cannot be identified.

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 proprietor.

Notices should normally be served either by delivery to the proprietor of the food business in person, or by a service such as Recorded Delivery that provides 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.

In situations where the manager is not the proprietor and cannot make decisions about structural works, the officer should, if possible, discuss the detail of the works to be carried out with a person in a position to authorise repairs before issuing a notice. Such discussions are desirable, but the issue of the notice should not be delayed.

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. The Act specifies 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 proprietor, although the officer may set a limit without the proprietor's agreement.

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.

The minimum allowable 14 days should normally be sufficient time for most notices requiring cleaning, unless conditions are so bad that emergency prohibition action is necessary.

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 occur.

There is no specific provision in the Food Safety Act 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 proprietor;
- any temporary action which the proprietor proposes to take to remedy the defect.

The 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 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 Act allows a proprietor to carry out measures of at least equivalent effect to those specified in the notice.

Notices should recommend that proprietors discuss alternative measures 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 a 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 proprietor that there is a proper review.

3.2.3.5: Compliance

The officer who served the notice should liaise with the proprietor and monitor the work being undertaken and encourage the 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 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 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 the proprietor wishes to do so.

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

If a 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 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.

CHAPTER 3.3: PROHIBITION PROCEDURES

3.3.1: Introduction

This Chapter deals with the use of the prohibition procedures of Sections 11 and 12 of the Act.

3.3.2: 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 hygiene or processing regulations.

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: 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 order 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 working days of an emergency prohibition notice being served, the day of service of the notice being Day 1.

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: Imminent Risk of Injury to Health

Section 12 can only be used if there is an “imminent risk” of injury to health.

The word “imminent” qualifies the word “risk”. There must always be an imminent risk of injury to health before an 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.

Such circumstances may exist, for example, if 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.

Other situations include:

- a process or treatment that introduces a teratogenic chemical (one that damages a developing foetus in the womb) into food, which may cause injury to a developing foetus, but the damage will not be apparent until the baby is born;
- a process or treatment that introduces a genotoxic chemical (one that damages genes or chromosomes) into food, the effects of which 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 6 of the Act.

However, the process or treatment which exposed the food to this chemical contamination should be dealt with under Section 12. 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.

The criteria for action still depend on the conditions in Section 11(2) being met, i.e. that either the construction or condition of the premises, or any equipment or the use of any process or treatment involve 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.

Action cannot be taken under Section 12 of the Act unless the existence of an imminent risk of injury to health can be demonstrated.

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 expertise².

An authorised officer exercising a right of entry under Section 32 of the Act 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 the 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

An emergency prohibition order or a prohibition order – both 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 an emergency prohibition notice, an emergency prohibition order or a prohibition order cannot be handed to the 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 proprietor is aware of the matters that constitute an imminent risk. Although this is included in the prescribed emergency prohibition notice, the 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 prohibition order, an emergency prohibition order, or an emergency prohibition notice by delivering it to the proprietor of the business, or each of the proprietors in the case of a partnership etc., by hand.

² The Institute of Food Science and Technology maintains a list of experts in particular fields

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 post, obtaining proof of posting and/or advice of delivery.

The document may be faxed to the 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 Section 50, 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 comes into 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 are taken during an inspection and in respect of which evidence may need to be given to a Court, including sketches and photographs. 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 the officers at the end of, or during a visit, both officers 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 re-occurred.

If the proprietor of the food business is convicted, the Court's attention may be brought to the provisions of Section 11(1) in order that the Court may consider making a 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 proprietor or manager of a food business 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 proprietor or manager.

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.

“Manager” in relation to a food business means any person who is entrusted by the proprietor with the day-to-day running of the business, or any part of the business.

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 Office to ensure that, if at all possible, applications for emergency prohibition orders are expedited.

The proprietor must be notified that the authorised officer intends to apply for an emergency prohibition order. A notice of application for an emergency prohibition order must be served on the proprietor at least one 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 purposes of 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 Section 11(1) in order for a prohibition order 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-visited prior to the hearing;
- evidence that the proprietor or manager 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 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 recorded in the Office of Fair Trading's (OFT) Central Register of Convictions³, 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

3.3.15.1: Affixing the Notice or Order on the Premises

Sections 11 and 12 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

³ The Office of Fair Trading, Central Register of Convictions, Craven House, 40 Uxbridge Road, Ealing, London, W5 2BS

required by the Food Authority. The authorised officer who initiated the action need not necessarily be involved.

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

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

3.3.15.2: Unauthorised Removal or Defacement of Notices or Orders

The Act makes no reference to defacing or removing a prohibition order, an emergency prohibition order, or an emergency prohibition 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 £2,000 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 proprietor must apply in writing to the Food Authority for a certificate lifting an emergency prohibition notice or order or a prohibition order. On receiving such a request, the authorised officer should re-visit 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 Section 12(8) 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 Section 12(9)(b)) 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 emergency prohibition notice may be issued before the application for an emergency prohibition order can be heard, the proprietor may still be prosecuted for the offence(s) against the regulations. The Food Authority should ensure that the court is informed in this situation.

A prohibition order on the proprietor of a food business can only be lifted on application by the proprietor to the Court that made the Order.

3.3.17: Breach of a Notice or Order

A person who knowingly contravenes a prohibition order is guilty of an offence under Section 11(5) and a person who knowingly contravenes an emergency prohibition notice, or an emergency prohibition order is guilty of an offence under Section 12(5) or (6).

The authorised officer should start proceedings for the offence under the appropriate Section 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 his view as to whether to endorse the warrant with bail. The authorised officer should use his professional judgement and take into account all relevant circumstances in his 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

Section 37 of the 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

Section 12(10) provides for the Food Authority to compensate the proprietor for losses arising from the service of the emergency prohibition notice if an 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 proprietor to mitigate his own loss;

or, if the 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 the Food Safety Act 1990.

3.4.2: When to Use Detention and Seizure Powers

It is presumed under Section 3 (2) of the Act 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 therefore serve a detention of food notice to prevent the use of the food for human consumption.

These 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: 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 decision to detain a whole batch, lot, or consignment may, however, have significant implications for the business concerned, and therefore needs careful consideration before a notice is served.

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.

3.4.4: 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.

3.4.5: 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) on any person who may be liable to prosecution for selling or producing unsafe food to attend before a Justice of the Peace, to be heard and to call witnesses.

3.4.6: Taking Action Without Inspecting

The provisions of Section 9 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 PHLS, the CCDC, or the Food Standards 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.

In non-metropolitan counties, this provision should only be used by authorised officers of district councils.

3.4.7: Dealing With Batches, Lots or Consignments of Food

Section 8(3) of the Act deals with food that fails to comply with food safety requirements, where the food is part of a larger batch, lot or consignment of food of the same class or description.

In such circumstances it is presumed, until the contrary is proved, that all of the food in the batch, lot or consignment fails to comply with food safety requirements.

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

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

3.4.8: Voluntary Procedures

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

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

CHAPTER 3.5: WASTE FOOD

3.5.1: Introduction

This Chapter provides practice 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 protection of both public and animal health, authorised officers should be fully aware of this framework when conducting inspections.

For the purposes of this guidance, “food waste” includes food material that is not fit or not intended for human consumption. “Food material” includes any material that could be used as food, or as an ingredient in food, whether produced by a food business or not.

3.5.2: Inspection of Food Businesses

Any inspection of a food business, including inspections of mobiles, 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.

3.5.3: Waste Meat and Meat Products

Any waste containing any meat or meat product, and any waste coming from premises on which such materials are handled, can only lawfully be disposed of by landfill, rendering or incineration. The feeding of such waste to livestock has been banned in England since 24th May 2001 by the Animal By-Products Order 1999⁴, as amended⁵ (the Order).

Such waste is described in the Order as “catering waste”.

Authorised officers should therefore pay particular attention to the disposal arrangements for such waste from businesses such as caterers, canteens, institutional kitchens, restaurants, take aways, food manufacturers and similar establishments.

⁴ As amended, SI 1999/646, made under the Animal Health Act 1981

⁵ SI 2001/1704, made under the Animal Health Act 1981

An authorised officer who suspects that waste from such a business is not being disposed of in accordance with the requirements of the Order should, if they do not enforce the Order themselves, pass details to the relevant enforcing authority⁶ or to the Divisional Veterinary Manager at the local office of the State Veterinary Service.

3.5.4: Waste from Retailers

Businesses that are not caterers also generate waste that falls into the definition of “catering waste”, e.g. butchers (cooked meats, pasties, etc), supermarkets and other retailers.

The disposal arrangements of these types of business should also be checked to ensure that food waste cannot re-enter the human food chain, and is not being used for feeding to livestock.

N.B. “catering waste” that comprises only bread and cake waste from supermarkets may be fed to livestock providing it has been kept separate at all times from any meat or meat products.

3.5.5: Waste from Abattoirs and Cutting Plants

The use and disposal of animal by-products that are not intended for human consumption from abattoirs, cutting plants, and similar establishments is strictly controlled.

Such material is categorised under the Order as either “high-risk” or “low-risk”.

High-risk material is broadly material that is not fit for human consumption, and generally includes everything that is not low-risk material. Such materials, when produced in licensed meat premises, are required by the Animal By-Products (Identification) Regulations 1995⁷ to be sterilised⁸ or stained on the premises on which they are produced. They are normally disposed of through rendering or incineration.

N.B. there are alternative disposal routes to rendering and incineration but they are unlikely to be used for material from slaughterhouses, etc. DEFRA’s Animal By-Products policy team can advise on current disposal options for such material: Tel: 020 7904 6408, as can the Divisional Veterinary Manager at the local office of the State Veterinary Service.

Low-risk material is generally material that is fit for human consumption but is not intended for that purpose. Such material can go to premises that have been approved or registered by the Minister under the Order. Approved premises include

⁶ The Animal By-Products Order was made under the Animal Health Act. As such, enforcement is the responsibility of the local authority in England and Wales, i.e. the County, London Borough, Unitary or Metropolitan District Council in England, or the Unitary Authority in Wales. Enforcement of animal health legislation is normally the responsibility of the local authority’s trading standards service

⁷ As amended, SI 1995/614, made under the Food Safety Act 1990

⁸ The sterilisation option is due to be removed from 31 December 2002

rendering plants and knacker's yards. Registered premises include pet food and pharmaceutical manufacturers.

Teaching and research establishments can also receive both high and low-risk material.

N.B. the explanations of 'high' and 'low-risk' material are very brief summaries that are used solely to illustrate differences in the respective regulatory controls that apply to them. Full definitions are set out in Article 3 of the Order. Further information and advice can be obtained from DEFRA's Animal By-Products Section, Tel: 020 7904 6802.

A central database of approved and registered animal by-products establishments is maintained by DEFRA's Animal By-Products Section. Corresponding databases are maintained for Scotland by SERAD, and for Wales by NAWAD.

3.5.6: Specified Risk Material

As part of the measures introduced to minimise potential human exposure to BSE certain parts of bovine, goat and sheep carcasses are required to be removed at the slaughterhouse or, in certain circumstances at cutting premises, and should therefore never be found in meat that is delivered to manufacturers, caterers or retailers. The treatment, use, transportation, storage and disposal of such material, known as specified risk material, is strictly controlled, including an absolute prohibition on the use of such material in food or animal feed.

These requirements are set out in Commission Regulation EC 999/2001 (as amended) which is directly applicable in all Member States. Arrangements for the enforcement of this Regulation in England are contained in the TSE (England) Regulations 2002⁹, and in Wales in the TSE (Wales) Regulations 2002¹⁰.

An authorised officer who becomes aware that specified risk material has not been dealt with in accordance with the relevant requirements should notify the Food Standards Agency at the earliest opportunity.

3.5.7: 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.

⁹ as amended, SI 2002/843

¹⁰ SI 2002/1416

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 3.6: DISTANCE SELLING

3.6.1: 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.

3.6.2: Location of the Seller

The ability of Food Authorities to enforce the Food Safety Act 1990 and regulations made under it 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 as transposed 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.

3.6.3: 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.

3.6.4: 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 the Food Safety Act 1990 and relevant regulations made under the Act, including the Food Labelling Regulations and the Food Safety (General Food Hygiene) Regulations 1995. 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;
- clearly marking consignments on the outermost packaging with the appropriate durability indication.

3.6.5: 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 with the exception of UK national provisions such as the Meat Products and Spreadable Fish Products Regulations 1984.

Food Authorities should generally use the single liaison role of LACORS to resolve problems relating to the distance selling of food from the EU.

3.6.6: Distance Selling of Food from Third Countries

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

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

3.6.7: Generic Distance Selling Legislation

Generic law regulating distance selling in the UK is set out in the Consumer Protection (Distance Selling) Regulations 2000¹¹, 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 (the DTI). Enforcement is the responsibility of the Office of Fair Trading (OFT) and Trading Standards Departments.

DTI, OFT, and LACORS have each published guidance on the Regulations for businesses, consumers, and enforcement agencies. Copies of the guidance are available either directly from the LACORS website at <http://www.lacors.gov.uk> or via links from the LACORS web site to the relevant DTI or OFT web addresses.

¹¹ SI 2000/2334

CHAPTER 3.7: BOTTLED WATERS

3.7.1: Introduction

This Chapter provides guidance to Food Authorities on enforcement of the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999¹² (the Regulations).

The Regulations transpose into UK legislation:

- Directive 80/777/EEC, as amended by Directive 96/70/EC, relating to natural mineral water and spring water;
- Directive 80/778/EEC as it applies to bottled waters other than natural mineral water.

3.7.2: 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 Food Standards Agency website at www.food.gov.uk/foodindustry/42877.

The most recent list of all recognised sources within the EU is available at http://europa.eu.int/comm/food/fs/sfp/mineral_water/mw_eulist_en.pdf.

3.7.3: 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 Food Standards 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.

3.7.4: 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.

¹² SI 1999/1540

3.7.5: 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 1991¹³, which specify the frequency of local authority monitoring of a range of compositional and microbiological parameters.

3.7.6: 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.

Bottled drinking waters are subject to the general labelling requirements of the Food Labelling Regulations 1996¹⁴.

¹³ SI 1991/2790

¹⁴ as amended, SI 1996/1499

SECTION 4: INSPECTIONS

CHAPTER 4.1: PURPOSE OF INSPECTION

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

CHAPTER 4.2: THE PLANNED INSPECTION PROGRAMME

All relevant material on the planned inspection programme is contained in the Code of Practice.

CHAPTER 4.3: THE INSPECTION

4.3.1: Introduction

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

4.3.2: Notice of Inspection

The general principle about pre-notification of inspections is set out in Directive 89/397/EEC which states in Article 4(4) that “as a general rule, inspections shall be carried out without prior warning”.

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.

4.3.3: Co-ordination of Inspection Visits

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 inspection visits. 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 visits. 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 technology¹⁵.

4.3.4: Shellfish Health Marks

As part of the monitoring of the use of shellfish health 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 health mark are in order. Food Authorities should co-operate with other Food Authorities in any random check through the production and distribution chain.

If any checks suggest that movement documents, health 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

¹⁵ The Institute of Food Science and Technology maintains a list of experts in particular fields

consider increasing the frequency of random checks through the distribution chain until they are satisfied that the appropriate procedures are being followed.

CHAPTER 4.4: INSPECTION OF APPROVED ESTABLISHMENTS – ADDITIONAL REQUIREMENTS

All relevant information on the inspection of approved establishments is contained in the Code of Practice.

CHAPTER 4.5: ACTION FOLLOWING INSPECTION

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

SECTION 5: PRODUCT-SPECIFIC REGULATIONS

CHAPTER 5.1: APPROVALS

5.1.1: Introduction

This Chapter deals with issues relating to approval of premises subject to product-specific food hygiene Regulations, covering delegation of powers; the effects of the Meat (Enhanced Enforcement Powers) (England) Regulations 2000; suspension of approval; and enforcement.

5.1.2: Delegation of Powers

Food Authorities should ensure that their powers to grant, refuse, suspend and amend approvals can be exercised effectively.

They should therefore consider whether such powers should be delegated to their lead officer for food hygiene and safety and/or other appropriately qualified and experienced authorised officer(s).

5.1.3: Enhanced Enforcement Powers

The Meat (Enhanced Enforcement Powers) (England) Regulations 2000 amended the product-specific Regulations that apply to fresh meat, meat products, and minced meat/meat preparations, by introducing additional enforcement provisions for use by authorised officers in premises that have been approved for the handling of these products.

These powers are available to authorised officers in addition to their powers under the Food Safety Act 1990.

5.1.4: Suspension of Approval

It may be appropriate to recommend the suspension of an approval as a result of issues that have arisen suddenly. In these cases, little in the way of background or enforcement history may exist. In most cases however, the recommendation for suspension will arise from circumstances where an operator has been warned of breaches of regulations and where the situation has worsened, resulting in a serious risk to public health.

5.1.5: Change of Occupier

In the event of a change of occupier both the prospective and existing occupiers are required to notify the Food Authority at least 21 days before any transfer takes place.

A Food Authority that receives such a notification should review the conditions of the existing approval and the intentions of the new occupier and decide whether any change in the operation of the establishment would be likely to materially affect the

conditions of approval. If there is, the Food Authority should consider whether it would be appropriate to use their suspension powers.

The Food Authority should consider suspending an approval if the pre-notification requirement is not met. The Food Authority should also consider suspending an approval if there is a current breach of the appropriate regulations, or adequate health inspection is currently being hampered at the time any transfer takes place. In the event that there has been a breach of a notice served on the previous occupier, a new notice should be served on the new occupier.

A suspension must be lifted once the deficiency has been addressed.

5.1.6: Supervision and Enforcement

Authorised officers may seize fresh meat, meat products or minced meat/meat preparations that have not been handled, stored or transported in accordance with the appropriate regulations. These meat products or minced meat/meat preparations may be treated, for the purpose of Section 9 (Inspection and Seizure of Food) of the Food Safety Act 1990 as failing to comply with the food safety requirements and dealt with accordingly.

5.1.7: Powers of Authorised Officers

The Meat (Enhanced Enforcement Powers) (England) Regulations 2000 amended the Meat Products (Hygiene) Regulations 1994, and the Minced Meat and Meat Preparation (Hygiene) Regulations 1995 by introducing new provisions that enable authorised officers to serve a notice to:

- prohibit the use of any equipment or part of an approved meat products/minced meat and meat preparations premises;
- specify that the rate of an operation is reduced, or it is stopped, where the enforcing authority has reasonable grounds for doing so.

Instances where the service of such a notice would be appropriate are those that involve structural or maintenance hygiene deficiencies that require immediate action.

Individual notices should be served in the light of each alleged deficiency in individual rooms or areas in various parts of the premises. In some circumstances the effect may be to stop the entire operation of the premises.

Appropriate circumstances that may lead to the service of a notice would include:

- where a current breach of the appropriate regulations exists;
- when an adequate health inspection is being hampered.

Such a notice must be served as soon as practicable and state the contravention and necessary action to remedy the breach. Once the Food Authority is satisfied

that action has been undertaken to remedy the breach of the regulations, a further written notice must be issued, withdrawing the original notice.

Appeals must be made within the period of one month from notice of a decision. Operators now have only 21 days from service of the decision to confirm their decision to appeal. Wherever possible, Food Authorities should deal promptly with any proposal by an occupier where this would avoid the need for a formal appeal.

An improvement notice under the Food Safety Act 1990 may be more appropriate for structural or maintenance problems that do not require immediate attention and may therefore be rectified in the longer term.

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

Guidance relating to shellfish can be found in Annex 7.

CHAPTER 5.4: MATTERS RELATING TO FRESH MEAT

All relevant material relating to fresh meat is contained in the Code of Practice.

SECTION 6: SAMPLING

6.1.1: Procurement of Samples

The Act allows 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 under Section 14 of the Act is anticipated following microbiological examination the sampling officer should purchase the sample.

6.1.2: Certificate by Food Analyst or Examiner

A food analyst or examiner is required to analyse or examine samples as soon as practicable and 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.

6.1.3: 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).

6.1.4: Samples for Analysis

6.1.4.1: Quantity of Samples for Analysis

The nature and quantity of any sample should be such as to enable the required analysis to be made. The nature of the samples that are appropriate will depend on the purpose for which the analysis is being undertaken. The quantity will vary according to the product and type of analysis to be carried out. The Public Analyst should be consulted in case of doubt.

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

6.1.4.2: Containers for Samples for Analysis

Samples of food which are not pre-packed or opened cans or packets of food, 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.

6.1.4.3: Transport and Storage of Samples for Analysis¹⁶

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.

6.1.4.4: Samples which Present Difficulties in Dividing into Parts

An exception to division into three parts applies where the authorised officer is of the opinion that division of the sample is either not reasonably practicable, or is likely to impede proper analysis. Regulation 6(4) of the Food Safety (Sampling and Qualifications) Regulations 1990¹⁷ allows for the sample to be submitted for analysis complete without division into three parts. There is no final part for the seller/owner, neither is there a final part to be retained. This procedure must therefore be used with caution. Situations where this procedure may be used will depend on the tests to be carried out but may include the following:

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

¹⁶ The Campden and Chorleywood Food Research Association publication "Guidelines for the preservation of official samples for analysis" includes further guidance

¹⁷ SI 1990/2463

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 un-opened 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.

6.1.4.5: 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 6.1.5.2 of the Code of Practice is entitled, on request, to a copy of the certificate of analysis.

6.1.5: 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.

6.1.5.1: 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.

6.1.5.2: Handling of Samples for Examination

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. Appropriate action to avoid contamination of the sample and microbial growth or death during sampling, transport and storage should therefore be taken.

6.1.5.3: Containers for Samples for Examination

Samples for microbiological examination should be taken and handled in a manner that eliminates the risk of contamination during the sampling process. Sampling

officers should have regard to any advice provided by the Food Examiner on the need to observe aseptic sampling techniques. The owner of the food should be given the opportunity if present to observe the sampling procedure.

6.1.5.4: Transporting and Storing Samples for Examination

Samples should be transported and stored under conditions that inhibit changes in microbial numbers and be delivered to the laboratory without undue delay.

6.1.5.5: 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.

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
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
EEC	European Economic Community
EMIs	Egg Marketing Inspectors
EU	European Union
FLEP	Food Law Enforcement Practitioners
Framework Agreement	Framework Agreement on Local Authority Food Law Enforcement
HACCP	Hazard Analysis Critical Control Points
LA	Local Authority
LACORS	Local Authorities Co-ordinators of Regulatory Services
MRM	Mechanically Recovered Meat
NAWAD	National Assembly for Wales Agriculture Department
NHS	National Health Service
OFT	Office of Fair Trading
OPOAO	other products of animal origin
PHLS	Public Health Laboratory Service
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
SFIA	Sea Fish Industry Authority
SFPA	Scottish Fish Protection Agency
SFSORB	Scottish Food Safety Officers' Registration Board
Shellfish	The Food Safety (Fishery Products and Live Shellfish)

The Agency
UK
VMHA

(Hygiene) Regulations 1998 definition: only
bivalve molluscs, echinoderms, tunicates
and marine gastropods
The Food Standards Agency
United Kingdom
Veterinary Meat Hygiene Adviser

ANNEX 2: EGG PRODUCTS

A.2.1: Introduction

This Annex provides specific guidance to Food Authorities on the application and enforcement of the Egg Products Regulations 1993¹⁸ (the Regulations).

The Regulations, which apply in Great Britain, implement Council Directive 89/437/EEC, as amended by Council Directives 89/662/EEC and 91/684/EEC. These lay down the health rules for the production and placing on the market of egg products for human consumption, or for the use of egg products in the manufacture of other foodstuffs for human consumption.

A.2.2: 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.2.3: Scope of the Regulations

The Regulations only apply to premises defined as “egg products establishments”. Egg products establishments are premises that are involved in:

- processing and heat treatment of raw eggs following removal of the shell and outer membrane including the production of liquid egg which is not intended to be transported to another premises;
- producing or handling liquid egg for the purpose of sale for human consumption;
- premises where eggs are broken out and chilled or frozen for onward transportation to approved processing premises;
- breaking out eggs to be used as ingredients for food prepared on the same premises.

Egg products establishments are divided between those that require approval under the Regulations and those that do not.

The Regulations lay down structural and operating standards for premises that require approval under the Regulations, and specify which eggs may be used and the circumstances in which they may be used for the manufacture of egg products.

Schedules to the Regulations set out detailed requirements for heat treatment, testing and specifications of finished products, and provisions for storage, transport, packaging and marking of egg products.

¹⁸ SI1993/1520

Where the Regulations make no specific provision, other relevant regulations, for example the Food Safety (General Food Hygiene) Regulations 1995¹⁹ will apply to operations in egg products establishments.

A.2.4: Egg Product Establishments that do not Require Approval

Premises in which egg products are simply used as ingredients in the manufacture of other products do not require approval under the Regulations.

This means that businesses such as bakers and caterers that break out eggs for use on the premises as ingredients in other foods that are produced on the same premises do not require approval.

Such businesses may use egg products obtained from Grade A eggs (as provided for under Council Regulation 1907/90/EEC), or from the eggs of ducks, geese, turkeys, guinea fowl or quail.

Alternatively, the eggs (which must not be cracked but may be ungraded) must be broken out at the farm on which they have been produced.

These eggs, and the egg products produced from them, must still meet the hygienic handling and storage requirements set out in Regulation 3(4)(ii).

A.2.5: Egg Product Establishments that Require Approval

Although the requirements of the Regulations apply to any premises in which egg products are handled, only premises that are involved in the manufacture or heat treatment of egg products require approval.

Premises requiring approval fall into two categories:

- (i) premises where egg products are heat treated;
- (ii) premises where egg products are removed from the shell for transport to another approved premises where they will be heat treated.

In the case of (ii) above the following conditions apply to eggs:

- prior to breaking out, eggs must not be cracked (or broken) and the shells must be fully developed;
- the liquid egg must not be manufactured from “melange”;
- the liquid egg must not be produced by centrifuging;
- incubated eggs or pulled eggs must not be used.

A.2.6: Applications for Approval

A food business operator who applies for approval for an egg product establishment should do so in writing to the Food Authority.

¹⁹ as amended, SI 1995/1763

The application should include the name and address of the applicant, the name and address of the premises, and a description of the type(s) and quantity of egg product to be produced.

A.2.7: Approval Process

The Food Authority should arrange for an authorised officer to carry out an inspection of the premises as soon as practicable after receipt of an application, including an examination of equipment to be used for the treatment of egg products.

Regulation 5(6) requires Food Authorities to respond to an applicant with their decision on approval within 28 days of receipt of the application. The response should indicate the decision and, where approval has been denied, the reason(s).

The Food Authority must issue an approval if it is satisfied that there is compliance with the Regulations.

The Food Authority must allocate a unique identification reference known as the approval number to each approved establishment. This should consist of the local authority prefix²⁰ followed by a three-digit number.

Packing centres are only permitted to break out eggs and send their egg products to another approved establishment if they have also been approved as egg product establishments. Packing centres that have been approved as egg products establishments must be notified to the Food Standards Agency, with an indication that they are also packing centres.

A.2.8: Post-approval Changes

An approved egg product establishment that wishes to make significant changes to its structure or the operating conditions must notify the Food Authority in writing.

A Food Authority that receives such a notification should establish whether the proposed changes would result in the establishment operating outside of the requirements of the Regulations.

The Food Authority should arrange an inspection of the establishment on completion of such work to establish that the business is operating within the requirements of the Regulations.

If the changes require amendments to the conditions of approval, the Food Authority must notify the Food Standards Agency of the changes.

A.2.9: Records

Food Authorities should maintain auditable records of the approval of establishments and subsequent inspections. The documentation should be detailed enough to allow

²⁰ The LA prefix is the unique code allocated to each Food Authority by the Food Standards Agency that indicates the area in which approved establishments are located

the Food Authority to verify that an approved establishment is operating in accordance with the terms of the approval and the requirements of the Regulations.

A.2.10: Treatment of Cracked Eggs at Approved Egg Products Establishments

An approved egg products establishment may use cracked eggs, providing they are broken out and heat treated as quickly as possible.

A.2.11: Treatment of Cracked Eggs that are Broken out at Packing Centres

Egg packing centres that are also approved egg products establishments may prefer to break out eggs to produce unpasteurised egg products rather than risk breakage before they are sent to another approved establishment for heat treatment.

Packing centres may be approved for breaking out cracked eggs only, but such approvals must require that the eggs are broken out immediately and the resulting unpasteurised egg products frozen or chilled (Schedule 5 of the Regulations), and transported to another approved establishment and heat treated within 48 hours.

Regulation 7 provides that eggs used to produce unpasteurised or non-heat treated products must not have been placed in an incubator, must be fit for human consumption, must have fully developed shells, and contain no breaks (Schedule 1 (2) (a) of the Regulations).

A.2.12: Operating Standards

Dirty eggs

Dirty eggs must be cleaned before they are broken out. Cleaning should take place in a room that is separated from any area where breaking out takes place, and separate from any other room where egg products are exposed.

Washed eggs must be dry before they are processed. Schedule 1 (10) of the Regulations allows for eggs to be disinfected as necessary after unpacking.

Centrifuging or crushing

The Regulations prohibit the use of centrifuges or crushing to break out egg products for human consumption or in the preparation of food for human consumption.

Centrifuges may only be used for the disposal of waste, and in such cases, the centrifuge must be situated in a room that is outside the boundaries of the approved establishment.

Authorised officers should satisfy themselves that such a waste disposal system is completely separate from the approved establishment, and 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.2.13: Health Marking

Every consignment of egg product that leaves an approved establishment must be labelled legibly and indelibly with the relevant health mark in accordance with Schedule 10 of the Regulations.

The health mark must include the approval number of the establishment, the temperature at which the product is to be maintained, and the percentage of egg products if supplemented by other foodstuffs. Each individual package of a bulk consignment should be labelled with the health mark. Larger bulk containers, such as tankers must be either labelled, or have appropriate accompanying documentation.

A.2.14: Pasteurisation and Heat Treatment

The Regulations require whole egg or yolk that has been broken out to be pasteurised. They specify a time and temperature combination of not less than 64.4°C for a minimum of 2.5 minutes, but allow alternative time/temperature combinations to be used if they achieve the same degree of destruction of vegetative pathogenic organisms as the prescribed process. The occupier must satisfy the Food Authority that any proposed alternative process is at least equivalent to the one specified in the Regulations and achieves the necessary level of destruction of vegetative pathogenic organisms.

In the treatment of albumen alone, where heat treatment is required but not necessarily full pasteurisation, no time/temperature parameters are specified. Food Authorities will need to be satisfied that the heat treatment process of such products is sufficient to ensure a reduction in the level of micro-organisms in the egg product to the levels laid down in Schedule 4 of the Regulations. Where a non-standard process is proposed, the onus is on the occupier to show that adequate research has been carried out and that at least equivalence to the levels laid down in the Regulations can be achieved.

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.2.15: Use of Hypochlorinated Water in Approved Egg Product Establishments

Where hypochlorinated water is used in an egg product establishment the food business operator must ensure that its use is properly controlled and does not expose foods intended for human consumption to any risk of contamination.

A.2.16: Alpha-amylase Test

Although not included in the EC Egg Products Directive, the regulations contain a requirement (carried over from previous national Regulations) that at least one sample of each batch of whole egg or yolk pasteurised using the specified time/temperature combination should be tested using the alpha-amylase test. This is intended to determine whether the pasteurisation process has been effective. This

test has been retained in UK national legislation with the industry's agreement and with the agreement of the European Commission and other Member States. The UK is not permitted to bar imports from other Member States, or third countries, where the test is not required.

A.2.17: Microbiological Tests

The Regulations include a number of microbiological standards and require occupiers to take samples from batches of egg products. Schedule 4, Part I, lays down microbiological standards that each batch of egg products should comply with, as well as the prescribed methods for carrying out these tests.

In circumstances where unsatisfactory microbiological results have been obtained from samples taken at the establishment, the Food Authority should require the occupier to undertake an increased level of microbiological sampling for a specified period and to re-examine any food safety management system such as HACCP that may be in place.

A.2.18: Other Criteria

Schedule 4, Part VI of the Regulations requires batches (see definition below) of egg products to be tested for lactic acid, butyric acid and succinic acid. Although there are no prescribed EU methods for testing for lactic, butyric or succinic 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 in Schedule 4, Part VI of the Regulations.

A.2.19: Sampling Plans

Authorised officers may help occupiers develop sampling plans since these also are not prescribed in the Regulations.

“Batch” is defined by the Regulations as a quantity of egg products that has been prepared under the same conditions, and in particular, treated in a single continuous operation.

“Continuous operation” is not defined but may be regarded as the uninterrupted processing that takes place between each point when equipment is shut down, idling, or cleaned. Agreement between the occupier and the Food Authority as to what constitutes a ‘batch’ would be constructive in developing a sampling regime.

A.2.20: Temperature Control, Storage and Transport

The Regulations do not require all egg products to be temperature-controlled, but in practice, all except very short shelf-life products, or liquid egg or concentrated egg products that have been “stabilised” to keep at ambient temperatures, will require temperature control.

While in storage, temperatures should be recorded continuously, the cooling rate must be such that the product reaches the required temperature as quickly as

possible, and the containers must be stored in such a way that air can freely circulate around them.

Once egg products that require temperature control have been produced or manufactured they must be stored at temperatures not exceeding:

- -18°C if deep frozen (quick frozen foods);
- -12°C, if frozen (foods other than quick frozen foods);
- +4°C, if chilled.

Establishments must keep eggs and egg products separate. Separate rooms must be available where necessary to avoid contamination; otherwise egg products may be stored in separate containers and areas from eggs and other ingredients.

Storage rooms must be capable of maintaining any required temperature controls.

During transport, egg products must be adequately protected from cross-contamination and maintained at the required temperatures.

Containers and vehicles used for transport must be designed and equipped to ensure that these requirements can be met.

The Regulations do not cover egg products that are stored in depots or warehouses outside approved egg products establishments. Such storage is covered by the Food Safety (General Food Hygiene) Regulations 1995.

A.2.21: Movement of Unpasteurised/Non-Heat Treated Egg Products

The Regulations permit the movement of unpasteurised egg products between approved establishments. Unpasteurised egg products must be frozen or kept chilled in accordance with Schedule 5, prior to and during movement. Containers of unpasteurised egg products should be marked (in addition to the other marking requirements set out in Schedule 10) with the following:

- “non-pasteurised egg products”;
- date and time of breaking of eggs;
- “to be treated at X” (X = destination).

In accordance with Regulation 7(4) an establishment which receives chilled unpasteurised egg products should treat them as soon as possible after arrival. Treatment must be carried out, at the latest, within 48 hours following the day of breaking out of the eggs.

A.2.22: Egg Marketing

Egg packing centres, whether or not approved as egg products establishments under the Regulations, are the responsibility of DEFRA in respect of egg quality and marketing regulations and are inspected by Egg Marketing Inspectors (EMIs). EMIs need to satisfy themselves that the premises and technical equipment are kept clean and in good repair and free from extraneous odours.

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

A.2.23: Training of Food Handlers

It is the responsibility of egg product manufacturers to ensure that food handlers, engaged in the food business, are supervised and instructed, and/or trained in food hygiene matters commensurate with their work activities.

A.2.24: Medical Certificates

The Regulations require medical certificates to indicate there is no reason why staff should not be allowed to work with or handle eggs or egg products. Although not specified in the Regulations it would be considered appropriate that these certificates are obtained prior to employment and renewed following an illness that could compromise food safety. Medical certificates must be renewed annually.

ANNEX 3: FISHERY PRODUCTS

A.3.1: Introduction

This Annex provides specific guidance to Food Authorities on the application and enforcement of the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998 as amended (the Regulations). The Regulations implement Council Directives 91/492/EEC (as amended by Council Directive 97/61/EC), 91/493/EEC (as amended by Council Directive 95/71/EC), and 92/48/EEC, which lay down the health rules for the production and placing on the market of live bivalve molluscs, fish caught by fishing vessels, and fishery products intended for human consumption, and Council Directive 96/43/EC relating to the financing of hygiene inspections of fishery products.

Guidance on live shellfish is contained in Annex 7.

A.3.2: 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, and therefore approve fishery products establishments, register certain markets and fishing vessels, and otherwise enforce the Regulations.

A.3.3: Scope of Approval

The Regulations do not apply to retail premises that only supply direct to the final consumer, i.e. supply only individual consumers and caterers. Such premises are subject to the Food Safety (General Food Hygiene) Regulations 1995, and the Food Safety (Temperature Control) Regulations 1995.

Auction and wholesale markets where fishery products are only displayed for wholesale and where no preparation, processing or chilling takes place (except at the request of a final consumer, i.e. at the request of an individual consumer or caterer), are not regarded as establishments and do not require approval. Such markets do, however, need to be registered with the Food Authority in accordance with Regulation 25 of the Regulations in addition to any registration under the Food Premises (Registration) Regulations 1991.

A.3.4: The Local Market Exemption

A fisherman who catches a small amount (as defined in the Regulations) of fish in any year and sells it in the UK direct to a retailer or to a final consumer, i.e. an individual consumer or caterer, is exempt from the requirements of the Regulations in respect of that small quantity. Such activities are, however, covered by the general provisions of the Food Safety (General Food Hygiene) Regulations 1995, and the Food Safety (Temperature Control) Regulations 1995.

A.3.5: Factory Vessels, Fishing Vessels and Vessels Cooking Shrimps or Molluscs

Any factory vessel registered in the UK under the Seafood (Conservation) Act 1967, on which fishery products are packaged after undergoing any filleting, slicing, skinning, mincing, freezing or processing needs to be approved for that purpose under the Regulations.

Fishing vessels on which only freezing is carried out are not regarded as factory vessels and therefore are not subject to approval.

Fishing vessels on board which only freezing is carried out are not regarded in the same way as factory vessels for the purposes of this part of the Regulations and therefore are not subject to approval, but they do need to be registered with the competent authority of the country in which they intend to land fishery products, in accordance EU legislation (Council Directive 91/493/EEC as amended).

Fishing vessels on board which only shrimps or molluscs are processed by cooking are required by Regulation 21 to be registered with the Food Authority unless the processing is to be supplemented subsequently by further cooking. Regard should also be had to the guidance on the local market exemption in paragraph A.3.4. above.

Vessels that operate from a number of different ports should be approved by, or registered with, the Food Authority in whose area the vessel operates most frequently or, where this is not obvious, the port of registration under the Merchant Shipping Act 1995.

A.3.6: 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 or microbiological analyses.

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.3.7: Charges for Inspection

The first sale in Great Britain of relevant landed fishery products is regarded as a chargeable transaction. Where this occurs, the vendor shall include the amount of the general landings charge in the price that the purchaser is charged. These charges should be made at the rate of 1 Euro per tonne of directly landed fishery products for the first 50 tonnes and 0.5 Euro per tonne for all subsequent quantities. If the fish are graded for freshness or size or the first sale transactions are or were grouped together at an auction or wholesale market, the Food Authority may reduce the charge by 55%.

Where products enter a preparation or processing establishment the proprietor or operator of that establishment is required to pay a charge as a contribution in respect of expenditure incurred in carrying out the health contract and product checks laid down in Chapter V of Schedule II to the Regulations. The charge is payable at a rate of 1 Euro per tonne of fishery products entering the establishment, but does not apply to products returned to an establishment in an identical form to that in which they were when they left it. The Food Authority may reduce the charge by 55% where preparation or processing is carried out on the same site as the first sale, or in an establishment in which operating conditions and guarantees as to the establishments own checks are such that inspection staff requirements can be reduced.

Proprietors or operators of establishments, other than those in which fishery products are prepared or processed, where fishery products are only chilled, frozen, packaged or stored are required to pay a charge in accordance with Part II paragraph 14 of Schedule 4 to the Regulations. When such inspections are made the Food Authority should charge on the basis of the actual cost of the inspection.

A.3.8: Labelling and Packaging

Chapter VII of Schedule 3 to the Regulations includes requirements relating to the use of identification marks on fishery products, and Chapter VI includes a provision concerned with the safety of the packaging. These requirements are in addition to general food labelling requirements and those on materials and articles in contact with food.

A.3.9: Intra-Community Trade

Because the Directive applies throughout the Community there are no restrictions on intra-Community trade in fishery products, providing identification marks are properly applied and otherwise in order. Any checks carried out by Food Authorities, including sampling, must be non-discriminatory, i.e. the same checks and no greater frequency apply to products of other Member States as apply to products originating in the UK.

A.3.10: Imports from Third Countries

Imports of fishery products from establishments and freezer and factory vessels in third countries must meet equivalent standards of hygiene to those that apply in the EU. Only those third countries that meet equivalent standards are authorised to export fishery products to the EU under the terms of Commission Decision 97/296/EC as amended.

Details of countries and establishments that are approved for the export of fishery products to the EU can be found on the Commission's web site²¹.

A.3.11: Information on Standards to be Applied

Information explaining the requirements of the Regulations may be found in guidelines published by the Sea Fish Industry Authority (SFIA). These guidelines were drawn up with the help of various sections of the trade and representatives of LACORS, the Chartered Institute of Environmental Health (CIEH), the Royal Environmental Health Institute of Scotland (REHIS) and Government Departments. The guidelines contain recommendations designed to help the fish industry comply with the requirements of the Regulations and achieve high quality standards and good industry practice that go beyond the requirements of legislation.

Food Authorities may use the guidelines 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 SFIA guidelines that are directed towards the achievement of good industry practice and high quality standards.

²¹ <http://www.europa.eu.int>

ANNEX 4: MEAT PRODUCTS

A.4.1: Introduction

This Annex provides specific guidance for Food Authorities on the application and enforcement of the Meat Products (Hygiene) Regulations 1994²² as amended (the Regulations). It should be read in conjunction with the Code of Practice, in particular the sections on General Enforcement, Inspections, and Product-specific Regulations.

A.4.2: Competent Authority Roles and Responsibilities

The Food Standards Agency is the UK central competent authority with lead responsibility for these Regulations.

Responsibility for enforcement of the Regulations at local level is shared between Food Authorities and the Meat Hygiene Service, acting on behalf of the Food Standards Agency²³.

Regulation 19 prescribes the supervision and enforcement responsibilities as follows:

- Food Authorities are responsible for approvals, supervision and enforcement in all stand alone meat product premises, including cold stores, ambient stores and re-wrapping centres;
- the Food Standards Agency is responsible through its network of Veterinary Meat Hygiene Advisers (VMHAs) for the approval of combined meat products premises. Combined meat products premises share a common curtilage with, or fall within the same curtilage as, a licensed slaughterhouse, or is any licensed cold store which stores both unpackaged fresh meat and unpackaged meat products. Enforcement and supervision in combined meat products premises is undertaken by the Meat Hygiene Service on behalf of the Food Standards Agency;
- enforcement responsibility is shared in combined cutting and meat products plants where any of the cut fresh meat is despatched off-site rather than used exclusively as a raw material for the meat product. In this case, the cutting room and associated parts, together with any shared facilities, will be licensed by the Food Standards Agency as fresh meat premises and supervised and enforced by the Meat Hygiene Service. The premises will also require separate approval as meat products premises by the Food Authority, which would be responsible for supervision and enforcement of the meat products activities within the plant covered by the approval. This follows from the definition of “combined premises” which does not include co-located licensed cutting activities and meat products operations. Consequently, these activities must be treated separately for approval and enforcement purposes if carried out on the same site.

²² SI 1994/3082

²³ The Food Standards Act 1999 (Transitional and Consequential Provisions and Savings) (England and Wales) Regulations 2000 (SI 2000/656). These Regulations transferred functions previously held by the Minister for Agriculture, Fisheries and Food to the Food Standards Agency from 1 April 2000

In circumstances where approval and enforcement responsibilities are unclear, Food Authorities should liaise with the Meat Hygiene Service and the relevant VMHA in England. The liaison arrangements are those laid down in Paragraph 1.1.9 of the Code of Practice.

A.4.3: Scope of the Regulations

The Regulations implement Directive 77/99/EEC (as amended) on health problems affecting intra-Community trade in meat products. They lay down the structural, hygiene and supervision standards for the production, distribution, storage and marketing of meat products. The Regulations apply in any meat processing premises, ambient store, re-wrapping centre and cold store handling or storing meat products, except where such premises are exempt. The term 'handling' includes manufacturing, preparing, processing (including secondary processing, such as slicing), packaging, wrapping, re-wrapping or storing unpackaged meat products.

The Regulations also cover first stage processing of other products of animal origin (OPOAO) intended for human consumption and specify the requirements for the manufacture within meat products premises of prepared foods made from ingredients of animal origin not covered by the Regulations.

A.4.4: Exemptions

The Regulations do not apply to establishments handling or storing meat products exclusively for sale or supply from those establishments to the final consumer (Regulation 3). Further guidance on the interpretation of "final consumer" is provided below.

Ambient stores and cold stores which handle only packaged meat products are also exempt as the definitions of 'ambient store' and 'cold store' only refer to unpackaged meat products.

Premises exempted under Regulation 3 must satisfy the requirements of Regulation 3A. This means that meat products or OPOAO handled within exempt premises for the purpose of sale or preparation for sale must have been manufactured from raw materials which comply with the relevant meat hygiene regulations, and prepared and manufactured in accordance with the Meat Products (Hygiene) Regulations 1994. This requirement was inserted by the Meat (Enhanced Enforcement Powers) (England) Regulations 2000²⁴ (and the corresponding regulations in Scotland and Wales). The effect of this amendment is to enable enforcement action (including seizure) to be taken outside approved premises against any operator of exempt premises who is in possession of meat products or OPOAO that have not been handled in accordance with the requirements of Regulation 3A.

A.4.5: Definitions

²⁴ SI 2000/225

Definitions of terms used in the Regulations are found in Regulation 2. This section provides further guidance on the definitions of the main types of foods covered by the Regulations.

Meat Products

A meat product is prepared from or with meat, which has undergone treatment such that the cut surface no longer has the characteristics of fresh meat. Relevant treatments include heating, smoking, salting, marinating, curing, drying or a combination of these processes. Therefore meat products include cooked meats, cooked meat pies, pizza containing meat, sandwiches containing cooked meats, black pudding, haggis, meat which has been marinated and cured products such as bacon.

Meat products containing a “small percentage of meat” and meat products in “hermetically sealed containers” (see relevant definitions in Regulation 2) also fall within this general definition.

The production of fresh meat, meat preparations (for example, raw sausages and flash fried products which are not fully cooked), minced meat and mechanically recovered meat are not covered by these Regulations.

Meat Based Prepared Meals

Meat based prepared meals are meat products in which meat and other foodstuffs (for example, vegetables) have been packaged together to create a meal and which require refrigeration or freezing for preservation. Examples include roast meat dishes with vegetables, meat curry with rice, and traditional cottage pies (minced meat with potatoes).

The definition specifically excludes sandwiches and products made with pastry, pasta or dough (e.g. meat pies, cannelloni, ravioli or lasagne, which are meat products). Similarly meat products such as “honey roast hams” are not regarded as meat based prepared meals, since they are merely glazed with honey.

Prepared Food

Prepared foods, other than meat products, are foods for human consumption prepared from raw materials of animal origin not otherwise covered by the Regulations. This would include, for example, fish products, egg products and honey. The hygiene standards for production in meat products premises are set out in Regulation 14.

Other Products of Animal Origin (OPOAO)

Regulation 2 defines the products that fall within this category. The Regulations relate only to first stage processing of OPOAO derived from the slaughtering process and passed fit for human consumption. For example, the rendering of animal fats into melted fat is covered by the Regulations, but subsequent processing of the melted fat into margarine is not. However, the requirements applicable to meat

products apply if the OPOAO undergoes further stages of processing that turn it into a meat product. In the case of stomachs, bladders and intestines, the first stage of processing includes cleaning, salting or drying and/or heating.

A.4.6: Interpretation of “Final Consumer”

The Regulations exempt establishments that sell or supply all of the meat products they produce directly to the final consumer (Regulation 3). However, these establishments would come within the scope of the Regulations if they also supplied other premises, including any in their ownership, not covered by the ‘final consumer’ definition.

‘Final consumer’ is defined in Regulation 2 and in practice covers the sale or supply of meat products to:

- the final purchaser for his or her personal consumption. This is intended to include purchases made by one person for consumption by another, for example, purchases on behalf of a relative, friend or neighbour, or as a gift for someone else, provided the meat products are not intended for re-sale;
- catering premises where the meat products are for consumption on those premises. Caterers who may serve food at a location other than at their own premises, such as event caterers or ‘meals on wheels’ operators, should also be regarded as falling within the ‘final consumer’ definition;
- all outlets selling the meat products as ready-cooked take away items for consumption off the premises. This will include such sales through retail shops as well as premises commonly recognised as take away outlets. Meat products need not be ready cooked when supplied to the take away outlet, e.g. they could be frozen or part-baked, but they must be ready to eat when sold as a take away item.

Establishments selling or supplying meat products on this basis should be regarded as selling/supplying to the final consumer and therefore exempt from the Regulations. In order to qualify for this exemption, the meat products must be sold/supplied directly to the final consumer. Sale or supply through a third party, such as a central distribution depot, cold store or cash & carry, would not count as a sale to the final consumer and the production establishment would need to be approved. Regulation 3 also specifically exempts the transportation of meat products to the final consumer.

In the majority of cases, enforcement officers will be able to determine if a manufacturer is supplying meat products to a caterer or take away premises. However, it may be more difficult to establish whether a manufacturer is supplying meat products to a retail shop for sale as a ready-cooked take away item. Some retail outlets may sell a range of ready cooked meat products, although the distinction between those sold as take away food and those which are not, may not always be clear. One important distinction is that meat products which are sold on a take away basis are usually eaten immediately or shortly after purchase. A short shelf life may also be an indication that a product is intended for the take away

market, although Food Authorities should not automatically assume that this is so in every case.

The burden of proof is on the establishment wishing to benefit from this part of the take away exemption to convince the Food Authority that meat products are being supplied for sale as take away food within the general understanding of that term. The Food Authority should also carry out appropriate checks to verify the manufacturer's claims. This might include checking with the manufacturer's customers, or with other Food Authorities, that the meat products supplied are being sold on a take away basis. Enforcement officers should also have regard to other evidence, such as delivery notes, commercial documents relating to raw materials used in the meat products and invoices, in deciding whether the final consumer exemption can be applied. Where a Food Authority decides to check less than 100 per cent of production for verification purposes, the quantity of product checked should be based on objective criteria and the reasons recorded in the Food Authority's file for the individual premises.

The Agency recognises that this aspect of the 'final consumer' definition is the most difficult to apply in practice. However, it is not possible to provide definitive advice on what might qualify as a ready-cooked take away meat product in all circumstances. Food Authorities are therefore advised to take a common sense approach when deciding whether a meat product is being supplied for the purpose of sale as a ready-cooked take away food. They should have regard, in particular, to the nature of the product and typical patterns or habits of consumption for that product. Food Authorities may find it helpful to discuss borderline cases with other Food Authorities to help inform their decisions.

Clarification is also frequently sought from the Agency on the application of the take away exemption to sandwich producers supplying meat sandwiches for sale through retail outlets. The third bullet point of the 'final consumer' definition permits an exemption provided the meat products are:

- supplied from the premises at which they are produced directly to the take away or retail outlet;
- sold from the take away or retail outlet as ready-cooked take away meat products for consumption off those premises.

It is the Agency's view that a meat sandwich does fall within the general description of a ready-cooked meat product and that manufacturers supplying the whole of their meat sandwich production directly to outlets selling them on a take away basis are exempt from the Regulations. However, manufacturers supplying any part of their meat sandwich production indirectly to take away or retail outlets, e.g. via a distribution depot, would not be exempt and would need to be approved.

The sale of sandwiches and meat products from vending machines is treated as a sale to the final consumer (under the third bullet point of the definition of 'final consumer') and is therefore exempt from the Regulations. Premises that supply these products to the vending machine operator will not, however, be exempt from the Regulations. Premises used by the vending machine operator solely for the

purpose of storing the meat products prior to filling the vending machine will be exempt from the Regulations.

Any premises exempted from the Regulations in accordance with the 'final consumer' definition will remain subject to the Food Safety (General Food Hygiene) Regulations 1995.

Food Authorities should note that the definition of 'final consumer' in the national regulations only applies within the UK. Other EEA Member States may have interpreted 'final consumer' in a different way. Therefore, the final consumer exemption should not be applied to any establishment intending to produce meat products for trade with other EEA Member States. All such establishments must be approved and all consignments of meat products must bear the British EC health mark and be accompanied by the appropriate commercial documentation. This applies regardless of whether the meat products are intended for direct consignment to catering or take away outlets located in other EEA Member States.

A.4.7: Approvals - Introduction

Part II of the Regulations is concerned with the approval of meat products premises. This section summarises the approval requirements and process and should be read in conjunction with Section 5 of the Code of Practice.

Preliminary discussions between the approval authority and potential applicants can provide a useful opportunity to discuss the approval requirements and process, identify any information requirements and consider issues that may need to be addressed by the applicant before the Food Authority can issue an approval.

A.4.8: Approval Conditions

All premises coming within the scope of the Regulations must be approved. Applications for approval must be submitted in writing to the Food Authority or, in the case of combined premises, to the regional VMHA. A model application form, which Food Authorities may wish to issue to prospective applicants, is contained in Annex 8.

Regulation 4 sets out the approval requirements for meat products premises and the conditions which must be satisfied in relation to the four categories of meat products listed in Regulation 4(4)(a). The requirements and conditions for the approval of ambient stores, re-wrapping centres and cold stores are specified in Regulation 5. Certain specified requirements in the Schedules must be noted in the approval document. Premises involved only in blending/mixing meat products, such as dried or dehydrated pieces of meat, with other foodstuffs which are then wrapped or packaged, should generally be regarded as a re-wrapping centre and subject to approval under Regulation 5.

A.4.9: Documentation on the Establishment

In order fully to assess compliance with the approval conditions, the approval authority will need to have access to a range of information about the establishment

and processes. The assessment of documentation provided by the applicant is therefore a significant factor in the inspection/approval process. Guidance on the documentation that an applicant should provide is attached at Appendix B. The required documentation may be provided during the preliminary discussions with the potential applicant or submitted with the application form, as required by the approval authority. Where any necessary documentation has not been submitted with the application form, the Food Authority should establish with the applicant that the documentation will be available for examination during the pre-approval inspection. The sample application template includes a tick list of documents that should be submitted in connection with an application for approval.

A.4.10: Identification of Responsible Persons

The Meat (Enhanced Enforcement Powers) Regulations 2000 have introduced several amendments requiring the identification of responsible persons associated with approved establishments. The purpose of these amendments is to facilitate effective enforcement by ensuring those responsible for the establishment and compliance with the legal requirements are known to the Food Authority.

In accordance with Regulations 4(6A) and 5(5A), inserted by the Enhanced Enforcement Powers Regulations, applications for an approval must include the name and principal business address of each person who is a manager, director or controller of the premises for which approval is sought. These information requirements are reflected in the model application template.

Regulation 5A requires the occupier of approved premises to notify the approval authority of any changes in the identity or principal business address of the directors, managers or controller of the approved establishment and any change in the occupier of the premises. The Regulation sets time limits for notifying the Food Authority of any such changes.

A.4.11: Approval Inspection

On receipt of an application form the approval authority should contact the applicant as soon as possible to arrange for an inspection of the premises. In the case of combined premises, the pre-approval inspection will be carried out by the regional VMHA, who will advise the Food Standards Agency on whether an approval should be issued.

The approval authority should only issue an approval following a thorough inspection of the premises and if all of the relevant conditions are satisfied. Confirmation of approval should be issued in writing to the establishment. This should specify the meat products activities for which the establishment is approved and any other conditions agreed between the establishment and approval authority as required under the Regulations. A standard format for approval notifications for use by approval authorities is contained in Annex 8.

If the pre-approval inspection identifies that improvements are required before approval can be granted, the approval authority should discuss and agree with the applicant a programme of necessary works. The Food Authority should confirm this

in writing to the applicant detailing the requirements in the Regulations that must be satisfied, the work needed to comply with the requirements and a time scale for completion. The Food Authority should advise the applicant that failure to complete the improvements satisfactorily could result in the application being refused and/or legal action for any statutory contraventions. This section of the guidance should be read in conjunction with Paragraph 5.1.8 the Code of Practice.

A decision to refuse to grant an approval should also be confirmed in writing and set out the reasons for the refusal. A standard format for refusals is contained in Annex 8.

A.4.12: Approval Code

The approval authority must issue a unique approval code to each premises it approves under the Regulations. This should be specified in the approval letter. The approval code should be in one of the accepted formats currently in use in the UK for the approval of meat products premises. Examples of the accepted formats are shown in Appendix C. Meat products premises located on the same site and integrated with a fresh meat slaughterhouse or cutting establishment may, at the request of the operator, use their fresh meat licence number as an approval code for their meat products activities. In such cases, the VMHA will notify the Food Standards Agency of this so that the fresh meat licence number can be confirmed as the approval code in the approval letter.

A.4.13: Industrial and Non-industrial Meat Products Premises

The approval authority must classify meat products premises approved under Regulation 4 as either “industrial” or “non-industrial”. These categories are defined in Regulation 2. The classification, and any special hygiene directions (see below), should be specified in the approval letter. Non-industrial establishments are exempt from the requirements of Part 1 of Schedule 2 and from requirements to provide non-hand operated taps and changing rooms (where lockers are available). Non-industrial establishments may use secure places (such as a chill cabinet) rather than separate rooms for the storage of raw materials or finished products.

The definitions of ‘industrial’ and ‘non-industrial’ specify the limits of weekly production applicable to each category. Classification should be based on the average weekly figure derived from the total yearly output of finished meat products or foie gras, as appropriate. When classifying premises as non-industrial, the enforcement authority should make clear to the business the basis for the classification and that subsequent changes to the business may lead to re-classification as an “industrial” premises, with the attendant structural requirements.

The Regulations allow Food Authorities to require a lower level of production in accordance with a **special hygiene direction** without effecting the classification of the premises as industrial or non-industrial. The special hygiene direction may be used in exceptional cases where, in the professional judgement of the authorised officer, the nature of the product and the production process pose an unacceptable health risk. The occupier of premises may appeal under Regulation 7(1)(e) against a special hygiene direction. The nature of any special hygiene direction should be

specified in the approval letter. This is accommodated within the standard approval notification template.

Where premises are approved both for the manufacture of meat products and as a re-wrapping centre, the re-wrapping element of the business will not count towards the weekly throughput when determining whether the plant should be classified as industrial or non-industrial. This is because approval as a re-wrapping centre is given under Regulation 5 and is separate from the meat products approval, which is given under Regulation 4.

A.4.14: Other Relevant Factors

In addition to assessing compliance with the approval conditions, Food Authorities should seek to establish during the pre-approval inspection that the operator has satisfactory arrangements in place before production begins to ensure the establishment will operate at the required standard once operation commences. Particular emphasis should be placed on assessing the occupier's 'own checks' and traceability arrangements. These include HACCP-based food safety management systems, cleaning procedures, hygiene training, water quality testing procedures, record keeping, correct use of raw materials and effective control to ensure the correct use of health marking and commercial documentation. The Food Authority should be satisfied with the plans and procedures for these matters before approval is given. Further advice on these aspects is contained in Paragraphs A.4.18 to A.4.31. of this Annex.

A.4.15: Revocation/Suspension of Approvals and Appeals

Regulation 6 specifies the circumstances under which the approval authority may revoke an approval. In addition, Regulation 6A, inserted by the Meat (Enhanced Enforcement Powers) (England) Regulations 2000 (and the corresponding regulations in Scotland, Wales and Northern Ireland), allows the approval authority to suspend an approval and specifies the circumstances in which this power can be used. Regulation 6A(4) provides for the lifting of suspensions. The Meat (Enhanced Enforcement Powers) Regulations have also amended Regulation 7 to broaden the range of circumstances under which an aggrieved party can appeal against an adverse decision by the approval authority in relation to an existing approval or an approval application. Further general guidance on the handling of approvals, revocations and suspensions in product-specific establishments is contained in the Code of Practice. Standard formats for use by Food Authorities to revoke or suspend approvals are contained in Annex 8.

A.4.16: Information Required by the Food Standards Agency

The Food Standards Agency maintains a list of all approved meat products premises in accordance with the requirements of Directive 77/99/EEC. This list is published on the Food Standards Agency website and updated regularly. In order to ensure this list is kept up to date, Food Authorities are required to inform the Food Standards Agency in writing of all new approvals, revocations or suspensions at the time of issue. A notification template that may be used by Food Authorities to notify the Agency is included in Annex 8.

A.4.17: Administrative Issues

Food Authorities should maintain records on each approval application, including copies of documentation supplied by the applicant, and recording progress with the application. Properly structured records provide a history of the establishment, continuity for new officers, and facilitate effective monitoring and inspection of the establishment. It will also assist the Food Authority in demonstrating the efficacy of its own supervision and enforcement arrangements in the context of the Local Authority Framework Agreement and the observations of the EU Food & Veterinary Office. Further guidance on the content of Food Authority records is contained in Annex 8.

A.4.18: Conditions for Handling, Storing and Marketing Meat Products - Introduction

Regulations 8-12 set out the conditions for the handling, storage and marketing of meat products. In summary, these lay down the requirements, with reference to the relevant Schedules, for the manufacture, wrapping, health marking, storage and transport of meat products. Meat products must be manufactured only from eligible raw materials, wrapped, packaged or labelled as specified and bear the correct health mark. Consignments must be accompanied in transit by the correct commercial documentation, which identifies the consigning establishment. Meat products intended for consignment to another EEA State must satisfy specific conditions. Products that do not meet these conditions can only be marketed within the UK. Regulations 8 and 12 lay down conditions for meat products manufactured from meat subject to animal health restrictions.

A.4.19: Raw Materials

Regulation 8(1)(b) requires meat products to be manufactured from raw materials in accordance with Part III of Schedule 2. The general rule is that meat products intended for consignment to another EEA State must be manufactured from meat ingredients which come from establishments approved or licensed to full EC trade standard and bear the appropriate EC health mark. This includes meat ingredients from establishments in third countries producing to EC hygiene standards and approved by the European Commission to import product into the EU. Only the British EC health mark may be applied to meat products intended for trade with another EEA State.

Meat products, minced meat and meat preparations used in meat products bearing the British EC health mark must come from approved premises. An exception to this is that the use of packaged meat products, minced meat and meat preparations bearing the EC health mark obtained from unlicensed premises, such as a cold store handling only packaged meat or a distribution centre, is permitted for use in the production of EC-status meat products.

Meat products must remain on the national market if they are produced from meat ingredients which are either unmarked or bear the British national health mark. This marketing restriction also applies to meat products produced from meat imported from third countries under national UK rules and meat products made with a

combination of EC-health marked meat and nationally restricted meat. Meat products in this category must bear the British national health mark. They must not bear the British EC health mark.

According to Paragraph 1(3)(b) of Part III of Schedule 2 an approved establishment may use nationally restricted meat at the same time and in the same premises as meat bearing an EC health mark subject to written authorisation from the enforcement authority. This arrangement is in accordance with the transitional provisions in Regulation 18. Any meat products made using the nationally restricted meat must bear the British national health mark (or the Foot and Mouth Disease health mark as appropriate). The enforcement officer should request a written application from the establishment seeking permission to use nationally restricted meat. The application should specify the origin of the nationally restricted meat and how its separation from EC status meat ingredients and meat products will be achieved. Such authorisations should be time-limited and reviewed regularly by the enforcement authority.

A.4.20: Health Marking

All meat products manufactured or wrapped/re-wrapped in approved premises must carry a health mark (Regulation 10(3)). As indicated above, meat products intended for consignment to another EEA State must carry the British EC health mark. All other meat products must bear either the British national health mark or the round mark if the product has been manufactured from fresh meat of certain species slaughtered in Great Britain between 1 February 2001 and 23 January 2002 inclusive, i.e. during the outbreak of Foot and Mouth Disease that occurred at that time.

The health mark must be in one of the formats prescribed in Part VI of Schedule 2 and be applied in accordance with Paragraphs 4-10 of that Part. Further advice on these requirements is given in Paragraph A4.43. of this Annex, which contains guidance specific to the Schedules. Examples of the British EC and national health marks, and the round Foot and Mouth Disease mark, for meat products are given in Appendix C. This Appendix also gives examples of the acceptable fresh meat health marks that may be applied to meat products from establishments co-located or integrated with licensed fresh meat establishments, subject to agreement by the approval authority.

Guidance on the requirements for the control and correct application of the health mark in respect of the duties of the occupier under Regulation 13 is given in Paragraph A.4.43 of this Annex.

A.4.21: Commercial Documentation

The requirements for the use of commercial documentation are set out in Regulation 12 and Part VII of Schedule 2. Paragraph 4, Part VII of Schedule 2 requires that meat products from premises approved under the Regulations must be accompanied at the first stage of marketing by the commercial document (such as an invoice, consignment or delivery note) issued by the occupier and referred to in Regulation 12(1)(b). The commercial document must bear the official approval code of the meat

products premises of origin. The first stage of marketing will be the first time the product is consigned to another establishment after it has become a meat product, whether or not it is in its finished state.

For transport and marketing at all subsequent stages the meat products must be accompanied by a commercial document which bears the official approval code of the consigning establishment and which identifies the enforcement authority for that establishment. The approval code for the establishment will be sufficient to identify the enforcement authority where this is the Food Authority. However, the approval code will not be sufficient where the Meat Hygiene Service is the enforcement authority. In this case the official approval code of the consigning establishment and the name and business address of the relevant Meat Hygiene Service office responsible for enforcement in the establishment must be included on the commercial documents. A separate commercial document will be required each time a consignment is transferred to another establishment.

Apart from these minimum requirements, the format and content of commercial documents is not prescribed. However, as a matter of good practice and to take account of the possible expectations of official control authorities in other EEA States, it is strongly recommended that commercial documents should include the following additional information:

- a description of the product and quantity;
- the names and addresses of both the consigning establishment and the establishment of destination;
- the date of issue of the commercial document and a company reference number so that the consignment can be readily identified.

The Regulations require the commercial document to be a physical document. There is no provision in either the Directive or the Regulations for this to be an electronic document. This is because an electronic document is not always tamperproof. However, if a company can demonstrate to the satisfaction of the Food Authority that its records and electronic document system are tamperproof and allow full traceability of the product, then consideration may be given, for the national market only, to the acceptance of electronic documentation. Meat products that move from the area of one Food Authority to another may only be accompanied by electronic documentation if both Food Authorities agree.

Product that is traded with other Member States must comply fully with the requirements of the Directive and a physical commercial document provided at all times.

Establishments that receive consignments of meat products must, under Regulation 12(4), retain the commercial documents for at least one year after receipt and make them available for inspection at the request of the enforcement authority. In the case of products that cannot be stored at ambient temperature, the commercial document should be held for no less than 6 months after the expiry of the appropriate durability date of the product. Companies wishing to hold original commercial documents at a

central point (such as head office) rather than at receiving premises, may be allowed to do so, although such documents must continue to be available to the authorised officer in connection with Food Authority supervision and enforcement at the receiving premises.

A.4.22: Enforcement Issues

Compliance with the requirements of Part III of the Regulations enables establishments to demonstrate that the meat products they produce satisfy food safety requirements. In addition, effective traceability arrangements, based around correct health marking and use of commercial documents, will facilitate the identification and control of food hazards on the market, both in the UK and abroad.

Approval authorities should ensure that meat product premises have satisfactory traceability systems in place before granting approval. These systems should permit the reconciliation of all meat products produced against corresponding incoming raw materials. The establishment should retain all documentation relating to the type, quantity and origin of raw material received. The use of raw material should be recorded and linked to outgoing batches/consignments of finished meat products. Establishments should retain and file all commercial documents and any health and veterinary certificates associated with deliveries of raw materials as well as copies of outgoing commercial documents for the periods specified in the Regulations. Procedures at the establishment should ensure that health marks are destroyed when wrapping/packaging containing incoming raw material is opened.

Enforcement authorities should check that these arrangements are working satisfactorily during primary and intermediate hygiene inspections. These checks should include documentary checks and checks on the origin of raw materials found in use at the establishment at the time of inspection. In addition, enforcement authorities should consider carrying out unannounced 'spot checks' on traceability systems outside their programmed inspections. The enforcement authority should record the results of all checks and take appropriate action to rectify any deficiencies identified.

Establishments should also maintain up to date information on their suppliers and customers so that the enforcement authority can check their status. Supplier details should include the type of raw material usually supplied by them and the approval code or licence number of the supplying establishment. It should be possible to distinguish approved/licensed suppliers from non-approved/licensed suppliers. In the case of suppliers and customers with several plants, the details of each plant should be recorded. The establishment could be asked to inform the enforcement authority of any new sources of supply so that the status/eligibility of the new supplier and raw materials can be monitored.

The scope of enforcement authority checks should include checks with nationally based customers of the establishment to ensure nationally restricted meat products stay on the national market. This could include checking with the customer that information on deliveries received corresponds with information held by the consigning establishment.

A.4.23: Meat Disease Control Requirements

Regulation 8(2), (3) and (4), and section D of Part VIII of Schedule 2 were inserted by the Meat (Disease Control) (England) Regulations 2000²⁵. Similar regulations were introduced in Scotland, Wales and Northern Ireland. These amendments, which came into force in England on 16 August 2000, enact the disease control requirements in Directive 77/99/EEC in respect of meat used in the manufacture of meat products. They prohibit the use of the British EC health mark on meat products manufactured from over-stamped meat, i.e. mainly from animals or slaughterhouses subject to animal disease restrictions, unless the meat has undergone one of the forms of treatment specified in section D of Part VIII of Schedule 2. Such meat products must be prepared under veterinary supervision and must be accompanied by the health certificate specified in Schedule 4 which confirms the meat products have been treated in accordance with the Regulations. Meat products subject to such treatment must be protected from contamination or recontamination. The over-stamped meat must be stored and transported separately at all times from other meat.

Enforcement authorities should ensure that meat products establishments under their supervision notify them if they intend to use meat subject to animal disease restrictions so that appropriate arrangements can be made for veterinary supervision of production and marking.

A.4.24: Health Certification for Single Market Trade

Regulation 12(1)(c) requires health certification of meat products consigned to another Member State when the product:

- i. contains meat from a slaughterhouse in an area restricted under the Animal Health Act 1981;
- ii. contains meat such as boar (male swine) meat, the use of which is restricted and which has to be specifically marked under Regulation 13(2)(c) or (d) of the Fresh Meat (Hygiene and Inspection) Regulations 1995, i.e. meat from:
 - male pigs used for breeding;
 - cryptorchid and hermaphrodite pigs;
 - uncastrated male pigs with a carcass weight in excess of 80kg in which a pronounced boar taint has been detected;
- iii. is intended to be sent to another EEA State after transit through a third country, in which case the product must be conveyed in a sealed means of transport.

In the case of (i) above, for meat products containing meat from areas restricted as a result of a disease outbreak, certification will be issued by DEFRA veterinary staff in accordance with Directives 80/215/EEC and 77/99/EEC. These veterinary health

²⁵ SI 2000/2215

certificates may have to be annotated in accordance with Council Decisions and will be issued by a DEFRA veterinarian direct to the exporter.

For meat products containing meat in categories (ii) and (iii), on receipt of an application completed by the exporter, the local Animal Health Divisional Office of DEFRA will issue a serially numbered blank certificate to the relevant enforcement authority, together with a copy of the exporter's application form. The enforcement authority should transcribe relevant details from the application form on to the health certificate, arrange for it to be signed by an authorised officer and send the original certificate to the exporter. The enforcement authority should retain a copy of the completed health certificate on file and send a copy to the local Divisional Veterinary Officer at the Animal Health Divisional Office.

It is the responsibility of the exporter to apply for a health certificate. Application forms are available from the exporter's local Animal Health Divisional Office or from DEFRA Products Exports Section, Animal Health (AIT – International Trade Unit – Products), 1A Page Street, London SW1P 4PQ (email: productexports@defra.gsi.gov.uk).

Meat products in hermetically sealed containers which have undergone one of the treatments referred to in Paragraph B(a) of Part VIII of Schedule 2 do not require a health certificate.

A.4.25: Duties of the Occupier - Introduction

Regulation 13 requires the occupiers of premises to take all necessary measures to ensure the Regulations are complied with at all stages of production or re-wrapping of meat products and other products of animal origin, in line with specified 'own checks'. The pre-approval inspection should include an assessment to ensure the 'own checks' arrangements in place are satisfactory and will enable the occupier to meet the requirements of the Regulations. As the effective implementation of 'own checks' arrangements underpins food safety, the assessment of ongoing compliance with these arrangements should form an integral part of programmed inspections.

A.4.26: Food Safety Management Controls

The Regulations require establishments to operate documented food safety management controls, following certain HACCP principles. The critical points relevant to the food operations and the associated monitoring and control arrangements put in place by the occupier must be acceptable to the enforcement authority before approval is granted. In determining the acceptability of food safety management controls, authorities should focus on the significant food safety hazards in the applicant business, taking into account the nature and, where relevant, scale of the operation.

Enforcement authorities should pay particular attention during inspections to ensuring the food safety management system is being monitored and controlled effectively. The establishment should be able to demonstrate that appropriate corrective action is taken and the food safety management system reviewed when critical points are breached.

A.4.27: Sampling Requirements

In accordance with Schedule 1, Part II, Paragraph A1, as amended, the duties of the occupier must include checks on the frequency and method of cleaning and disinfection of equipment and instruments used for working on raw materials and products, and of premises infrastructure. These items must be kept in a satisfactory state of cleanliness and repair. Regulation 13(1)(c) includes a discretionary requirement for the taking of samples by the occupier to check the effectiveness of cleaning and disinfection. Whether or not such samples should be taken will depend on the extent to which they are necessary to ensure the effective monitoring of the food safety management system.

Although not specifically identified as an 'own check' in Regulation 13, enforcement authorities should also expect to see the sampling requirements for meat products in hermetically sealed containers reflected in the food safety management system in premises where such products are manufactured. The sampling requirements for these products are specified in Schedule 2, Part III, Section B of the Regulations.

Schedule 2, Part IV of the Regulations also permits enforcement authorities to take samples to assess the efficacy of checks carried out by the occupier in accordance with Regulation 13. The type and number of samples taken by the authority will depend on such factors as the nature and size of production and scope of the food safety management system in operation at the establishment.

Enforcement authorities should satisfy themselves that chemicals used in food production areas, especially chemicals that may come into contact with food through use on surfaces, and equipment used with food, are suitable for such purposes. Enforcement authorities should also satisfy themselves that the application and use of such chemicals is carried out properly and is adequately supervised. Authorities may wish to encourage occupiers to maintain an up to date list of chemicals used in the establishment and provide staff with instructions for their correct use. Checks on chemicals and their use should be an integral part of inspections.

A.4.28: Acceptability of Laboratories

The Regulations require that laboratory facilities provided, or used, by the establishment for analysing or examining samples taken by the occupier in accordance with the legal requirements are acceptable to the enforcement authority. The Regulations do not expressly require the use of accredited laboratories. However, an accredited laboratory has the advantage of being able to produce a certificate to that effect which in turn reduces the burden of assessment on the approval authority.

Laboratories may seek accreditation from a number of organisations, such as, the United Kingdom Accreditation Service (UKAS) (formerly NAMAS) or Lloyds Register Quality Assurance. This list is not exhaustive and implies no endorsement by the Food Standards Agency of the specific organisations mentioned in this paragraph.

In the case of an accredited laboratory, the approval authority should examine the original accreditation certificate and schedule which details the tests and methods which the laboratory is approved to carry out. The authority should also check:

- the identity of the accreditation body;
- with the accreditation body that the laboratory's certification is still valid;
- that the tests and methods undertaken by the laboratory on behalf of the establishment are, in fact, those specified in the schedule to the accreditation certificate.

Laboratories without formal accreditation may be acceptable, although the process to establish acceptability is likely to be more involved than for a non-accredited laboratory. In order to assess the acceptability of a non-accredited laboratory, an authority should satisfy itself that:

- the laboratory uses standard specified techniques, for example, a relevant British or international standard or a technique recognised as being appropriate;
- the techniques used are properly documented;
- sampling procedures are properly documented, including the location of sampling points, type of sample, collection of sample and delivery of sample to the laboratory. The documentation should also include a schedule of parameters for which tests are required and the methods to be used;
- the relevant laboratory staff are appropriately qualified and trained in the relevant techniques.

In order to determine the acceptability of a non-accredited laboratory, the enforcement authority may wish to consult the Public Analyst or Food Examiner (Public Health Laboratory Service) who can advise regarding the suitability of the methods used by a particular laboratory. Where this is deemed necessary, authorities are advised to obtain independent written certification from the Public Analyst or Food Examiner regarding the acceptability of such methods. This approach is also relevant to determining the acceptability of a test or method carried out by an accredited laboratory but for which the laboratory is not specifically accredited.

Where the enforcement authority is satisfied with the chosen laboratory, it should confirm this as part of the approval notification. As the laboratory arrangements must be acceptable to the enforcement authority on a continuing basis, the approval notification should indicate that any changes to these arrangements must be agreed in advance with the enforcement authority. The acceptability of the laboratory arrangements should be verified as part of the on-going enforcement inspection process.

A.4.29: Control and Correct Use of the Health Mark

This section of the guidance should be read in conjunction with Paragraphs A.4.20. and A.4.43. of this Annex (on Part VI of Schedule 2), which summarise the requirements for health marking of meat products.

Regulation 13(1)(e) places a duty the occupier to ensure that health marking is controlled and carried out properly. Part VI of Schedule 2 (supervision of production) places a responsibility on the enforcement authority to check that the occupier is satisfying these requirements. In order to meet these obligations, it is necessary for the system operated by the establishment to control and apply the health mark to be discussed and agreed with the enforcement authority.

Enforcement authorities should be satisfied that establishments have a system in place to ensure that access to health marking equipment and health marked material, such as labels, wrapping and packaging, is properly controlled. The arrangements for ordering health marked materials, and/or printing them on-site as appropriate, should be agreed. The establishment should designate specific staff to take responsibility for ordering/printing and issuing health marked materials and have a system in place for recording this.

The quantity of health marked materials ordered or printed should be reconcilable with the quantity of finished meat products produced. Records should also be able to account for any health marked material that may have been discarded as a result of damage. Establishments should also ensure that the relevant employees receive proper instruction in the correct application of the health mark and use of health marked wrapping/packaging etc.

Enforcement authorities should check during programmed inspections that establishments are maintaining satisfactory control over the health marking arrangements and take appropriate action to rectify deficiencies. These regular checks should be supplemented by occasional spot checks.

A.4.30: Imminent Health Risk

Regulations 13(1)(f) and (g) outline the duties of the occupier and the enforcement authority if an imminent health risk becomes evident in the production of meat products. The occupier is required to notify the Food Authority immediately if routine testing identifies a possible health risk. The Food Authority should determine the extent of any health risk and take appropriate action to protect public health. In the event of an imminent health risk, the occupier must withdraw from the market products obtained under technologically similar conditions and which are likely to present a similar risk. Withdrawn product must be held under the supervision and control of the enforcement authority until it is destroyed or re-used as permitted under Regulation 13(1)(g).

Authorised officers should have regard to the advice in the Code of Practice relating to inspection, detention and seizure of suspect food and the food alert arrangements when taking action under this Regulation. If subsequent investigations and/or samples prove to be satisfactory then it may be assumed that an "imminent health risk" does not exist and the products should not be withheld from sale on these grounds. The authorised officer should seek further expert guidance if in doubt about

the potential risk to the final consumer following notification of a laboratory examination which reveals a possible health risk.

A.4.31: Hygiene Training of Factory Staff

Regulation 13(2) requires the occupier to ensure that workers in the establishment are given appropriate instruction and training in hygiene matters appropriate to their responsibilities. The approval authority should examine the staff training programme, including records of any training received and copies of qualifications, as part of the pre-approval assessment. In determining whether staff training programmes are acceptable, approval authorities should note that attendance on formal training courses leading to a qualification is not an express legal requirement and will not always be necessary to satisfy the Regulations. For example, classroom-based courses culminating in a written exam may not be the most appropriate or effective way of addressing the training requirements of staff with particular language or literacy needs. The value of in-house and on-the-job training in this context should be considered alongside more traditional training approaches. However, it would be entirely reasonable to expect managerial, technical and supervisory staff responsible for developing, implementing and overseeing food safety management arrangements and other technical food safety matters to be appropriately qualified.

Assessment of staff training programmes should be a feature of the enforcement authority's ongoing inspection programme. The occupier should maintain up to date records of training received by staff, including any refresher or update training and copies of any qualifications. These should be available for inspection when requested by the enforcement authority.

A.4.32: Miscellaneous Provisions

A.4.33: Prepared Food

The manufacture of prepared food obtained from raw materials of animal origin on approved meat products premises must be carried out in compliance with the requirements of Regulation 14. The production of prepared foods must be checked in accordance with the duties of the occupier under Regulation 13.

A.4.34: Other Products of Animal Origin (OPOAO)

The requirements for the production, sale and transportation of OPOAO are specified in Regulations 15-17 and in the relevant parts of Schedules 1, 2 and 5. The types of products covered by the definition of OPOAO are described in Paragraph A.4.5. of this Annex.

Currently, stand alone premises manufacturing only OPOAO do not require approval although they must register with the appropriate local Food Authority under the Food Premises (Registration) Regulations 1991.

N.B. However, in order to complete transposition of Article 11(1) of Directive 77/99/EEC, the Food Standards Agency will shortly be introducing amendment

regulations requiring standalone OPOAO premises to be authorised by the approval authority in addition to being registered. This amendment will address one of the findings in the report of the Food and Veterinary Mission to the UK in January 2001 to evaluate the operation of official controls over meat products, minced meat and meat preparations.

Stand alone premises manufacturing only OPOAO and satisfying the requirements of the Regulations should be issued with a unique premises identification code by the appropriate Food Authority. This code should appear on commercial documents accompanying OPOAO consignments (Regulation 17(1)), including consignments despatched to other EC Member States. There is no prohibition on EC trade in OPOAO produced in accordance with the Regulations. However, in order to facilitate trade with other EC Member States, it is recommended that the premises code is reproduced on the commercial document in the style of the meat products health mark.

Where OPOAO are produced in a slaughterhouse, such as the initial treating of casings, the fresh meat licence number should double as the OPOAO premises identification code. The approval number will fulfil the same function for OPOAO produced in approved meat products premises.

Commercial documents must be kept for at least one year by any establishment receiving a consignment of OPOAO (Regulation 17(2)). The same principles which apply to commercial documents relating to meat products, described above, also apply to commercial documents associated with consignments of OPOAO.

The Regulations do not require the health marking of OPOAO or foodstuffs containing them, such as powdered soups or bakery products made from melted animal fats (e.g. lard).

A.4.35: Meat Products and OPOAO from Northern Ireland, the Isle of Man and the Channel Islands

Regulation 23 requires that meat products and OPOAO from Northern Ireland, the Isle of Man or the Channel Islands must have been handled or stored in establishments there which comply with conditions equivalent to those in the Meat Products (Hygiene) Regulations 1994, as amended. Such meat products must be health marked in accordance with the Regulations.

Guidance on the Schedules

A.4.36: Schedule 1: General Conditions

A.4.37: Part I – General Conditions for Approval of Establishments

Store Rooms for Raw Materials and Products

Paragraph 3 requires 'a sufficiently powerful refrigeration plant' to keep chilled or frozen raw materials and meat products at the temperature indicated on the packaging (i.e. in accordance with Regulation 11). There is no specific requirement

for automatic temperature recording equipment, or for any temperature measuring equipment to be provided. However, where storage temperatures are regarded as a critical point under Regulation 13(1)(a), the enforcement authority should be satisfied that the occupier's arrangements ensure the critical point is effectively monitored and controlled, and that appropriate records are kept in accordance with Regulation 13(1)(d).

The use of wooden walls in chilling, refrigeration, freezing and deep-freezing rooms, is allowed provided the rooms were built before 1 January 1983. Whilst the use of wooden walls is permitted in these circumstances, such wood should be treated and kept in a good state of repair so as not to create an unacceptable hygiene risk.

Pest Proofing

Pest control measures required under Paragraph 5 should be proportionate to the size of the establishment and the scale and nature of the food operations. Premises should be pest-proofed and have a pest control programme. There should be evidence of periodic checks by the occupier to verify these arrangements are working effectively.

Cleaning & Disinfection of Equipment and Utensils

Paragraph 8 as amended by the Meat Products (Hygiene) (Amendment) Regulations 1999²⁶ permits an alternative method for disinfecting equipment and utensils, other than by water of a temperature of not less than 82°C. Any alternative method permitted by the approval authority must be specified in the approval document issued to the establishment and have an equivalent effect to disinfecting in water at a temperature of not less than 82°C. The onus is on the business to demonstrate to the approval authority that any alternative method achieves the same effect.

Changing Rooms and Hand-washing Facilities

Non-industrial establishments are exempt from the requirement in Paragraph 11 for changing rooms if lockers are provided instead, and from the requirement for non-hand operated taps.

Lockable Rooms/Devices for Enforcement Officers

Paragraph 12 as amended by the 1999 amendment Regulations clarifies that a lockable device big enough for the storage of equipment and materials will be sufficient for less frequent enforcement attendance. The establishment is still required to make an adequately equipped, lockable room available for the exclusive use of the enforcement authority if the enforcement presence is frequent or permanent. While the level of frequency is not defined in the Regulations, attendance of an enforcement officer on average, more than once a week, might be considered as "frequent".

Cleaning & Disinfection of Means of Transport

²⁶ SI 1999/683

Paragraph 15 as amended by the 1999 amendment Regulations requires that the enforcement authority must agree to the use of facilities for cleaning and disinfecting means of transport, which are not situated in the establishment. Before giving such agreement, the authority should be satisfied that these facilities achieve an acceptable standard of hygiene. The onus is on the occupier to demonstrate that any such external facilities would achieve acceptable hygiene standards.

Drainage Requirements

Paragraph 16, as inserted by the 1999 amendment Regulations, permits derogations from the requirements to lay flooring to facilitate drainage, the provision of equipment to remove water, and taps in parts of the establishment where water is not used as part of the manufacturing process. However, these facilities must be provided in other parts of the premises, where required.

A.4.38: Part II – General Conditions of Hygiene

A – General conditions of hygiene applicable to establishments, equipment and tools

Part A.1 – Cleaning & Disinfecting (Duties of the Occupier)

The frequency and means of disinfecting establishments, equipment and tools, as inserted by the 1999 amendment Regulations, are discussed in Paragraph A.4.27. of this Annex in the context of the duties of the occupier.

Part A.2 – Animals and Pests

The prohibition on animals entering rooms during working hours is intended to allow guard dogs to enter premises for security purposes at times when work is not taking place. Where it is necessary for guard dogs to enter work areas, thorough cleaning and disinfection should be carried out prior to commencement of food preparation. The requirements for pest control should be read with the requirements in Paragraph 5 of Part 1 of Schedule 1, as outlined above.

Detergents, disinfectants and similar substances

Paragraph 5, as amended by the 1999 amendment Regulations, requires detergents, disinfectants and similar substances to be used in accordance with manufacturers' instructions so as to avoid any adverse effect on machinery, equipment, raw materials and products. There is no longer an explicit requirement for these materials to be acceptable to the enforcement authority, although the authority should satisfy itself that such materials are being applied and stored correctly. The 1999 amendment Regulations deleted the requirement for a cupboard to hold cleaning materials in favour of a "facility".

B – General conditions of hygiene applicable to staff

The requirements for staff hygiene are set out in Schedule 1, Part IIB of the Regulations. Paragraph 1 relates to personal hygiene. Paragraph 2 requires the

occupier to take measures to prevent persons liable to contaminate raw materials and products from handling them. New staff must demonstrate, by way of a medical certificate, that they have no medical impediment to working on or handling raw materials or meat products.

These requirements imply that establishments should have a policy for the health supervision of staff. This should include arrangements for staff to notify management:

- if they know or suspect they are suffering from, or that they are a carrier of, a disease likely to be transmitted through food;
- if they are afflicted with a skin wound, a skin infection, sores, diarrhoea or with any analogous medical condition;
- when they return to work after a period of illness.

Enforcement officers should refer for guidance to the publication “Food Handlers - Fitness to Work”²⁷.

A.4.39: Schedule 2 – Special Conditions

A.4.40: Part II – Special Conditions of Hygiene for Premises Preparing Meat Products

Containers in Direct Contact with the Ground

Paragraph 2 prohibits raw materials, ingredients, meat products, OPOAO and their containers from making direct contact with the ground. This does not preclude indirect contact through wheels or sheeting, providing such items are maintained in a hygienic state and do not pose a risk of contaminating the foodstuffs they hold.

A.4.41: Part III – Requirements for Raw Materials to be Used for the Manufacture of Meat Products

Guidance on raw material requirements is contained Paragraph A.4.19. of this Annex.

Products of Animal Origin

Paragraph 4, as inserted by the 1999 amendment Regulations, requires products of animal origin, other than meat, used in meat products to come from establishments that comply with the requirements of the relevant hygiene regulations.

A.4.42: Part V – Wrapping, Packaging & Labelling

Hygiene Requirements

²⁷ Food Handlers – Fitness to Work: Guidance for Food Businesses, Enforcement Officers and Health Professionals, Department of Health, 1995

Paragraphs 1-4 specify the hygiene requirements for the wrapping, packaging and labelling of meat products. These activities must take place under satisfactory hygiene conditions. Care should be taken to avoid contaminating foodstuffs where meat products are manufactured and wrapped/packaged in the same room. Enforcement authorities should be satisfied that wrapping/packaging materials are handled in a hygienic manner and that the wrapping and packaging materials comply with the Materials and Articles in Contact with Food Regulations 1987²⁸, as amended, and the Plastics Materials and Articles in Contact with Food Regulations 1998²⁹.

Where traditional practice involves transporting unwrapped meat products, e.g. unwrapped meat pies placed in re-usable plastic trays, the plastic trays can be considered as the packaging. Unwrapped products placed in open trays, which are then stacked, should have some form of cover/sheet placed on the top tray of the stack to protect the products during transit.

Labelling of Meat Products not Intended for the Final Consumer

This guidance reflects the requirements of Paragraph 6 as amended by the 1999 amendment Regulations.

The preparation date of meat products not intended for the final consumer must be visibly and legibly displayed on or with the packaging. Alternatively, establishments may apply a code (such as a batch number) to the packaging. Where a code is used, it must be possible for the customer (i.e. not the final consumer) and enforcement authority to relate the code to the date of preparation. If the date of preparation is used this should be the date that the product becomes ready to leave the establishment. These requirements will further assist traceability of meat products in addition to the health marking and commercial documentation measures.

The 1999 amendment Regulations permit information relating to the date of preparation to be “with” the packaging instead of appearing on the packaging itself. Acceptable examples of this arrangement would include recording details of the preparation date or a code on the commercial document or bulk storage carton, if there is one. Other arrangements may be acceptable and should be considered on their merits.

Enforcement authorities should note that this flexibility applies only to meat products for the national market. The date of preparation of the product, or the code, must be visibly and legibly displayed on the packaging in all other cases. Consignments displaying the code or date “with the packaging” rather than on the packaging itself are vulnerable to challenge by official control authorities in other Member States.

A.4.43: Part VI – Health Mark

Descriptions of Health Mark

²⁸ As amended, SI 1987/1523

²⁹ SI 1998/1376

Paragraphs 1 to 3 describe the required formats to be used for the British EC and national health marks. Examples of the acceptable formats are contained in Appendix C.

Meat products made from fresh meat of certain species of animals slaughtered in Great Britain in the period 1 February 2001 to 23 January 2002 must bear the round mark as described in Paragraph 3A³⁰. The round health mark need not be applied if the meat product has been treated in accordance with Article 4(1) of Council Directive 80/215/EEC, or subjected uniformly throughout to a pH value of less than 6, in which case the British EC or national health mark may be applied as appropriate.

The requirement to use the round mark does not apply to meat products made from fresh meat deemed eligible for intra-Community trade in accordance with Commission Decisions 2001/172/EC, 2001/356/EC and 2001/740/EC.

Enquiries regarding Foot and Mouth restrictions applicable to intra-Community and third country trade in meat products from the UK should be addressed to DEFRA.

Application of the Health Mark

The remaining Paragraphs of Part VI, as amended by the 1999 amendment Regulations, specify the requirements for applying the health mark to meat products, including to the wrapping, packaging and labelling. All meat products must be health marked either on the product itself or the wrapping/package. Flexibility is permitted for the marking of individual meat products in specific circumstances (Paragraph 6, as amended by the 1999 amendment Regulations).

The main requirements are (Paragraphs 4, 5 and 7):

- health marking must be carried out during or immediately after manufacture or wrapping, as appropriate;
- meat products must bear the health mark in an easily visible place: the mark must be legible, indelible and easy to distinguish;
- the mark may be applied directly to the meat product (Paragraph 7) or, if individually wrapped, to the wrapping or a label affixed to the wrapping;
- where health marked meat products are subsequently placed in packaging, the mark must also be applied to the packaging, unless the meat product is individually wrapped and packaged, in which case the mark need only be applied to the packaging;
- the health mark may be pre-printed on wrapping, packaging or labels used with meat products;

³⁰ Inserted by the Foot and Mouth Disease (Marking of Meat, Meat Preparations and Meat Products) Regulations 2002 (SI 2002/118)

- if applied to the wrapping, the health mark must be applied in such a way that either the health mark or the wrapping to which it is affixed is destroyed on opening the wrapping. It should not be possible to reuse such wrapping. The requirement to destroy the health mark on opening does not include health marked cardboard sleeves which enclose meat products in sealed trays as they are regarded as labels and not part of the wrapping.

Where the health mark is applied directly to the product in accordance with Paragraph 7, the method of application must be specified in the approval document issued by the approval authority. It follows that the method of application must be acceptable to the approval authority. The health mark must conform to the rules of visibility, legibility etc, and the method of application should not compromise the safety of the product.

This requirement came into effect on 31 March 1999 as a result of the 1999 amendment Regulations. Guidance issued by Government in 1999 to accompany those Regulations advised authorities to issue revised approval documents to establishments that were applying the health mark directly to meat products in an acceptable fashion before the new legal requirement had come into force. Authorities were advised to issue revised approval documents at the next routine inspection following the introduction of the 1999 amendment Regulations. It is expected that all authorities will, by now, have reissued such revised approval documents where necessary. Where this is not the case, authorities should issue revised approval documents immediately after the next programmed inspection.

Health Marking of Individual Meat Products

Paragraph 6, as amended by the 1999 amendment Regulations, specifies the circumstances in which the health marking of individual meat products is not required. These circumstances are where meat products:

- are wrapped and packaged individually and the health mark is applied to the packaging;
- are contained in a sales unit and the health mark is applied to the external surface of that unit. There is no definition of a 'sales unit' and enforcement officers should use professional judgement in deciding what a 'sales unit' might reasonably be in individual situations. Meat products packaged in containers with a removable outer cardboard sleeve may come within this category. This is because the outer cardboard sleeve cannot be treated as a printed label affixed to the wrapping. The fact that the outer sleeve is removable means that it is not affixed to the wrapping. The health mark may, in these cases, be applied to the outer sleeve;
- form a consignment intended for further processing or wrapping in an approved establishment, provided the health mark of the consigning establishment appears on the external surface of the consignment together with a clear indication of the intended destination. The recipient establishment must keep a record of the

quantities, type and origin of meat products received in accordance with this paragraph for the period laid down in Regulation 13(1)(d);

- are not wrapped or packaged but are sold in bulk by the manufacturer directly to a retailer and the manufacturer's health mark is applied to the container carrying them. The manufacturer must maintain a record for the period laid down in Regulation 13(1)(d) of the quantities and type of the meat products consigned together with the name of the recipient.

Meat Products Containing Other Foodstuffs

Paragraph 9, as inserted by the 1999 amendment Regulations, stipulates that only one health mark should be applied to meat products which contain other foodstuffs of animal origin, such as fishery products, dairy products or egg products. It is no longer necessary to include the various suffixes - PFEM - in the approval code to denote the type of animal origin content in the product. Establishments should therefore use a single approval code, regardless of the range of products of animal origin they produce. This is without prejudice to any agreement permitting a meat products establishment co-located or integrated with a licensed fresh meat plant to use the fresh meat licence number as the approval code for meat products.

Other animal origin foodstuffs brought in for use as ingredients in meat products must come from approved establishments in accordance with Paragraph 4, Part III of Schedule 2 (raw materials).

Establishments that produce meat products and other foodstuffs of animal origin on-site require separate approval under the relevant product-specific regulations.

Hermetically Sealed Containers

Paragraph 10, as inserted by the 1999 amendment Regulations, requires the health mark for products in hermetically sealed containers (e.g. bottles, jars and cans), to be applied indelibly to the container itself. The health mark must conform to the general requirements for visibility, legibility etc. Acceptable forms of application include pressing, embossing or moulding the health mark into the container or the lid. The health mark could also be printed directly onto the container or lid provided it satisfied the requirement for indelibility. The health mark must not be applied to, or obscured by, any label on the container.

A.4.44: Part VII – Storage & Transport

Storage of Meat Products

Paragraph 1, as amended by the 1999 amendment Regulations, permits additional options for the storage of meat products. It is now acceptable to store chilled/frozen meat products in an approved cold store as an alternative to specified rooms at the manufacturing establishment. Meat products suitable for storage at ambient temperatures may be stored in another suitable storage area provided it is of solid construction, is easy to clean and disinfect, and is approved by the enforcement authority.

These alternative arrangements do not include any specific requirement for automatic temperature recording or measuring equipment to be provided in rooms storing chilled/frozen meat products. However, where storage temperatures are regarded as a critical point under Regulation 13(1)(a), the enforcement authority should be satisfied that the occupier's arrangements ensure the critical point is effectively monitored and controlled, and that appropriate records are kept in accordance with Regulation 13(1)(d).

Commercial Documentation

Guidance on commercial documentation is contained in Paragraph A.4.21. of this Annex.

A.4.45: Part VIII – Special Conditions for Pasteurised or Sterilised Meat Products in Cans and Other Hermetically Sealed Containers

Paragraph A2(c) - Calibration of Thermometers

The requirement for thermometers of heating equipment to be checked against calibrated thermometers should be regarded as a method for monitoring critical points, under Regulation 13(1)(b), relevant to the manufacture of meat products in cans or other hermetically sealed containers. Enforcement authorities should satisfy themselves that the occupier is checking the accuracy and reliability of such instruments at appropriate frequencies in accordance with the establishment's food safety management system.

Section B – Occupier Checks by Sampling

This Section of the Regulations has been slightly revised by the 1999 amendment Regulations. It specifies the process checks and sampling that the occupier must undertake in respect of meat products in hermetically sealed containers, and the frequency of those checks and samples. This section also specifies certain record keeping requirements. Any of these checks/samples that are regarded as critical to the safety of meat products in hermetically sealed containers must be reflected in the establishment's documented food safety management system.

Section D – Meat Disease Control Requirements

Section D of this part of the Regulations, as inserted by the Meat (Disease Control) (England) Regulations 2000, specifies the treatments to be applied to meat products manufactured from over-stamped meat in order to render them eligible for intra-Community trade. Section D should be read in conjunction with Regulation 8(2) and Paragraph A.4.23 of this Annex.

A.4.46: Part IX – Special Conditions for Meat-Based Prepared Meals

Cooling Cooked Meat Products Prior to Mixing

The requirements in Paragraph 2(a) for the cooling of cooked meat products used in prepared meat-based meals have been amended twice. The current requirements are those laid down in the Meat Products (Hygiene) (Amendment) (England) Regulations 2000³¹, which amended Paragraph 2(a). Similar regulations have been introduced in Scotland, Wales and Northern Ireland.

Paragraph 2(a) permits three alternative methods for cooling cooked meat products for use in prepared meat-based meals:

- sub-paragraph 2(a)(i) requires the cooked meat product to be mixed with the other ingredients in the prepared meal as soon as practically possible after cooking. However, the time during which the temperature of the meat product (not the resulting mixture) is between 60°C and 10°C must not exceed two hours. This time/temperature combination should be reflected in the establishment's food safety management system as a critical point for the purposes of Regulation 13(1)(b) and should be monitored and controlled accordingly;
- sub-paragraph 2(a)(ii) requires the cooked meat product to be cooled by refrigeration to 10°C or less before it is mixed with the other ingredients;
- sub-paragraph 2(a)(iii) requires all other methods of cooling (apart from those specified in the other two options) to be specified in the approval document for the establishment. The approval document should specify the relevant meat-based prepared meals for which alternative methods of cooling meat products are approved. The use of alternative cooling methods not specified in the approval document would amount to a breach of the approval conditions applicable to the establishment.

The onus is on the establishment to demonstrate to the satisfaction of the approval authority that their alternative method of cooling meat products for use in meat-based prepared meals ensures the safety of the product. Time/temperature combinations for alternative cooling should be reflected in the establishment's food safety management system as a critical point for the purposes of Regulation 13(1)(b) and should be monitored and controlled accordingly.

A.4.47: Schedule 3 – Storing, Re-wrapping and Assembly of Meat Products

A.4.48: Part II – Requirements for Re-wrapping Centres

General Requirements

Paragraphs 1(a) and (b) specify the requirements for the approval of re-wrapping centres. The use of the term “appropriate” in this context relates to what is necessary to ensure the safety of the meat products handled in re-wrapping centres. Approval authorities should decide on a case by case basis which of the approval conditions are appropriate in specific circumstances. In doing so, they should use professional judgement, based on a risk assessment of the meat products operations to be carried out in the re-wrapping centre.

³¹ SI 2000/790

Health Marking

Paragraph 2 specifies the health marking requirements for meat products in re-wrapping centres. Health marking should conform to the requirements in Part VI of the Schedule.

A.4.49: Part III – Requirements for Cold Stores

Paragraph 1 specifies the requirements relevant to the approval of cold stores. Approval authorities should observe the same principles in determining what is appropriate as those outlined above for re-wrapping centres.

The requirement in Paragraph 2(c) for cold stores to have recording thermometers or recording telethermometers implies that automatic temperature recording equipment should be provided rather than manual measuring equipment.

A.4.50: Schedule 5 - OPOAO

A.4.51: Part II – Special Conditions for Rendered Animal Fats, Greaves and By-Products

The 1999 amendment Regulations introduced a number of typographical corrections into Part IIA. The amendment Regulations also revised the table in Paragraph 10 of Part IIB to include under 'Pigs' a new section for 'Lard and other pork fat for refining' with appropriate FFA and Maximum Peroxide limits.

A.4.52: Part III – Special Conditions for Stomachs, Bladders and Intestines

The 1999 amendment Regulations substituted Part III with a revised text. Much of the original text has been retained with minor adjustments and some renumbering.

The previous Paragraph 1, regarding premises and equipment for use with OPOAO, has been replaced with a requirement that raw materials shall come from animals judged suitable for human consumption following ante-mortem and post-mortem checks.

Paragraph 2, previously Paragraph 5, is essentially the same except that products which cannot be kept at ambient temperature before dispatch must now be held at a temperature of less than 3°C. This compares with the deleted requirement for such products to be held at a temperature not exceeding 3°C.

A.4.53: APPENDIX A - MEAT PRODUCTS HYGIENE STATUTORY INSTRUMENTS

The Meat Products (Hygiene) Regulations 1994 (SI 1994 No. 3082)

The Meat Products (Hygiene) (Amendment) Regulations 1999 (SI 1999 No. 683)

The Meat Products (Hygiene) (Amendment) (England) Regulations 2000 (SI 2000 No. 790)

The Meat (Enhanced Enforcement Powers) (England) Regulations 2000 (SI 2000 No. 225)

The Meat (Disease Control) (England) Regulations 2000 (SI 2000 No. 2215)

The Foot and Mouth Disease (Marking of Meat, Meat Preparations and Meat Products) Regulations 2002 (SI 2002 No. 118)

A.4.54: APPENDIX B - GUIDANCE ON DOCUMENTS TO BE PROVIDED BY AN ESTABLISHMENT IN ADVANCE OF APPROVAL

Approval authorities need a range of documentation in order to assess an application for approval and compliance with approval conditions. This Appendix provides guidance on the range of documentation which an establishment should provide to assist the approval process. As a minimum, the following should be provided:

- a plan of the premises indicating:
 - layout of establishment;
 - location of equipment;
 - water distribution within the establishment including all outlets and sampling points;
 - drainage system;
 - location of pest control baiting/trapping points;
 - work flows for each product line;
 - indications/draft plans of any alterations proposed;
- the documented food safety management system. This should show the hazard analysis for each process (or process group where appropriate, i.e. in small businesses), and include details of how the proposed critical points were established and validated, including the results of any sampling, and the proposed monitoring and control arrangements;
- 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;
- complaints procedure;
- up to date list of suppliers;
- up to date list of customers (National, EU, 3rd Country).

A.4.55: APPENDIX C – MEAT PRODUCTS HEALTH MARKS EXAMPLES



Meat Products British EC health mark indicating eligibility for trade with other Member States and that the product comes from a plant approved to handle products containing less than 10% meat (shown by the inclusion of 8-).



Meat Products British National health mark indicating eligibility for trade on the national market only and that the product comes from a plant approved to handle products containing less than 10% meat (shown by the inclusion of 8 -).



Both versions of the Meat Products British EC health mark indicating eligibility for trade with other Member States.



Both versions of the Meat Products British National health mark indicating eligibility for trade on the national market only.



Both versions of the Meat Products British EC health mark indicating eligibility for trade with other Member States. In this case the plant is co-located with an MHS enforced meat plant and the occupier has opted to use the MHS licence number as the approval code.



Meat Products British FMD mark indicating eligibility for trade on the national market only and contains meat of certain species produced in GB between 1 Feb 2001 and 23 Jan 2002.

ANNEX 5: MINCED MEAT AND MEAT PREPARATIONS

A.5.1: Introduction

This Annex provides specific guidance for Food Authorities on the application and enforcement of the Minced Meat and Meat Preparations (Hygiene) Regulations 1995³² as amended (the Regulations). It should be read in conjunction with the Code of Practice, in particular the sections on General Enforcement, Inspections, and Product-specific Regulations.

A.5.2: Competent Authority Roles and Responsibilities

The Food Standards Agency is the UK central competent authority with lead responsibility for these Regulations.

Responsibility for enforcement of the Regulations at local level is shared between Food Authorities and the Meat Hygiene Service, acting on behalf of the Food Standards Agency³³.

Regulation 12 prescribes the supervision and enforcement responsibilities as follows:

- Food Authorities are responsible for approvals, supervision and enforcement in all stand alone minced meat and meat preparations establishments;
- the Food Standards Agency is responsible through its network of Veterinary Meat Hygiene Advisers (VMHAs) for the approval of combined minced meat or meat preparations premises. Combined minced meat or meat preparations premises share a common curtilage with, or fall within the same curtilage as, a licensed slaughterhouse or cutting premises, or are any licensed cold store which stores both fresh meat and unpackaged minced meat or meat preparations. Supervision and enforcement in combined minced meat and meat preparations premises is undertaken by the Meat Hygiene Service on behalf of the Food Standards Agency.

In circumstances where approval and enforcement responsibilities are unclear, Food Authorities should liaise with the Meat Hygiene Service and the relevant VMHAs in England. The liaison arrangements are those laid down in paragraph 1.1.9 of the Code of Practice.

A.5.3: Scope of the Regulations

The Regulations implement Council Directive 94/65/EC laying down the requirements for the production and placing on the market of minced meat and meat preparations, in particular structural, hygiene and supervision standards. The

³² SI 1995 No. 3205

³³ The Food Standards Act 1999 (Transitional and Consequential Provisions and Savings) (England and Wales) Regulations 2000 (SI 2000 No. 656). These Regulations transferred functions previously held by the Minister for Agriculture, Fisheries and Food to the Food Standards Agency from 1 April 2000

Regulations apply to premises engaged in the production and storage of minced meat and meat preparations, except where such premises are exempt. For the purpose of these Regulations, 'production' means manufacturing, preparing, processing, packaging, wrapping or rewrapping.

The Regulations permit derogations from certain requirements for minced meat and meat preparations produced for the UK national market which, traditionally, are intended to be cooked before consumption. Minced meat and meat preparations produced in accordance with the relevant derogations must remain on the national market and must not carry a health mark.

A.5.4: Exemptions

The Regulations do not apply to the following premises/activities (Regulation 3A):

- premises producing or storing minced meat and meat preparations exclusively for direct sale in the UK to the final consumer from those premises or from sales points adjacent to those premises. Further advice on the 'final consumer' definition is given below;
- the production of mechanically recovered meat (MRM);
- the production or sale of minced meat intended for use as a raw material in the production of sausage meat destined for inclusion in a meat product.

Premises exempted under Regulation 3 must satisfy the requirements of Regulation 3A. This means that minced meat and meat preparations handled within exempt premises for the purpose of sale or preparation for sale must have been manufactured from raw materials which comply with the relevant meat hygiene regulations or, where appropriate, the Products of Animal Origin (Import and Export) Regulations 1996 and be prepared and manufactured in accordance with the Minced Meat and Meat Preparations (Hygiene) Regulations 1995.

This requirement was inserted by the Meat (Enhanced Enforcement Powers) (England) Regulations 2000 (and the corresponding regulations in Scotland and Wales). The effect of this amendment is to enable enforcement action (including seizure) to be taken outside approved premises against any operator of exempt premises who is in possession of minced meat or meat preparations that have not been handled in accordance with the requirements of Regulation 3A.

A.5.5: Final Consumer Definition

'Final consumer' is defined in Regulation 2 and for the purpose of these Regulations, includes sales or supply of minced meat and meat preparations to:

- the final purchaser for his or her personal consumption. This is intended to include purchases made by one person for consumption by another, for example, purchases on behalf of a relative, friend or neighbour, or as a gift for someone else, provided the meat products are not intended for re-sale;

- catering premises where the minced meat or meat preparations are for consumption on those premises. Caterers who may serve food at a location other than at their own premises, such as event caterers or 'meals on wheels' operators, should also be regarded as falling within the 'final consumer' definition;
- all outlets selling the minced meat or meat preparations **as ready-cooked take away food** for consumption off the premises. This implies that the minced meat and meat preparations are supplied to the take away outlet in a raw state and cooked on the premises for take away sale.

Government guidance that accompanied the introduction of the Regulations in 1995 indicated that the detailed standards required in the Regulations were inappropriate for small butchers supplying limited quantities of minced meat or meat preparations to the final consumer each day via other local outlets. The original guidance concluded that the requirements of the Food Safety (General Food Hygiene) Regulations 1995 were more appropriate and would provide an adequate level of consumer protection in relation to these activities. Consequently, authorised officers were advised that up to one tonne or 50% of total weekly production of minced meat and meat preparations (whichever is less), supplied daily to other outlets, may be treated as supplying the final consumer as in the scenario outlined in the first bullet point above.

The Food Standards Agency has reconsidered the original 1995 guidance and has concluded that it remains sound. In reaching this view, the Agency has had regard to the European Commission proposals for new consolidated hygiene regulations, which are likely to amend significantly the current EC hygiene requirements relating to the production of minced meat and meat preparations. The Agency therefore believes it would be appropriate to retain this guidance pending the outcome of the EU negotiations and advises authorised officers to continue to apply as appropriate the flexibility for small butchers outlined in the previous paragraph.

It is not intended that the Regulations should apply to domestic production which supplies the final consumer through outlets such as markets operated by the Women's Institute or charities or to meals on wheels catering operations. Any premises handling minced meat and meat preparations not covered by these Regulations are subject to the Food Safety (General Food Hygiene) Regulations 1995.

A.5.6: Definitions

These Regulations apply to the production of minced meat and meat preparations as defined in Regulation 2.

Minced Meat

Minced meat is defined as meat which has been minced into fragments or passed through a spiral screw mincer and includes such meat containing not more than 1 per cent added salt.

Meat Preparation

The definition of 'meat preparations' would include:

- raw sausages and burgers (including burgers which have been formed from pure minced meat and which contain no other ingredient);
- flash fried products which are not fully cooked (for example chicken cordon bleu);
- any pastry product containing meat, such as uncooked sausage rolls or "ready to cook" meals, in which the meat has not been thoroughly heat treated or cooked prior to sale. This includes such products containing small amounts of meat;
- fresh cuts or joints of meat to which sauce, marinade, foodstuffs or seasonings have been added (e.g. peppered or barbecue steak, marinated chicken drumsticks/wings, meat containing stuffing). However, retail packs containing fresh meat only are not meat preparations;
- minced meat containing any seasoning, more than 1 per cent added salt or other foodstuffs (for example donor kebab meat).

Mechanically Recovered Meat (MRM)

Product obtained by mechanical means from the residual meat on flesh bearing bones of any species including poultry or game and flows in puree form should be regarded as MRM. Meat that has been processed with the prime objective of removing bones or bone fragments, or for desinewation, should not be considered as MRM. Product from "Baader" machines may or may not come within the definition of MRM, depending on both the raw material used and the drum mesh size, which determines the consistency of the end product, (i.e. the meat could not be regarded as MRM if it did not flow in puree form).

MRM may not be used in the production of any type of minced meat. Community legislation concerning the use of MRM in meat preparations remains unclear. The GB Regulations permit its use in meat preparations for trade. However, other EEA Member States may not interpret the Community legislation in the same way. Approved premises considering using MRM in meat preparations intended for trade should therefore be advised to seek the advice of the importing agent in the Member State concerned. Appendix 1 contains further guidance on the use and health marking of MRM.

A.5.7: Approvals - Introduction

Part II of the Regulations is concerned with the approval of minced meat and meat preparations premises. This section summarises the approval requirements and process and should be read in conjunction with Section 5 of the Code of Practice.

Preliminary discussions between the Food Authority and potential applicants can provide a useful opportunity to discuss the approval requirements and process, identify any information requirements and consider issues that may need to be addressed by the applicant before the Food Authority can issue an approval.

A.5.8: Approval Conditions

Premises that produce minced meat or meat preparations intended for consignment to another EEA Member State must be approved. Only approved premises may apply the health mark to minced meat or meat preparations.

Applications for approval must be submitted in writing to the Food Authority or, in the case of combined premises, to the regional VMHA. A model application form, which Food Authorities may wish to issue to prospective applicants, is contained in Annex 8.

Regulation 4 sets out the approval requirements for minced meat and meat preparations. The conditions that must be satisfied in relation to these two categories of product are listed in Regulation 4(2)(a).

A.5.9: Documentation on the Establishment

In order fully to assess compliance with the approval conditions, the Food Authority will need to have access to a range of information about the establishment and processes. The assessment of documentation provided by the applicant is therefore a significant factor in the inspection/approval process. Guidance on the documentation that an applicant should provide is attached at Appendix 2. The required documentation may be provided during the preliminary discussions with the potential applicant or submitted with the application form, as required by the Food Authority. Where any necessary documentation has not been submitted with the application form, the Food Authority should establish with the applicant that the documentation will be available for examination during the pre-approval inspection. The sample application template includes a tick list of documents that should be submitted in connection with an application for approval.

A.5.10: Identification of Responsible Persons

The Meat (Enhanced Enforcement Powers) Regulations 2000 have introduced several amendments requiring the identification of responsible persons associated with approved establishments. The purpose of these amendments is to facilitate effective enforcement by ensuring those responsible for the establishment and compliance with the legal requirements are known to the Food Authority.

In accordance with Regulation 4(4A), inserted by the Enhanced Enforcement Powers Regulations, applications for an approval must include the name and principal business address of each person who is a manager, director or controller of the premises for which approval is sought. These information requirements are reflected in the model application template.

Regulation 4A requires the occupier of approved premises to notify the Food Authority of any changes in the identity or principal business address of the directors, managers or controller of the approved establishment and any change in the occupier of the premises. The Regulation sets time limits for notifying the Food Authority of any such changes.

A.5.11: Approval Inspection

On receipt of an application form the Food Authority should contact the applicant as soon as possible to arrange for an inspection of the premises. In the case of combined premises, the pre-approval inspection will be carried out by the regional VMHA, who will advise the Food Standards Agency on whether an approval should be issued.

The Food Authority should only issue an approval following a thorough inspection of the premises and if all of the relevant conditions are satisfied. Confirmation of approval should be issued in writing to the establishment. This should specify the activities for which the establishment is approved and any other conditions agreed between the establishment and the Food Authority as required under the Regulations. A standard format for approval notifications for use by Food Authorities is contained in Annex 8.

If the pre-approval inspection identifies that improvements are required before approval can be granted, the Food Authority should discuss and agree with the applicant a programme of necessary works. The Food Authority should confirm this in writing to the applicant detailing the requirements in the Regulations that must be satisfied, the work needed to comply with the requirements and a time scale for completion. The Food Authority should advise the applicant that failure to complete the improvements satisfactorily could result in the application being refused and/or legal action for any statutory contravention. This section of the guidance should be read in conjunction with paragraph 5.1.7 of the Code of Practice.

A decision to refuse to grant an approval should also be confirmed in writing and set out the reasons for the refusal. A standard format for refusals is contained in Annex 8.

A.5.12: Approval Code

The Food Authority must issue a unique approval code to each premises it approves under the Regulations. This should be specified in the approval letter. The approval code should be in the appropriate format specified in Schedule 7. Where approved premises also hold a fresh meat licence (i.e. combined premises), the licence number of the establishment may be used as the approval code for their minced meat and meat preparations activities. In such cases, the VMHA will notify the Food Standards Agency of this so that the fresh meat licence number can be confirmed as the approval code in the approval letter. In the case of premises handling different types of food products (e.g. fishery products, meat products, minced meat or meat preparations) the Food Authority should, with the agreement of the applicant, consider using one approval code for the entire premises.

The Food Authority may also approve premises where only part of those premises is engaged in the handling of minced meat and meat preparations, providing the appropriate conditions of the Regulations are met in that part of the premises. However, the health mark may only be applied to minced meat and meat preparations produced within the scope of the approval. For example, burgers made

in a non-approved part of the premises must not carry the health mark. The hygiene of the minced meat or the meat preparations must not be adversely affected by the production of other foodstuffs.

A.5.13: Non-industrial Premises

The Food Authority must decide whether premises producing only meat preparations, or a combination of meat products and meat preparations qualify as "non-industrial" in order to apply the relevant provisions of Regulation 4. The total weekly output from the premises of finished meat preparations and, if appropriate, meat products is the basis for classification. The premises qualifies as "non-industrial" where the total does not exceed 7.5 tonnes per week. Where possible, the classification should be based on the average weekly figure derived from the total yearly output of finished meat products and/or meat preparations. Premises that produce minced meat cannot qualify as "non-industrial" in any circumstances.

When formally classifying premises as non-industrial, the Food Authority should make clear to the business the basis of the classification. It should also make clear in writing that any subsequent changes in size and nature of the business may lead to re-classification of the premises, with attendant additional structural requirements.

'Non-industrial' premises are defined in Regulation 2, and may take advantage of the following derogations from the structural requirements:

- hand operated taps (as opposed to knee or foot operated) may be installed near work stations;
- secure lockers may be provided instead of changing rooms;
- wrapping may be carried out in the same room as the manufacture of meat preparations, provided that the operation constitutes a single production cycle and the safety of the end product is not compromised.

All other relevant requirements of the Regulations must be satisfied.

A.5.14: Other Relevant Factors

In addition to assessing compliance with the approval conditions, Food Authorities should seek to establish during the pre-approval inspection that the operator has satisfactory arrangements in place before production begins to ensure the establishment will operate at the required standard once operation commences. Particular emphasis should be placed on assessing the occupier's 'own checks' and traceability arrangements. These include HACCP-based food safety management systems, cleaning procedures, hygiene training, water quality testing procedures, record keeping, correct use of raw materials and effective control to ensure the correct use of health marking and commercial documentation. The Food Authority should be satisfied with the plans and procedures for these matters before approval is given. Further advice on these aspects is provided in subsequent sections of these guidance notes.

A.5.15: Revocation/Suspension of Approvals and Appeals

Regulation 5 specifies the circumstances under which the Food Authority may revoke an approval. In addition, Regulation 5A, inserted by the Meat (Enhanced Enforcement Powers) (England) Regulations 2000 (and the corresponding regulations in Scotland, Wales and Northern Ireland), allows the Food Authority to suspend an approval and specifies the circumstances in which this power can be used. Regulation 5A(4) provides for the lifting of suspensions. The Meat (Enhanced Enforcement Powers) Regulations have also amended Regulation 6 to broaden the range of circumstances under which an aggrieved party can appeal against an adverse decision by the Food Authority in relation to an existing approval or an approval application. Further general guidance on the handling of approvals, revocations and suspensions in product-specific establishments is contained in the Code of Practice. Standard formats, for use by Food Authorities to revoke or suspend approvals, are contained in Annex 8.

A.5.16: Information Required by the Food Standards Agency

The Food Standards Agency maintains a list of all approved meat products premises in accordance with the requirements of Directive 94/65/EC. This list is published on the Food Standards Agency website and updated regularly. In order to ensure this list is kept up to date, Food Authorities are required to inform the Food Standards Agency in writing of all new approvals, revocations or suspensions at the time of issue. A notification template that may be used by Food Authorities to notify the Agency is included in Annex 8.

A.5.17: Administrative Issues

Food Authorities should maintain records on each approval application, including copies of documentation supplied by the applicant, and recording progress with the application. Properly structured records provide a history of the establishment, continuity for new officers, and facilitate effective monitoring and inspection of the establishment. It will also assist the Food Authority in demonstrating the efficacy of its own supervision and enforcement arrangements in the context of the Framework Agreement and the observations of the EU Food & Veterinary Office. Further guidance on the content of Food Authority records is contained in Annex 8.

A.5.18: Registration of Premises

Premises subject to the Regulations but which do not wish to be approved under them must be registered. For the purpose of the Regulations, registration means registered under the Food Premises (Registration) Regulations 1991, as amended, licensed under any of the fresh meat hygiene regulations, or approved under the Meat Product (Hygiene) Regulations 1994. Premises falling into the last two categories are automatically considered to be registered by virtue of the fresh meat licence or meat products approval applicable to the establishment, and separate registration is not required. Stand alone minced meat or meat preparations establishments that are not approved must register with the Food Authority under the Food Premises (Registration) Regulations 1991. Details of premises that are

registered should be held locally by Food Authorities. Food Authorities are not required to notify this information to the Food Standards Agency.

A.5.19: Duties of the Occupier - Introduction

Regulation 11 requires occupiers of approved and registered premises to take all necessary measures to ensure the Regulations are complied with at all stages of production of minced meat and meat preparations and specifies 'own checks' to be carried out. 'Own checks' include the need to identify any points that are critical to the safety and hygiene of the product and establish and implement methods to control and monitor them. The pre-approval inspection (or initial inspection in the case of registered premises) should include an assessment to ensure the 'own checks' arrangements in place are satisfactory and will enable the occupier to meet the requirements of the Regulations. In determining whether occupiers have met these requirements, authorised officers should focus on those matters affecting food safety, taking into account the nature and size of the operation. As the effective implementation of 'own checks' arrangements underpins food safety, the assessment of ongoing compliance with these arrangements should form an integral part of programmed inspections.

A.5.20: Food Safety Management Controls

The Regulations require the occupier to operate documented food safety management controls, following certain HACCP principles. The critical points relevant to the food operations and the associated monitoring and control arrangements put in place by the occupier must be acceptable to the Food Authority. In determining the acceptability of food safety management controls, Food Authorities should focus on the significant food safety hazards in the premises, taking into account the nature and, where relevant, scale of the operation.

Food Authorities should pay particular attention during inspections to ensuring the food safety management system is being monitored and controlled effectively. The occupier should be able to demonstrate that appropriate corrective action is taken and the food safety management system reviewed regularly and whenever critical points are breached.

A.5.21: Acceptability of Laboratories

The Regulations require that laboratory facilities provided, or used, by the establishment for analysing or examining samples taken by the occupier to check compliance with the hygiene standards are acceptable to the Food Authority. The Regulations do not expressly require the use of accredited laboratories. However, an accredited laboratory has the advantage of being able to produce a certificate to that effect which in turn reduces the burden of assessment on the Food Authority.

Laboratories may seek accreditation from a number of organisations, such as, UKAS or Lloyds Register Quality Assurance. This list is not exhaustive and implies no endorsement by the Food Standards Agency of the specific organisations mentioned in this paragraph.

In the case of an accredited laboratory, the Food Authority should examine the original accreditation certificate and schedule which details the tests and methods which the laboratory is approved to carry out. The Food Authority should also check:

- the identity of the accreditation body;
- with the accreditation body that the laboratory's certification is still valid;
- that the tests and methods undertaken by the laboratory on behalf of the establishment are, in fact, those specified in the schedule to the accreditation certificate.

Laboratories without formal accreditation may be acceptable, although the process to establish acceptability is likely to be more involved than for a non-accredited laboratory. In order to assess the acceptability of a non-accredited laboratory, a Food Authority should satisfy itself that:

- the laboratory uses standard specified techniques, for example, a relevant British or international standard or a technique recognised as being appropriate;
- the techniques used are properly documented;
- sampling procedures are properly documented, including the location of sampling points, type of sample, collection of sample and delivery of sample to the laboratory. The documentation should also include a schedule of parameters for which tests are required and the methods to be used;
- the relevant laboratory staff are appropriately qualified and trained in the relevant techniques.

In order to determine the acceptability of a non-accredited laboratory, the Food Authority may wish to consult the Public Analyst or Food Examiner (Public Health Laboratory Service) who can advise regarding the suitability of the methods used by a particular laboratory. Where this is deemed necessary, Food Authorities are advised to obtain independent written certification from the Public Analyst or Food Examiner regarding the acceptability of such methods. This approach is also relevant to determining the acceptability of a test or method carried out by an accredited laboratory but for which the laboratory is not specifically accredited.

Where the Food Authority is satisfied with the chosen laboratory, it should confirm this as part of the approval notification. As the laboratory arrangements must be acceptable to the Food Authority on a continuing basis, the approval notification should indicate that any changes to these arrangements must be agreed in advance with the Food Authority. The acceptability of the laboratory arrangements should be verified as part of the on-going enforcement inspection process.

A.5.22: Control and Correct Use of the Health Mark

Regulation 11(1)(e) places a duty on the occupier to ensure that health marking is controlled and carried out properly. Schedule 6 (supervision of production) places a

responsibility on the Food Authority to check that the occupier is satisfying these requirements. In order to meet these obligations, it is necessary for the system operated by the establishment to control and apply the health mark to be discussed and agreed with the Food Authority.

Minced meat and meat preparations destined for trade with another EEA State may only be produced in premises approved for that purpose and must be health marked. Minced meat and meat preparations produced to UK national standards in either approved or registered premises must not be health marked. The Food Authority should be satisfied that the business has adequate, auditable, systems in place to ensure these requirements are satisfied and that only eligible raw materials are being used in the manufacture of minced meat or meat preparations for EEA trade.

Where health marking is permitted, the Food Authority should also be satisfied that access to health marking equipment and material (e.g. labels) is properly controlled and limited to those staff involved and supervising health-marking activities. The arrangements for ordering health marked materials, and/or printing them on-site as appropriate, should be agreed. The establishment should designate specific staff to take responsibility for ordering/printing and issuing health marked materials and have a system in place for recording this. The quantity of health marked materials ordered or printed should be reconcilable with the quantity of finished meat products produced. Records should also be able to account for any health marked material that may have been discarded as a result of damage. Establishments should ensure that the relevant employees receive proper instruction in the correct application of the health mark and use of health marked wrapping/packaging etc.

Food Authorities should check during programmed inspections that establishments are maintaining satisfactory control over the health marking arrangements and take appropriate action to rectify deficiencies. These regular checks should be supplemented by occasional spot checks.

A.5.23: Imminent Health Risk

Regulations 11(1)(f) and (g) outline the duties of the occupier and the Food Authority if an imminent health risk becomes evident in the production of any minced meat or meat preparation. The occupier is required to notify the Food Authority immediately if routine testing identifies a possible health risk. The Food Authority should then determine the extent of any health risk and take appropriate action to protect public health. For example, the presence of salmonellae in minced meat or meat preparations which will be cooked prior to consumption should not automatically be considered an imminent health risk as the organism will be destroyed by thorough cooking.

In the event of an imminent health risk, the occupier must withdraw from the market products obtained under technologically similar conditions and which are likely to present a similar risk. Withdrawn product must be held under the supervision and control of the Food Authority until it is destroyed or re-used as permitted under Regulation 11(1)(g). If subsequent investigations and/or samples prove to be satisfactory then it may be assumed that an imminent health risk does not exist and the products should not be withheld from sale on these grounds. The authorised

officer should seek further expert guidance if in doubt about the potential risk to the final consumer following notification of a laboratory examination which reveals a possible health risk.

Authorised officers should have regard to the advice in the Code of Practice relating to inspection, detention and seizure of suspect food and the food alert arrangements when taking action under this Regulation.

A.5.24: Hygiene Training of Factory Staff

Regulation 11(2) requires the occupier to ensure that workers in the establishment are given appropriate instruction and training in hygiene matters appropriate to their responsibilities. The Food Authority should examine the staff training programme, including records of any training received and copies of qualifications, as part of the pre-approval assessment. In determining whether staff training programmes are acceptable, Food Authorities should note that attendance on formal training courses leading to a qualification is not an express legal requirement and will not always be necessary to satisfy the Regulations. For example, classroom-based courses culminating in a written exam may not be the most appropriate or effective way of addressing the training requirements of staff with particular language or literacy needs. The value of in-house and on-the-job training in this context should be considered alongside more traditional training approaches. However, it would be entirely reasonable to expect managerial, technical and supervisory staff responsible for developing, implementing and overseeing food safety management arrangements and other technical food safety matters to be appropriately qualified.

Assessment of staff training programmes should be a feature of the Food Authority's ongoing inspection programme. The occupier should maintain up to date records of training received by staff, including any refresher or update training and copies of any qualifications. These should be available for inspection when requested by the Food Authority.

A.5.25: Temperature Control

Regulation 11(2)(b) requires the occupier to mark the packaging with a clear indication of the temperature at which the food should be stored and transported. The Regulations specify the temperature requirements of minced meat and meat preparations which are destined for the Single Market but do not indicate temperature requirements for the national market. In the latter case, the occupier should determine appropriate storage and transport temperatures using risk analysis. Where returnable trays are used for wrapped meat preparations and the label on the meat preparation is clearly visible, the temperature indication on the label will be sufficient.

Where products are subject to the Quick Frozen Food Regulations 1990, the various storage and transport temperatures will be those required by these Regulations. Therefore packaging which is labelled to indicate that the products have undergone quick freezing need not also bear the storage and transport temperatures laid down in the 1990 Regulations. However, it may be that other Member States do not interpret this provision in the same way and for trade, it is strongly advised that the

agent in the recipient Member State is consulted on the requirements in that Member State.

A.5.26: Conditions for Marketing Minced Meat & Meat Preparations

A.5.27: Production of Minced Meat for Trade with EEA States

Regulation 7(1) sets out the conditions for the production of health marked minced meat intended for trade within the EEA. Minced meat that is allowed to be traded between EEA Member States must be manufactured from EC health marked meat derived from bovines, pigs, sheep or goats. The use of red meat which has been imported and examined in accordance with the Products of Animal Origin (Import and Export) Regulations 1996 is also permitted. Minced meat containing or made from poultry, game or any other species may not be health marked and therefore may not be traded. Heart muscle cannot be used in minced meat that bears the health mark. Further restrictions on the type of meat which can be incorporated into minced meat are laid down in Schedule 4, Paragraph 2 of the Regulations.

Regulations 7(1)(b) and 8(1)(b) require all pig meat to be incorporated into health marked minced meat or meat preparations to "have been examined for trichinae or have undergone the appropriate treatment as described in Council Directive 77/96/EEC". In order to ensure consistency between various sets of regulations in this country, this requirement shall only apply to minced meat or meat preparations containing pig meat intended for consignment to Germany or Denmark. Fresh pig meat destined for these two Member States and produced in this country must be examined or have undergone the appropriate treatment under Part IX, of Schedule 10 of the Fresh Meat Hygiene Regulations. An expected proposal from the Commission outlining the scope of derogations from the requirements to examine or treat pig meat for trichinae has so far not emerged. The situation is therefore unchanged since 1995.

Regulation 7(1)(i) requires beef or veal to be de-boned prior to being frozen as well as specifying the maximum storage times for different types of frozen meat which may be manufactured into health marked minced meat. However, the de-boning of meat from sheep and pigs may take place immediately before mincing although the maximum storage times remain. The occupier should retain appropriate documentation in order to satisfy the authorised officer that these storage periods have not been exceeded and to record when de-boning took place. Where frozen minced meat has been added to minced meat in order to accelerate the chilling process, this should be declared clearly on the label. Minced meat that is packaged and consigned as chilled meat must be cooled to a temperature of 2°C as quickly as possible. If the cooling has been enhanced by the addition of a limited quantity of frozen meat, a maximum time of 1 hour from the addition is specified for such cooling.

Compositional requirements for minced meat are laid down in Regulations 7(1)(o), for trade within the EEA, and 7(2)(e), for national market production, and set out in detail in Schedule 11. These compositional requirements only apply if any of the designations in Schedule 11 are used to describe the product.

A.5.28: Production of Minced Meat for the National Market

The minimum conditions for the production of non-health marked minced meat are set out in Regulation 7(2). This takes account of the different ways minced meat is consumed in Member States and provides some important derogations for the production of minced meat which is traditionally intended to be cooked prior to consumption. These derogations are only allowed for minced meat that does not bear the health mark and is therefore restricted to the national market. Health marked minced meat produced according to the requirements of Regulation 7(1) may also be sold on the national market.

The derogations permissible for national trade are as follows:

- all types of health marked meat are permitted in the manufacture of minced meat with the sole exception of meat from solipeds. Heart muscle may also be incorporated into such mince. The cuts of meat which must not be incorporated into minced meat are set out in Schedule 4, Paragraph 2;
- premises need not be approved under the Regulations, but they must be registered as defined in Regulation 2;
- the following extra labelling requirements are not mandatory:
 - species, % mixture if several are used;
 - date of preparation on non-retail packs;
 - % of fat under ;
 - collagen/meat protein % ;
- there is no requirement for a commercial document/health certificate;
- transport need not be in accordance with Schedule 10;
- no eighteen, twelve or six month maximum storage times for frozen meat used in the production of minced meat;
- no specified cooling rates nor post-production storage temperatures;
- no restriction on the time that chilled meat may be used after slaughter;
- no ban on ionising radiation or U/V treatment, subject to existing national regulations.

Meat used as a raw material in minced meat for the national market must bear a health mark and either originate from licensed fresh meat premises or have been imported into the UK in accordance with the Products of Animal Origin (Import and Export) Regulations 1998. Consequently, minced poultry meat and minced game meat may be produced for the national market and, if appropriate exported to third countries.

Approved premises may produce both health marked minced meat and non-health marked minced meat in the same building. The occupier must ensure, however, that there is either time or spatial separation between the production of health marked and non-health marked minced meat. Providing there is no possibility of cross-contamination it is feasible to produce health marked and non-health marked minced meat in the same room at the same time providing it is done on separate production lines. The occupier should also ensure that detailed records are kept on, amongst other things, the types of raw meat used in each production run. This requirement is necessary in order for the authorised officer to ensure that only permitted raw materials have been used in the manufacture of health marked minced meat. If only one production line exists the operator must ensure that the equipment is thoroughly cleaned before it is used to produce health marked minced meat.

A.5.29: Poultry Minced Meat and Minced Game Meat in Meat Products

Poultry or game meat mince may be incorporated into meat products (for example spring rolls) which are eligible for Single Market trade. If the meat products bear the EC health mark, the pre-prepared minced meat production premises must be approved under the Regulations unless the minced meat is produced as part of a continuous process in the meat products plant. Minced meat from non-approved minced meat premises may not be used in the production of meat products intended for the Single Market.

A.5.30: Poultry Minced Meat and Minced Game Meat in Meat Preparations

Poultry or game meat mince may be incorporated into meat preparations (for example uncooked sausage rolls) for Single Market trade. If the meat preparations bear a health mark, the minced meat premises in which the minced meat was produced must be approved under the Regulations, unless the minced meat is produced as part of a continuous process in the meat preparations premises. Minced meat from non-approved minced meat premises may not be used in meat preparations intended for the Single Market.

A.5.31: Production of Meat Preparations for trade with EEA States

Regulation 8(1) sets out the conditions for the production of health marked meat preparations intended for EEA trade. With the sole exception of meat from solipeds, meat preparations may be manufactured from any type of EC health marked meat (red meat, poultry meat and the game meats) or meat which has been imported in accordance with the Products of Animal Origin (Import and Export) Regulations 1998.

The guidance in Paragraph A.5.27 regarding trichinae testing also applies to meat intended for use in the production of meat preparations.

Regulation 8(1)(c) specifies the maximum storage times for different types of frozen meat that may be manufactured into health marked meat preparations. The occupier should retain appropriate documentation in order to satisfy the authorised officer that these storage periods have not been exceeded.

Regulation 8(1)(d) specifies the temperatures at which health marked meat preparations must be stored. The temperature requirements differ depending upon the type of meat that has been used to manufacture the meat preparation. If a combination of meats have been used, the lowest of the relevant temperatures must be met. For example, if fresh meat and offal are combined, the lower maximum temperature of 3°C will be required. The temperature requirement for meat preparations that contain minced meat which has been produced as part of a continuous process (i.e. not pre-prepared minced meat) need not apply. In this case the type of meat used in production (for example poultry or red meat) will determine the temperature requirement. The occupier should ensure these temperature requirements are in keeping with the requirements of other relevant EEA States prior to export.

Meat preparations may contain minced meat. The minced meat may be produced on site or be obtained from other premises. In the latter case it is considered to be pre-prepared minced meat. However, the minced meat does not need to comply with any of the specified requirements for minced meat if it is produced as part of a continuous process in the production of meat preparations and would therefore not be considered to be pre-prepared minced meat. Incidental storage is permitted as part of the continuous process and may include overnight storage if too much meat has been minced on one day. All other requirements specified in the Regulations for the production of the meat preparation must be met. If pre-prepared minced meat is used, it:

- must meet the standards specified for Single Market trade in minced meat if it is obtained in a pre-prepared form from other premises;
- must at least meet the standards for national market minced meat, if it is obtained in a pre-prepared form from other premises or from the same site if the meat preparation is only intended for the national market;
- in the case of poultry or game meat which is to be used in the production of health marked meat preparations, must be produced in approved premises. However, a health mark must not be applied to poultry or game minced meat. To ensure compliance with the appropriate requirements of Regulation 7(1) the operator must provide documented evidence to that effect when requested by the authorised officer or the operator of the meat preparations premises.

A.5.32: Production of Meat Preparations for the National Market

The minimum conditions for the production of non-health marked meat preparations are outlined in Regulation 8(3). This permits several derogations for the production of meat preparations which are traditionally cooked prior to consumption. These derogations are only allowed for meat preparations that do not bear the health mark and are therefore restricted to the national market. Health marked meat preparations produced to the standards specified in Regulation 8(1) or equivalent can also be sold on the national market. The derogations permissible for national trade are as follows:

- all types of health marked meat is permitted in the manufacture of meat preparations with the sole exception of meat from solipeds;
- premises need not be approved under the Regulations, but they must be registered as defined in Regulation 2;
- the following extra labelling requirements are not mandatory preparations:
 - species, % mixture if several are used;
 - date of preparation on non-retail packs;
 - For meat preparations made from minced meat;
 - % of fat under ;
 - collagen/meat protein % ;
- wrapping, packaging and cooling specifications do not apply;
- transport need not be in accordance with Schedule 10;
- no eighteen, twelve or six months maximum storage times for frozen meat;
- no post-production storage temperatures;
- no commercial documents or health certificates;
- meat preparations containing minced meat need not use minced meat which complies with Regulation 7(1) (see Paragraph A.5.31).

Approved premises may produce both health marked meat preparations and non-health marked meat preparations in the same building. The occupier must, however, ensure that there is either time or spatial separation between the production of health marked and non-health marked meat preparations. Providing there is no possibility of cross-contamination it is feasible to produce health marked and non-health marked preparation in the same room at the same time as each other providing it is done on separate production lines. The occupier should also ensure that detailed records are kept on, amongst other things, the types of raw meat used in each production run. This requirement is necessary in order for the authorised officer to ensure that only permitted raw materials have been used in the manufacture of health marked meat preparations. If only one production line exists the operator must ensure that the equipment is thoroughly cleaned after the production of meat preparations for the national market and before it is used to produce health marked meat preparations.

A.5.33: Use of Commercial Documents and Certification for Trade

Commercial Documentation

Minced meat and meat preparations produced in approved premises and which are intended for trade with another EEA State must be accompanied by a commercial document (e.g. an invoice, consignment or delivery note) issued by the occupier

(Regulation 9). When products are dispatched, the commercial document should include:

- the approval code of the consigning establishment;
- in the case of frozen minced meat, the month and year of freezing;
- in the case of minced meat destined for Finland or Sweden, a statement that the minced meat is free from salmonella.

Premises receiving commercial documents should keep them for at least one year after receipt or 6 months after the expiry of the appropriate durability date of the product, whichever is longer. Commercial documents should be made available for inspection at the request of the Food Authority. Companies wishing to hold commercial documents at a central point (such as head office) may be allowed to do so although such documents must continue to be available for inspection by the Food Authority. Commercial documents must be physical documents. However, for ease of retention they may be reproduced on microfiche or as computer records providing they are true copies of the original documents, and contain a representation of the approval code or health mark appearing on the original document.

Health Certification

The Regulations and the following guidance have been drafted on the basis that the requirement in Article 5(2)(f) of Directive 94/65/EC for meat preparations traded with another EEA State to be accompanied by a health certificate is an error. To date, the European Commission has not brought forward amending legislation to correct this error. Consequently, competent authorities in other EEA States may take a literal interpretation of the Directive and require consignments of health marked meat preparations to be accompanied by a health certificate. Therefore, anyone wishing to trade meat preparations with another EEA State should be strongly advised to check the requirements with the importer in the recipient country and act accordingly.

Businesses may apply to DEFRA for health certificates if they consider it necessary to facilitate trade. This is, however, a commercial decision and not a statutory requirement. Applications should be made to DEFRA Products Exports Section, Animal Health (AIT - International Trade Unit - Products), 1A Page Street, London SW1P 4PQ (email: productexports@defra.gsi.gov.uk).

Veterinary health certification of minced meat and meat preparations consigned to another EEA State is required in the following circumstances:

- the consignment contains minced meat or meat preparations from a premises in an area restricted under the Animal Health Act 1981, in which case the procedure at Paragraph A.5.34 below will apply (Regulation 9(1) (b) (i));

- the product is intended to be sent to another EEA State via a third country which is not an EEA member state, in which case the product must be conveyed in a sealed means of transport (Regulation 9(1) (b) (ii));
- the product is intended for export to a third country via another EEA State and that EEA State requests that veterinary certification is provided (Regulation 9(2)). Such requests should be on a case by case basis and not a matter of routine.

It is the responsibility of the exporter to apply to DEFRA for the relevant health certificate. Existing certification requirements for minced meat and meat preparations exported direct to third countries remain unchanged.

A.5.34: Meat Disease Control Requirements

Paragraph 7 of Schedule 4 and Paragraph 3 of Schedule 5 were inserted by the Meat (Disease Control) (England) Regulations 2000³⁴. Similar regulations were introduced in Scotland, Wales and Northern Ireland. These amendments, which came into force in England on 16 August 2000, prohibit the use of over-stamped meat, i.e. mainly from animals or slaughterhouses subject to animal disease restrictions, in minced meat and meat preparations. The types of meat covered by these restrictions are specified in Regulation 13(3)(e) to (i) of the Fresh Meat (Hygiene and Inspection) Regulations 1995 and Paragraph 6 of Schedule 11 to the Poultry Meat etc. (Hygiene and Inspection) Regulations 1995.

A.5.35: Foot and Mouth Disease Restrictions

In accordance with Regulations 7(5) and 8(6), a health mark must not be applied to minced meat or meat preparations respectively made from fresh meat of certain species of animals slaughtered in Great Britain in the period 1 February 2001 to 23 January 2002³⁵. These requirements were introduced as a result of the outbreak of Foot and Mouth Disease that occurred at that time.

A.5.36: Enforcement Issues

Food Authorities should ensure that all minced meat and meat preparations establishments, including those supplying only the national market, have systems in place to comply with the relevant marketing requirements. For establishments wishing to trade with other EEA States, satisfactory arrangements should be in place before approval is granted.

Food Authorities should pay particular attention to the eligibility of raw material used, traceability arrangements and, where appropriate, control of health marking. These systems should permit the reconciliation of all minced meat and meat preparations produced against corresponding incoming raw materials. Establishments should retain all documentation relating to the type, quantity and origin of raw material

³⁴ SI 2000 No. 2215

³⁵ Inserted by the Foot and Mouth Disease (Marking of Meat, Meat Preparations and Meat Products) Regulations 2002 (SI 2002, No. 118)

received. The use of raw material should be recorded and linked to outgoing batches/consignments of finished product. Establishments should retain and file all commercial documents and any health and veterinary certificates associated with deliveries of raw materials as well as copies of outgoing commercial documents, where required, for the periods specified in the Regulations. Although not expressly required by the Regulations, procedures at establishments should ensure that health marks are destroyed when wrapping/packaging containing incoming raw material is opened.

Food Authorities should check that these arrangements are working satisfactorily during primary and intermediate hygiene inspections. These checks should include documentary checks and checks on the origin of raw materials found in use at the establishment at the time of inspection. Food Authorities should also consider carrying out unannounced spot checks on traceability systems outside their programmed inspections. Food Authorities should record the results of all checks and take appropriate action to rectify any deficiencies identified.

Establishments should also maintain up to date information on their suppliers and customers so that the Food Authority can check their status. Supplier details should include the type of raw material usually supplied by them and the approval code or licence number of the supplying establishment. It should be possible to distinguish approved/licensed suppliers from non-approved/licensed suppliers. In the case of suppliers and customers with several plants, the details of each plant should be recorded. The establishment could be asked to inform the Food Authority of any new sources of supply so that the status/eligibility of the new supplier and raw materials can be monitored.

The scope of a Food Authority's checks should include checks with nationally based customers of the establishment to ensure nationally restricted minced meat and meat preparations stay on the national market. This could include checking with the customer that information on deliveries received corresponds with information held by the consigning establishment.

A.5.37: Guidance on the Schedules

A.5.38: Schedules 1, 2 and 3: Conditions for Approval of Establishments

These Schedules apply to both Single Market and national trade. They specify the requirements that establishments must satisfy in order for an approval to be issued.

Staff engaged in the manual production of minced meat and meat preparations are required to wear masks covering the mouth and nose. Manual production in the case of minced meat means the manual chopping of minced meat for example with a curved cutting knife. Even if the production of minced meat and meat preparations involves a significant element of manual handling, Food Authorities should only insist upon the wearing of masks if a public health risk is clearly evident if they are not used.

Similarly, staff engaged in the manual production of minced meat and meat preparations are required, if so directed by the Food Authority, to wear smooth

moisture proof gloves which are either disposable or capable of being cleaned or disinfected. The above guidance relating to the wearing of face masks should also be applied in relation to gloves.

A.5.39: Schedule 4: Conditions for the Production of Minced Meat

This Schedule applies in full to the production of minced meat for the Single Market. Paragraphs 1, 2 and 6 apply only to minced meat produced for national trade.

Paragraph 2(c) prohibits the use of meat containing bone fragments in the production of minced meat. It is inevitable that bone fragments imperceptible to the consumer (but detectable upon sample analysis) may be present in de-boned meats and this should be allowed by the authorised officer. The authorised officer should ensure that adequate care has been taken during production to eliminate fragments perceptible to the consumer.

All parts of the bovine head from cattle slaughtered in the United Kingdom are classified as "specified bovine material" and as such can no longer be used for human consumption. The term 'masseters' is considered to mean the muscles of the cheek and those closely allied to them. The definition does not include muscles of the lip or nose, the papillae of the cheek, the soft palate or any glandular material.

Paragraph 6 requires that if minced meat is deep frozen it can only be frozen once. However, it is acceptable for frozen meat to be used in the production of minced meat which is then subsequently deep frozen as minced meat.

A temperature of 12°C is specified for the production area of health marked minced meat (Paragraph 3). Authorised officers may use hazard analysis to determine the extent of the "production area" which need not necessarily be the actual production room. The overriding objective is to maintain product temperature in order to minimise any risk to health. No other production area temperatures are specified. However, the occupier must ensure that the production of non-health marked minced meat and all types of meat preparations take place in rooms at temperatures which will not cause any risk to public health. This may be achieved by subjecting the chilled product to room temperatures for such a short time that the internal temperature of the product does not rise significantly. Where the schedules require a recording thermometer or telethermometer to be installed in the production room, a basic maximum/minimum thermometer will suffice. However, if a maximum/minimum thermometer is used, it is essential that the thermometer be reset at the beginning of each day's production, monitored during production and the maximum and minimum temperatures recorded at the end of each day. These records must be retained for inspection. As a consequence of the additional documentation which is necessary, some operators may view the recording thermometer or the telethermometer as a cost-effective alternative to manual recording. In any case, temperature records should always be retained.

A.5.40: Schedule 5: Conditions for the Production of Meat Preparations

All parts of Schedule 5 apply to the production of meat preparations destined for the Single Market. For the national market, meat preparations need only be produced to the requirements of Paragraphs 1 and 2(b) of this Schedule.

A.5.41: Schedules 7-10:

Schedule 7 specifies the requirements for health marking and labelling of minced meat and meat preparations intended for EEA trade. It does not apply to minced meat and meat preparations produced for the national market.

Schedule 8 specifies the requirements for wrapping and packaging minced meat and meat preparations. It applies to minced meat destined both for trade with other EEA States and the national market and meat preparations intended for trade with other EEA States. For the national market, meat preparations should be wrapped and packaged according to risk assessment principles under general food hygiene legislation.

Schedule 9 specifies the requirements for storing minced meat and meat preparations. It applies to consignments destined for Single Market trade. For products destined for the national market only Paragraphs 4 and 5 apply.

Schedule 10 specifies the requirements for transporting minced meat and meat preparations destined for Single Market trade. This Schedule does not apply to consignments destined for the national market, which should be transported in accordance with general food hygiene legislation.

A.5.42: Schedule 11: Sampling Requirements and Compositional and Microbiological Criteria for Minced Meat

This Schedule applies to minced meat for both Single Market and national trade, although not all the requirements apply to the latter.

A.5.43: Compositional Criteria

The table in Paragraph 1 lays down the compositional criteria for minced meat, specifically the maximum permissible fat content and the maximum collagen/meat protein percentages. However, in accordance with Regulation 7(2)(e), the compositional criteria do not apply to non-health marked minced meat made from sheep or goat meat.

A.5.44: Designations

Where any of the designations in the first column are used on the packaging to describe the product, the corresponding requirements for total fat content and collagen content of meat protein must be met (see below).

A.5.45: Fat Content

If the declared description of minced meat is one of the designated descriptions the maximum fat content will vary from 7% to 30% according to the requirement.

A.5.46: Collagen/Meat Protein %

If the declared description of minced meat is one of the designated descriptions, the maximum collagen content in the total meat protein will vary from 12% to 18%. The table refers to the final percentage for collagen/meat protein which is calculated as follows:

$$\frac{\text{Collagen}}{\text{Meat Protein}} \times 100 = \% \text{ in Table}$$

For example, if the description of "lean minced beef" or "lean minced pork" is used, to achieve the final maximum percentage specified in the table of 12%, to every part collagen there should be no less than 8.33 parts meat protein. Any recognised analytical method can be used to determine the collagen content of the minced meat.

If the requirements of Paragraph 1 apply, the operator should establish by daily sampling that the average daily production of minced meat meets the appropriate compositional criteria. Once confirmation of compliance is established and, if all production methods including the specifications for the cuts and types of meat used remain unchanged, *only periodic sampling* is required. If any part of the production process is changed (for example a change in recipe or supplier) confirmation of compliance should be re-established and sampling on a periodic basis can be resumed. By this means, the occupier will again be able to build a catalogue of documentary evidence.

An occasional sample which exceeds the requirements for either the fat content or the collagen/meat protein percentages should not jeopardise the consignment as consignments are not held pending the results of such sampling. It should, however, be regarded as an indication that the production process needs to be re-examined. The authorised officer should focus on the overall daily or periodic averages and not individual results. For consignments destined for trade with other Member States, operators may consider the inclusion of past documentation regarding compositional data to be of value.

The intention of the Directive is that where the consumer sees the exact wording ("designations" listed below) to describe minced meat, then they can expect the relevant compositional requirements to apply. Where those specific designations are not used, then the consumer cannot expect the compositional requirements to have been met. The designations are:

- "lean minced" used in relation to meat of any permitted species;
- "minced pure" used in relation to meat from bovine animals;
- "minced" used in relation to meat of any permitted species containing pig meat;
- "minced" used in relation to sheep meat or goat meat.

Clearly other interpretations could have serious implications for the industry both in this country and in other Member States. For example, a strict interpretation of the second bullet point above might be that any minced meat containing beef alone (i.e. "pure") must meet the relevant requirements. This would make it illegal to describe as "minced beef" any range of economy minced beef currently available throughout the Community - in turn this would make marketing of such products extremely difficult. It is believed that the intention of the Directive was that the word "pure" should indicate particular quality rather than production from a single species.

Therefore, for the domestic market, authorised officers should consider the compositional requirements as applying only when the specific wordings (designations) are used. Avoiding use of the word "pure" unless the compositional requirements are to be met, is a trade practice that eliminates any risk of confusion. For example, "pure minced beef" might be confused by the consumer as being "minced pure beef". However, "100% minced beef" does not contain the word "pure" and is therefore not covered, nor would "pure ground beef".

Examples which should not fall within the designations include:

- "super lean mince";
- "lean ground beef" or "ground beef";
- "minced beef - 80% lean";
- "prime mince";
- "beef mince".

This list is not exhaustive. It is not the intention of the Regulations to disrupt the range of minced meat which is currently available to the UK consumer and which the customer is used to (for example "super lean minced meat" through "lean" to "economy"). Nor is it intended that all minced meat should fall within the specified designations. However, only those minced meats which producers wish to comply with the compositional criteria may use the specific designations described above.

However, for trade with other Member States, producers should consider the possibility that a different interpretation may be applied in the recipient Member State. Producers wishing to trade minced meat are therefore strongly advised to seek guidance from the importing agent as to the requirements of the designation used and compositional standards in the Member State concerned.

The designations apply as above to pre-prepared mince intended for use in meat preparations. The compositional criteria do not, however, apply to the resultant meat preparation, or its labelling.

Any declared designation of minced meat other than those listed in the Regulations need not comply with the requirements of Paragraph 1 of this Schedule. Beef burgers are not included in any designation in these Regulations.

A.5.47: Microbiological Criteria

Paragraph 2 lays down the microbiological criteria and Paragraphs 3-8 provide guidance on the interpretation of the results of samples taken under Regulation

11(2)(c) for minced meat which is destined for either the single or national markets - specifically for aerobic mesophilic bacteria, *Escherichia coli*, *Staphylococcus aureus* and *salmonellae*.

The Regulations require the operator to introduce some form of hazard analysis to minimise the risk of microbiological contamination. In view of this, the microbiological requirements should be considered as guidelines in support of risk assessment for both the Single and national market. An occasional sample which exceeds the requirements should be regarded as an indication that the production process needs to be re-examined. The authorised officer should focus on the rolling values and not individual results. However, this is without prejudice to the requirement to take action when sampling results signify the potential for an imminent health risk. For consignments destined for trade with other Member States, operators may consider the inclusion of past documentation regarding microbiological criteria to be of value.

A.5.48: Sampling Frequency and Method

Minced Meat and Pre-Prepared Minced Meat for Trade

At least one representative sample (consisting of five individually sampled units bulked together) should be taken from the minced meat on a daily basis during production in order for five samples (after a maximum of five working days) to be tested individually. Each sample should be tested on or as near as possible to the day of sampling. The five separate sets of microbiological results should then be interpreted using the criteria laid down in Schedule 11(2) - (6) inclusive (Paragraph A.5.49). Using this approach, rolling values can be used to determine compliance (i.e. a single day's production will be categorised several times).

Minced Meat for the National Market

At least one representative sample (consisting of five individually sampled units bulked together) should be taken from either the meat intended for the production of minced meat for the national market, or if preferred from the final product, on a weekly basis, in order for five samples (after a maximum of five working weeks) to be tested individually. It will be at the operator's discretion as to which point a sample is taken. Each sample should be tested on or as near as possible to the day of sampling. In the case of meat, each sample should be taken from deep inside the muscle after the surface has been cauterised. The five separate sets of microbiological results should then be interpreted using the criteria laid down in Schedule 11(2) - (6) (see Paragraph A.5.49). Using this approach, the rolling results can be used to determine compliance.

If the samples have been taken from meat, the operator may consider it appropriate to test the final product in the interests of hygiene and in order to meet the risk management procedures of Regulation 11. However, while this is desirable it is not a requirement of the Regulations.

The samples may be tested using either liquid or solid media. The decision rests with the operator and the appropriate testing laboratory as to which approved methodology is used (e.g. ISO, BSI, NAMAS).

DN: in order to complete transposition of Directive 94/65/EC, the Agency will shortly be introducing amendment regulations to bring UK law into line with the Directive in respect of requirements for salmonella testing and the sampling of minced meat for the national market. The above section of the draft guidance is therefore subject to revision.

A.5.49: Interpretation of Microbiological Results

Paragraphs 3-6 in this Schedule deal with the interpretation of the sample results. The five samples will give five separate microbiological results, interpretation of which will place the product into one of the following four categories:

- *Category A - Fully Satisfactory*
All results fall at or below the lower threshold;
- *Category B - Acceptable*
Acceptable, providing that no more than two of the results are between the lower and upper threshold. If more than two results fall between the lower and upper threshold then Category C will apply;
- *Category C - Unacceptable*
If more than two results fall between the upper and lower threshold (as described in Category B) or any result falls above the upper threshold (but below the microbic limit) the operator should seek further advice from a competent person in order that production standards can be scrutinised. The occupier must also scrutinise the production process and take further samples in accordance with Regulation 11 in order to prove that future production runs comply with the microbiological criteria.

The above guidance need not apply, however, if the number of aerobic microorganisms at 30°C exceed the upper threshold (but are below the microbic limit) and all other criteria are fulfilled. The occupier should, however consider submitting further samples for analysis.

If premises consistently produce minced meat which falls within Category C, authorised officers should ensure that the minced meat is intended to be thoroughly cooked prior to consumption;

- *Category D - Unsatisfactory*
If any result exceeds the microbic limit the product must be considered an imminent risk to health and the appropriate action outlined in Paragraph A.5.23 should be undertaken. The guidance regarding the presence of *Salmonellae* contained in these paragraphs should be followed in particular.

A.5.50: Schedule 13: Sampling Requirements and Microbiological Criteria for Meat Preparations

This Schedule applies to meat preparations for both Single Market and national market trade.

A.5.51: Microbiological Criteria

Paragraph 1 of this Schedule lays down the microbiological criteria and Paragraphs 2-6 provide guidance on the interpretation of the results for meat preparations which are destined for either the Single or national market - specifically *Escherichia coli*, *Staphylococcus aureus* and *Salmonellae*.

The Regulations require the operator to introduce some form of hazard analysis to minimise the risk of microbiological contamination. In view of this, the microbiological requirements should be considered as guidelines in support of risk assessment for both the single and national market. An occasional sample which exceeds the requirements should be regarded as an indication that the production process needs to be re-examined. The authorised officer should focus on the rolling mean values and not individual results. However, this is without prejudice to the requirement to take action when sampling results signify the potential for an imminent health risk. For consignments destined for trade with other Member States, operators may consider the inclusion of past documentation regarding microbiological criteria to be of value.

A.5.52: Sampling Frequency and Method - Meat Preparations for Both the National and Single Market

At least one representative sample (consisting of five individually sampled units bulked together) should be taken from either the meat intended for the production of meat preparations, or if preferred from the final product, on a weekly basis in order for five samples (after a maximum of five weeks) to be tested individually. Each sample should be tested on or as near as possible to the day of sampling. In the case of meat, each sample should be taken from deep inside the muscle after the surface has been cauterised. The five separate sets of microbiological results should then be interpreted using the criteria laid down in Schedule 13(2) - (5) (see Paragraph A.5.53). Using this approach, rolling mean values can be used to determine compliance (i.e. a single day's production will be categorised several times).

If the samples have been taken from meat, the operator may consider it appropriate to test the final product in the interests of hygiene and in order to meet the risk management procedures of Regulation 11. However, whilst this is desirable it is not a requirement of the Regulations.

The samples may be tested using either liquid or solid media. The decision rests with the operator and the appropriate testing laboratory as to which approved methodology is used.

DN: in order to complete transposition of Directive 94/65/EC, the Agency will shortly be introducing amendment regulations to bring UK law into line with the Directive in respect of requirements for salmonella testing in meat preparations. The above section of the draft guidance is therefore subject to revision.

A.5.53: Interpretation of Microbiological Results

Paragraphs 2-5 inclusive advise on how to interpret the sample results. The five samples will give five separate microbiological results, interpretation of which will place the product into one of the three categories:

- *Category A - Fully Satisfactory*
All results fall at or below the lower threshold;
- *Category B - Acceptable*
Acceptable, providing that no more than two out of the five samples have results which fall between the upper and lower thresholds in the case of *Escherichia coli* or one out of the five samples in the case of *Staphylococcus aureus*. If these tolerances are exceeded the guidance issued in Category C will apply;
- *Category C - Unsatisfactory*
If any result exceeds the tolerances in Category B or falls above the upper threshold then the operator should consult a competent person in order that production standards are scrutinised. The occupier should take further samples in accordance with Regulation 11 in order to prove that future production runs comply with the microbiological criteria. Whilst there is no microbic limit for meat preparations, if a competent person considers the product to be an imminent risk to health the appropriate action outlined in Paragraph A.5.23 should be undertaken. The guidance regarding the presence of *salmonellae* contained in these Paragraphs should be followed in particular.

A.5.54: APPENDIX A - FURTHER GUIDANCE ON MECHANICALLY RECOVERED MEAT

Health Marking

A Single Market health mark cannot be applied to MRM as there are no harmonised standards for its production. However, a special 'health mark' or code may have to be applied under the bilateral agreements the UK has for trade in raw MRM with other countries. This 'health mark' or code only confirms that the MRM has been manufactured in an establishment approved under other product-specific hygiene legislation. Further advice on bilateral agreements for trade in MRM, and any marking requirements, may be obtained from DEFRA Products Exports Section, Animal Health (AIT - International Trade Unit - Products), 1A Page Street, London SW1P 4PQ (email: productexports@defra.gsi.gov.uk).

Trade within the European Union

Trade within the EU in raw MRM is not permitted unless the MRM is destined for a premises which is approved under Directive 77/99/EEC (meat products) for heat treatment.

If MRM is incorporated into a meat product the meat product must be heat-treated before being traded with another EEA State.

MRM is not permitted in minced meat intended for trade with another EEA State. The inclusion of raw MRM is permitted in meat preparations subject to the guidance given elsewhere in this document.

Trade within Great Britain

Raw MRM may be freely traded within Great Britain.

MRM may be incorporated into a meat product which is then heat treated.

The inclusion of raw MRM is permitted in meat preparations but not in minced meat.

In these cases, the MRM production unit need not be approved or licensed.

In these cases, the MRM production unit must be approved or licensed as appropriate under the Hygiene Regulations, the Meat Products (Hygiene) Regulations 1994 or the Minced Meat and Meat Preparations (Hygiene) Regulations 1995, but need only be registered under the Food Premises (Registration) Regulations 1991 as amended.

Trade with Third Countries

Bilateral agreements with third countries may be agreed for trade in MRM and these are normally a matter for DEFRA to negotiate in the usual way. (See DEFRA contact details above).

A.5.55: APPENDIX B - GUIDANCE ON DOCUMENTS TO BE PROVIDED BY AN ESTABLISHMENT IN ADVANCE OF APPROVAL

Food Authorities need a range of documentation in order to assess an application for approval and compliance with approval conditions. This Appendix provides guidance on the range of documentation which an establishment should provide to assist the approval process. As a minimum, the following should be provided:

- A plan of the premises indicating:
 - layout of establishment;
 - location of equipment;
 - water distribution within the establishment including all outlets and sampling points;
 - drainage system;
 - location of pest control baiting/trapping points;
 - work flows for each product line;
 - indications/draft plans of any alterations proposed;
- the documented food safety management system. This should show the hazard analysis for each process (or process group where appropriate, i.e. in small businesses), and include details of how the proposed critical points were established and validated, including the results of any sampling, and the proposed monitoring and control arrangements;
- 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 any 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;
- complaints procedure;
- up to date list of suppliers;
- up to date list of customers (National, EU, 3rd Country).

ANNEX 6: MILK AND MILK PRODUCTS

A.6.1: Introduction

This Annex provides specific guidance to Food Authorities³⁶ on the requirements of the Dairy Products (Hygiene) Regulations 1995³⁷ (the Regulations) which apply in England and Wales. The Regulations implement the requirements of Council Directive 92/46/EEC (as amended by Directives 92/118, 94/71 and 96/23 and Commission Decision 94/330), Commission Decision 95/116/EC, and Commission Decision 95/340/EC, which lay down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk based products from cows, ewes, goats and buffaloes, intended for human consumption.

A.6.2: Competent Authority

The Food Standards Agency is the UK central competent authority with lead responsibility for these Regulations.

Responsibility for enforcement of the Regulations at local level is shared between Food Authorities and the appropriate Minister (Regulation 16).

Food Authorities approve dairy establishments, and otherwise enforce the Regulations except in the cases listed below:

Requirements in Regulation 4 relating to the registration of production holdings and the subsequent supervision and inspection of registered production holdings (apart from animal health checks - see below). These are dealt with on behalf of the Food Standards 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 12 (2) 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 4 Part 1 Paragraph 2). These are also dealt with by the DHI. (The separate guidelines mentioned above also cover enforcement of these requirements).

Checks on the health of animals (Schedule 3 Part 1) which are the responsibility of producers, and are normally carried out by producers' private veterinary surgeons. Food Authorities may check records of these checks during their programmed inspections. In addition Agriculture Departments will be responsible for carrying out official tests for TB and brucellosis where appropriate.³⁵

Premises that operate both as a production holding and a processing establishment are registered by the Food Standards Agency as a production holding, and approved by the Food Authority as a dairy establishment.

³⁶ Guidance on Officially Tuberculosis Free status and the Dairy Products (Hygiene) Regulations 1995, as circulated under cover of the CEHO letter Ref: CEHO/00/7 of 13 March 2000 is still extant

³⁷ As amended, SI1995/1086

A.6.3: Scope of the Regulations

The Regulations cover 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), packaging, bottling, and wrapping or re-wrapping (processing establishments);
- collection of raw milk (collection centres);
- standardisation of fat content of raw milk (standardisation centres).

Premises that handle milk or milk-based products only when processing non-dairy products do not fall within the scope of the Regulations.

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.6.4: Definitions

“Milk” is defined in Regulation 2. It includes raw milk and milk that has undergone some form of heating, i.e. thermisation or heat-treatment e.g. pasteurisation, UHT, sterilisation.

“Milk-based product” is also defined in Regulation 2, although the European Commission has issued further guidance on products that come within the definition. This guidance is as follows:

- “milk products”: includes whey, cream, cheese, butter, butter milk, butter oil, anhydrous milk fat, yoghurt, kefir, partly or wholly dehydrated milk products, caseins, caseinates and lactose;
- “composite milk-based products where no part replaces or is intended to replace any milk constituent”: includes products such as half-fat butter where all of the fat is dairy fat and the rest of the product is water, but not yellow fat spreads containing mainly butter plus a small amount of vegetable fat (since the vegetable fat replaces milk fat, which is a milk constituent);
- “milk or a milk product is an essential part either in terms of quantity or for characterisation of the product”.

Commission document VI/8972/93 helps to clarify the type of composite milk-based products that come within the scope of the Directive. The crucial factor is how the term “essential part” is defined, so that composite products that only contain a small proportion of milk or milk products are generally excluded, e.g. milk chocolate, biscuits containing butter, whisky cream. The document does not specify a minimum percentage of milk/milk product ingredients, but a guideline figure of 50% is inferred. A composite milk product may contain less than this amount if the ingredient is essential to characterise the product. Examples of composite milk products include dairy ice cream, custard and rice pudding. If a Food Authority is unclear as to whether a product is a milk-based product 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: Exemptions

Premises producing or handling dairy products solely for their own consumption, or premises that handle products solely for supply otherwise than by sale, are exempt from all provisions of the Regulations. Authorised officers should note, however, that “sale” has the extended meaning in Section 2 of the Food Safety Act.

Catering establishments and retail (shop) premises are exempt from all provisions of the Regulations except those relating to raw cows' drinking milk in Regulation 12, thermised cows' milk Regulation 9(8) and the heat-treatment of cream and ice cream in Schedule 6. This exemption is intended to cover premises such as cafés, caterers, shops, ice cream vans, and milk floats (and applies when they are selling direct to the ultimate consumer). The exemption also covers institutions such as prisons/schools that process milk/milk products for supply to inmates/pupils etc. The exemption for caterers and retail premises also applies to domestic or retail premises that supply the ultimate consumer through outlets such as markets operated by the Women's Institute or charities or to meals on wheels catering operations. Such exempt premises are, however, subject to the general provisions of the Food Safety (General Food Hygiene) Regulations 1995³⁸, and the Food Safety (Temperature Control) Regulations 1995³⁹.

A.6.6: Processors/Retailers of Raw Milk/Raw Milk Products

Regulation 3 provides that on-farm processors of raw drinking milk (i.e. those wrapping/packing/bottling raw milk) or producers of raw milk-based products made from raw milk produced on the farm premises who sell such products exclusively direct to the ultimate consumer (including from their own milk van) are exempt from approval.

However such premises need to meet the general hygiene requirements for processing establishments in Schedule 2 Part III of the Regulations and requirements in Regulation 13 on duties of occupiers (except for testing and record keeping requirements). Food Authorities are responsible for enforcing these requirements.

³⁸ as amended, SI1995/1763
³⁹ SI1995/2200

Processors selling to cash and carries etc. or to other retail outlets or to distributors that are a separate business must be approved.

The restrictions on sales of raw cows' drinking milk in Regulation 12 of the Regulations are enforced by the Dairy Hygiene Inspectorate at farm level.

Food Authorities are responsible for enforcing the requirements of Regulation 12 (3) in respect of sales of raw cows' drinking milk on milk delivery rounds and for enforcing the microbiological standards in Schedule 4, Part 1, Paragraph 2 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 under the general registration provisions of the Food Premises (Registration) Regulations 1991⁴⁰.

A.6.7: 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. Regulations 6, 9 and 17 cover derogations that Food Authorities may authorise, subject to there being no risks to product safety or public health. These include derogations for low capacity dairy establishments, long maturing cheeses and limited throughput production lines.

A.6.8: Establishments Processing Milk-Based Products

Under Regulation 6, Food Authorities may grant derogations from Part I and Section A of Part II of Schedule 2 on the approval of establishments that use less than 2 million litres of milk per year to make milk-based products.

Establishments that only produce liquid milk as the end product are not eligible for these derogations.

Food Authorities must consider each case on its merits, taking account of any potential risks to product safety or public health.

In order to qualify for these derogations, new businesses must apply in writing for approval as per Regulation 6, and either produce documentary evidence of the quantity of milk processed by the establishment in the previous year, or provide an undertaking that the quantity processed will not exceed 2 million litres per year.

Businesses that have been granted such derogations should be able to produce, when reasonably requested to do so, documentary evidence of the quantity of milk processed in the previous year.

A.6.9: Limited Production of Heat-Treated Drinking Milk

⁴⁰ as amended, SI1991/2825

Processors of limited production of heat-treated drinking milk are exempt from the requirement to mechanically fill and automatically seal containers, providing the alternative filling and sealing method is hygienic.

Under Regulation 2(1), limited production in relation to the production of heat treated drinking milk means production by means of a 'separate circuit' within any dairy establishment of no more than 2 million litres of milk per year. 'Separate circuit' is defined as production 'by means of separate equipment or installations, or in a clearly separate place or at a different time from the production of other dairy products, in that establishment'. Food Authorities may therefore grant exemptions for each production line or each production at separate times up to the 2 million litres limit, subject to there being no risks to product safety or public health.

A.6.10: Long Maturing Cheeses

Under Regulation 9(12), 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.6.11: Establishments Operating Without Approval

If an authorised officer becomes aware of an establishment handling dairy products that is not approved but should be, reference should be made to Chapter 5.1 of the Code of Practice.

A.6.12: Eligibility for Trade with Other Member States

Only products from approved establishments that bear an EC health mark in the statutory form (see below) can freely and legally be traded with other Member States.

A.6.13: Health Marking

Subject to the provisions in Regulation 15 (temporary derogations), all products or consignments from approved establishments must carry a health mark in the statutory form, regardless of whether they are intended to be traded on a national or on a Community basis.

The health mark must include the establishment's approval number allocated by the Food Authority, and the UK identification mark to enable the establishment to be traced. It is the responsibility of the occupier to ensure that the health mark is properly applied (Regulation 13(1)(e)), that products are not marked with a health mark when they are not entitled to be (Regulations 11(4) and 24(1)), and that they are not marketed without a health mark. Authorised officers should satisfy themselves that these requirements are met and that other precautions are taken to

avoid any confusion between dairy products that are eligible to be health marked and those that are not.

A.6.14: Certification of Products and Use of Commercial Documents

Authorised officers should periodically check that milk based products and bulk heat treated drinking milk are accompanied during transport by a commercial document (e.g. an invoice, consignment or delivery note) issued by the occupier of the last establishment, that includes the information specified in the Regulations.

Separate health certification of dairy products consigned to other Member States is not required. Certification requirements for dairy products exported to third countries remain subject to the requirements of the competent authorities of the importing countries.

Imports into the EU from third countries that are permitted to export milk or milk based products to the EU must be accompanied by the relevant health certification (see Regulation 22).

Premises receiving commercial documents should keep them for at least one year after receipt, or in the case of products that cannot be stored at ambient temperature, at least 6 months after expiry of the appropriate durability date of the product. Companies with several premises may retain commercial documents in a central point rather than at individual receiving premises. However, such documents must be available for inspection when individual receiving premises are subject to an inspection by an authorised officer.

Food Authorities may permit the electronic storage and exchange of commercial documents where they are satisfied that the arrangements to do so will maintain the required degree of product traceability. Such arrangements may include liaison with the Food Authority into whose area the documents will be received.

A.6.15: Testing for Residues, Raw Milk and Other Standards

Regulation 13(1)(b)(iii) requires appropriate testing for residues and Regulation 13(1)(b)(iv) and (vi) requires that samples are taken for checking compliance with raw milk and end product standards and that appropriate checks are carried out to detect the presence of added water by occupiers or first purchasers.

Occupiers or purchasers have to make their own judgement as to the frequency of checks and testing (except in the case of plate count and somatic cell counts standards in Schedule 3 where the frequency is laid down). In determining what level of sampling by operators is appropriate, Food Authorities should have regard to any advice issued by the Food Standards Agency or by LACORS.

Frequency should be based on risk assessment. In most cases, Food Authorities simply need to check records of tests that have been carried out by occupiers or purchasers. The extent of record keeping required under Regulation 13(1)(c) will depend on the frequency of testing. On-site or off-site laboratories are acceptable for undertaking analysis of samples, providing they are suitably equipped, competent,

and follow accepted techniques and practices to examine and analyse samples which are appropriate to the tests being undertaken. Accreditation of laboratories is not required at present but if they are accredited, it should be in respect of the type of analysis undertaken.

A.6.16: Imports of Dairy Products from the Community and Third Countries

Food Authorities should note that Regulations 9(13) and 11(2) exempt imported dairy products, unless they are subsequently handled in the UK, from certain requirements, such as the animal health rules, that apply to UK products under the Regulations. These requirements are enforced in the country of origin. Imported products are not exempt from storage, transport, labelling, or commercial documentation requirements.

Imported dairy products from third countries also require health certification.

Regulation 22 bans imports of cows' milk and cream, and permits imports of other dairy products from third countries only if they are listed in EC Decision 95/340 as amended and accompanied by appropriate health certification (see EC Decision 95/343 for models).

However, this Regulation will be amended by the Dairy Products (Import Conditions) Regulations when these come into force and implement EC harmonised rules for imports of dairy products from third countries. In the meantime authorised officers should accept imports of heat-treated and raw cows' milk for further processing and cows' cream pending amendment of the Regulations.

Because the Vertical Hygiene Directives apply throughout the European Union there are no restrictions on intra-Community trade, provided that the required identification marks and documentation are in order. Any checks carried out by authorised officers on imported products from other Member States, including sampling, must be non-discriminatory, i.e. the same checks and no greater frequency than for products originating in the UK.

A.6.17: Guidance on Schedules

A.6.18: Schedule 1 Conditions for Registration of Production Holdings

The requirements relating to the registration of production holdings are not enforced by Food Authorities in England and Wales.

N.B. The licensing of production holdings in Scotland is the responsibility of Food Authorities.

A.6.19: Schedule 2: Conditions for Approval of Dairy Establishments

Part I

General conditions of hygiene for Dairy Establishments

Potable Water

The requirement in Paragraph 1(g) for a supply of potable water may be a problem for some processors e.g. on farms where supplies may not, in all respects, meet the requirements of the Private Water Supplies Regulations 1991⁴¹. DoE Circular 24/91 (Welsh Office Circular 68/91) gives guidance to local authorities on their duties under these Regulations including action that should be taken to improve supplies. Authorised officers should consider tap variations when sampling water. Free chlorine in water samples needs to be inactivated before microbiological analyses are undertaken and authorised officers need to check that this is done. General queries on the Private Water Supplies Regulations in England may be sent to the DEFRA, Water Supply and Regulation Division, Zone 3/G21, Ashdown House, 123 Victoria Street, London SW1E 6DE. In Wales queries should be sent to the Environment Division of the National Assembly of Wales, 1st Floor, Cathays Park, Cardiff, CF1 3NQ.

Changing rooms

Under Paragraph 1 (h), a separate changing room will only be necessary where the size of the operation warrants it. For example, in a farm processing operation, facilities in a nearby farmhouse may suffice depending on the element of risk. Hand washing and toilet facilities do not have to be part of the changing facilities but must be reasonably accessible bearing in mind the scale and size of the establishment. Elbow operated taps or normal taps fitted with elbow-operated extensions are acceptable. Hand operated taps with an automatic cut off are also acceptable.

Storage of Detergents and Other Substances

The requirement in Paragraph 1(i) only relates to the storage of detergents, disinfectants and similar substances that may be hazardous. Substances may be stored in the same room as raw materials and dairy products are stored or processed, provided there is no risk of cross-contamination.

Working areas

The requirement in Paragraph 2(2) for separate working areas should be interpreted according to the nature of the operation. In most cases physical separation e.g. by walls, partitions, pipes etc. will be possible between different raw material/handling operations. However, in low risk operations clearly separated work areas in a single large space or time separation between processes may be acceptable, depending on the circumstances.

Flooring

Under Paragraph 2 (3)(a), flooring can be of any form provided it is waterproof. Suitable equipment should be available where residual water needs to be removed.

Walls

⁴¹ SI1991/2790

The requirement in Paragraph 2 (3)(b) for walls to be covered with light coloured coating should be interpreted as meaning that any colour that enables dirt, soiling and damage to be readily identified is acceptable. Coating can be of any appropriate form.

Washing facilities

The requirement in Paragraph 2 (3)(g) for adequate hand washing facilities relates only to working areas, not storage or office areas. Such facilities do not need to be physically located in working areas (depending on perceived risk) but must be readily accessible e.g. in a nearby farmhouse.

Part II

Special conditions for approval

Mechanical filling and automatic sealing

In Paragraph A2, the requirement for equipment for mechanical filling and automatic sealing of containers applies only in the case of heat treated drinking milk and liquid milk-based products (i.e. cream (excluding clotted cream), drinking yoghurt etc.) but not ice-cream. This is a requirement from which a derogation can be granted for low capacity establishments in respect of liquid products or limited production lines (in the case of heat-treated drinking milk). The requirement does not apply to churns, tanks (which should be interpreted as including "bag in the box" packs), or any container with a capacity of over 4 litres.

Cooling equipment

A record of thermometer calibration under Paragraph A3 can be kept in any form, e.g. written or on computer, providing it can be made available for inspection by authorised officers. The frequency of calibration should take account of any manufacturer's recommendations, and operators should have evidence that thermometers and other key equipment are reliable. If there is doubt, appropriate further checks may need to be made by the authorised officer.

Reusable Containers

In Paragraph A 4(b) 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.

Standardisation Equipment

The requirement in Paragraph A5 for standardisation equipment and containers for storing standardised milk will only apply when an establishment produces standardised milk i.e. whole milk which has had its fat content adjusted as allowed under EC Regulation 2597/97.

Milk purification equipment

Filters, clarifiers and centrifuges are acceptable for removing impurities from milk under Paragraph A 6 and Sections B and C.

Heat treatment equipment

The requirements in Paragraph A 7(1)(a) should not be applied to batch pasteurisers. Alternative heat treatment equipment (including batch pasteurisers) is acceptable provided hygiene requirements are met. Food Authorities are not required to give written authorisation but should do so whenever possible.

Heat treatment is a critical control point under Regulation 13(1)(b) and operators will need to have reliable means of monitoring its effectiveness. It is recommended practice that all equipment for heat-treating milk should be properly calibrated and that the temperature shown on the thermographs should match the temperature on a certified accurate indicating thermometer. Frequency of checks by operators will depend on use but operators should have evidence that equipment is functioning correctly and retain thermograph records. The failure of an operator to control heat treatment or maintain corresponding records should be viewed as a serious matter. If authorised officers are concerned about the efficiency or effectiveness of heat treatment equipment and/or occupiers' records they should undertake their own further checks.

Part III

General Conditions of Hygiene

Exclusion of Animals

Under Paragraph A(1) "animal" should be interpreted as including pests such as insects, birds and vermin as well as cats and dogs and farm animals.

Equipment used for other products

Under Paragraph A4 working areas, instruments and equipment may be used for work on other foodstuffs or other milk based products fit for human consumption but intended for non-food use, e.g. casein for industrial purposes, at the discretion of the authorised officer.

Disinfectants

Under Paragraph A12 any disinfectants that are suitable for use with foodstuffs and effective when used in accordance with the manufacturers' instructions should be regarded as acceptable.

A.6.20: Schedule 3 Requirements for Raw Milk

Part I

Animal Health Standards

Regarding requirements in Paragraph 1, producers are responsible for ensuring that these are met through private veterinary inspections at regular intervals (frequency dependent on circumstances). Such inspections can take place when a farmer's private veterinary surgeon is present for other purposes. Producers 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. Food Authorities retain powers to serve Heat Treatment Notices under Regulation 20 of the Milk and Dairies (General) Regulations 1959⁴² where appropriate.

Requirements in Paragraph 2 (a) (tuberculosis and brucellosis in cows and buffaloes) and Paragraph 2(c) (brucellosis in goats and sheep), are administered by Agriculture Departments. Where animals do not meet these requirements, milk has to be heat treated if it is to be sold for human consumption (see Regulation 9 (10)). Food Authorities have the power to serve Heat Treatment Notices where appropriate, as indicated.

Part II

Raw milk standards

Added Water

The prime responsibility for checking for added water rests with occupiers of establishments or first purchasers who may continue to use established methods for doing this such as BS 3095. However, the Regulations no longer deal with added water checks in respect of cows' drinking milk.

Authorised officers will need to check records kept by occupiers or first purchasers and also undertake spot checks to ensure that water is not being added to raw milk. In the case of milk delivered from several holdings spot checks need to be carried out on the holdings. If an initial check indicates that water may have been added, authorised officers will need to take an authentic sample i.e. at the point of

⁴² as amended, SI1959/277

production on the holding(s) representing the milk of one morning and/or evening's milking. If this shows that water is being added, they should consider appropriate action.

Other standards

In the case of the standards laid down in Paragraph 2 for plate counts and somatic cell counts, the Regulations specify a minimum frequency of sampling by the operator/purchaser. Authorised officers need to ensure that operators/purchasers are carrying out the specified sampling programme except in the case of standards for plate count in Paragraphs 2(c) and (d) (raw goats', ewes' or buffaloes' milk) where officers may allow more infrequent sampling by operators provided they are satisfied with the standards being achieved. In respect of other standards, operators/purchasers need to draw up their own risk-based sampling programmes and perform random checks to satisfy themselves that the required standards are being met. Authorised officers should check operators'/purchasers' records, and when they have concerns about the test results, consider random official checks to satisfy themselves that the required standards are being met.

Paragraph 4 requires the somatic cell count standard to be checked when the milk is collected from each production holding. Each purchaser should keep records of the counts of milk intake and take at least one sample per month from the milk of each production holding. Two samples per month should also be taken to check plate counts. From this data the dairy/purchaser should calculate the three-month geometric mean in respect of somatic cell counts and the two-month geometric mean in respect of plate counts, and notify the producer's Food Authority when the geometric mean exceeds the standards for somatic cells or plate counts.

Council Directive 92/46/EEC is ambiguous about the action to be taken when these standards are breached. In the absence of further clarification from the Commission, the following interpretation should be adopted.

If the standards are breached, dairies/purchasers have to resolve problems with individual producers during the following three-month investigation period. During this period, the dairy/purchaser should advise the producer that the standards have been exceeded, of the consequences of continuing to exceed the standards by the end of the 3 month period, and that local enforcement officers may carry out some investigations. The producer should also be advised about sources of guidance on how to improve results. The dairy/purchaser should also monitor subsequent individual sample results closely and keep the producer informed. However, if the milk from the production holding continues to fail the standards at the end of the three-month period, then the dairy/purchaser must not accept any more milk from that production holding. If the producer subsequently provides evidence to the satisfaction of the dairy/purchaser and the Food Authority that the standards are being met, then the dairy/purchaser may resume taking supply from that producer.

When Food Authorities are notified that the plate count and/or somatic cell count limits have been exceeded, they should consider whether the milk sold from that production holding constitutes a health risk (regardless of the fact that the three-month investigation by the dairy/purchaser will be in train). In particular Food

Authorities should liaise with the dairy/purchaser about the individual sample results that contributed to the failure, and subsequently, and liaise with the DHI about hygiene standards at the production holding. The intended treatment/processing of the milk, and its intended end use, should be taken into account. Many producers resolve problems quickly when alerted to issues about meeting the standards and thus there may be instances where the Food Authority's consideration results in no formal action at all. Somatic cell counts in excess of 400,000 per ml do not necessarily indicate a health risk, but if very high levels of somatic cell counts or total bacterial counts (TBCs) continue to be recorded, the need for formal action by the authorised officer must be considered.

A Heat Treatment Notice may be served where there is evidence or reasonable grounds for suspecting that any person has been infected or is ill as a result of consuming milk, or that milk is contaminated.

Statutory action should normally be considered if there is a serious risk to human health, e.g. if pathogenic micro-organisms are found in ready-to-drink milk that will not be subjected to further heat-treatment. This statutory action may be taken at any time, including before the end of the three-month investigation period. If standards continue to be breached at the end of the three-month period, the Food Authority should check records held by the dairy/purchaser to ensure that milk is not collected from that production holding until there is evidence that the standards are met.

In undertaking sampling authorised officers should take account of provisions of the Food Safety (Sampling and Qualification) Regulations 1990⁴³ as well as Section 6 of the Code of Practice

A.6.21: Schedule 4 Requirements for Drinking Milk

In the case of a failure of heat treated drinking milk to meet the requirements for plate count at 21°C per ml after incubation in Part III Paragraph (c), authorised officers should only consider taking enforcement action if there has also been a failure of the requirements for coliforms (or possibly the phosphatase test) as the plate count at 21°C test is known to be unreliable. They should bear in mind particularly the need to ensure that heat treatment carried out by operators is effective.

The requirements in Part I Paragraph 2 apply before and after packing (wrapping) to raw cows' milk sold at the farm gate or used for farmhouse catering, and to raw goats' and ewes' milk sold to the ultimate consumer or to other outlets. The DHI enforces standards relating to raw cows' drinking milk on the farm premises. Food Authorities are responsible for enforcement of standards relating to raw goats' and ewes' milk and for the standards at Part I Paragraphs 1 & 2 that are applicable to raw cows' drinking milk after packing (wrapping) at the farm and during delivery to the doorstep. The plate count standard of 20,000 applies to raw cows' drinking milk at the farm, whereas that for 50,000 at 30°C per ml applies during delivery. The standards for *Staphylococcus aureus* and *Salmonella spp* and the requirement

⁴³ SI1990/2463

for the milk to be free of pathogens at harmful levels apply to all raw cows' drinking milk after packing (wrapping) at the farm and during delivery.

A.6.22: Schedule 5 Requirements for Milk Used for the Manufacture of Milk-based Products

In Paragraph 1 the acceptability of raw milk applies from the arrival of the milk at the processing area of farm premises. 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 approving authority is required whenever it is anticipated that these times will be exceeded.

The Regulations do not require such authorisations to be made in writing but Food Authorities are encouraged to do so whenever practicable.

In addition to other records required under Regulation 13(1)(c) establishments are required to keep records of data produced by recording thermometers in respect of manufacture of dairy products for a period of 2 years (or for 2 months in the case of products that cannot be stored at ambient temperature) and authorised officers should refer to these to check that treatment of milk has been carried out correctly. They should also check that temperature recording devices are properly calibrated.

A.6.23: Schedule 6 Requirements for Milk-based Products

Part I

Microbiological criteria

Operators are required to carry out their own checks in accordance with Regulation 13 to demonstrate that their production meets the required standards. Authorised officers should encourage businesses to draw up sampling programmes that are related to the scale of the operation and the risk associated with the product.

Authorised Officers should check records of tests carried out by operators and if they have concerns about the test results or about the hygiene of the operation as a whole, they should carry out further checks as necessary, following the sampling plans laid down in the Schedule (i.e. n, c, m, M). Authorised officers should contact their Food Examiner if they need advice on organisms that might be classed as pathogenic.

Food Authorities should advise operators that they must take remedial measures without delay where they encounter problems in meeting standards. In cases where there is immediate danger to human health or failure to meet standards for *listeria*, *salmonella*, or coliform guidelines, operators should notify food Authorities and discuss appropriate action, including withdrawal procedures. Authorised officers should investigate as necessary, and if there is a potential danger to human health arising from the operation as a whole, take appropriate enforcement action.

Authorised officers should also advise operators of the guidelines for indicator organisms which should help them in ensuring proper operation of their establishments and in carrying out checks on their products (see Appendix). It should be noted that, as these are only guidelines, certain products within the categories may not meet the standards mentioned.

Part II - VI

These requirements relate to heat treated cream made from cows' milk and dairy ice cream made from cows', goats', ewes' and buffaloes' milk. They apply to any premises selling or handling heat treated cream and dairy ice cream, including retail premises such as catering establishments and ice cream vans. Heat treatment requirements for non-dairy ice cream are covered by the Ice Cream (Heat Treatment) Regulations 1959⁴⁴. There may be a problem under the Regulations with the time-temperature process applicable to UHT ice-cream. If this occurs, some flexibility may be permitted in respect of the time-temperature requirements in this Schedule, providing the alternatives give equal assurances in terms of product safety and public health.

Regarding sampling see comments under Schedule 3.

Regarding methods of analysis see comments under Schedule 11.

A.6.24: Schedule 7 Storage Requirements

Paragraphs 1 and 2 relate to storage conditions on a production holding which are part of registration conditions. Registration conditions are enforced by the DHI. Authorised officers should liaise with the DHI particularly in cases where operators wish to derogate from temperature requirements for technological reasons, since Food Authorities need to agree this.

Temperatures in Paragraphs 3 to 7 apply at treatment establishments. In addition the requirements at Paragraphs 5 and 6 relate to storage at premises other than treatment establishments, including storage/distribution depots, cash and carries and wholesalers. The requirement for storage temperatures to be registered could be met through records on a computer or in any other form bearing in mind the nature and scale of the operation.

A.6.25: Schedule 8 Transport Requirements

Part I

Temperature

Doorstep deliveries and other products sold at retail are not covered by the temperature requirements of the Regulations.

⁴⁴ SI1959/734

Part II

Hygiene

These requirements do not apply to deliveries direct to consumers. Precise frequency for cleaning of tanks/containers in Paragraph 3 will depend on the circumstances of the operation and its size. Authorised officers may wish to undertake spot checks to ensure that adequate cleaning is taking place.

Part III

Commercial Document

The requirement for certain products to be accompanied by a commercial document giving specified details applies only to products transported in bulk e.g. by tanker. It does not apply to deliveries direct to consumers. The document can be an invoice/advice note or any other document (in original or copy form). As UK approval numbers indicate the approving authority by virtue of the LA prefix, there are likely to be very few cases where information in Paragraph 1(d) will need to be indicated.

Where a consignment is subsequently split into separate consignments, a copy of the commercial document must accompany each consignment. Requirements relating to retention of commercial documents in Regulation 11 are not applicable to retail outlets as they are outside the scope of the Regulations.

A.6.26: Schedule 9 Wrapping and Packaging

Wrapping and packaging may take place in the same room as processing, providing there is no risk of contaminating the products. In addition, designated areas within the same room for wrapping, packaging and storage will be acceptable particularly in the case of small-scale establishments.

In Paragraph 3(b) the requirement for wrapping and packaging to be brought to the establishment in a protective cover would not apply to returnable glass bottles brought back to an establishment on milk floats (although such bottles would need to be stored so as to prevent contamination).

In Paragraph 3(d) automatic assembly of packaging would include on line assembly of aseptic packaging. In some small scale establishments packaging is only assembled when brought into the packaging area and authorised officers should allow this to continue provided that assembly is undertaken hygienically.

The requirement in Paragraph 3(e) that staff may not handle both packaging and unwrapped products will be difficult for small-scale establishments with only a few staff. In such cases staff should be allowed to continue with both activities provided authorised officers are content that effective precautions are being taken to prevent contamination of products.

In Paragraph 3(f) the requirement does not apply to products which undergo further processing after packaging e.g. blast chilling/blast freezing.

There is an exemption from the requirement in Paragraph 4 for sealing of containers of certain products to be carried out automatically in the case of limited production of heat treated drinking milk providing there is no risk to public health. In addition automatic sealing is not required for churns, tanks, or containers of over 4 litres.

A.6.27: Schedule 10 Labelling and Health Marking

Milk or milk products on retail sale or delivered to the ultimate consumer are not required to carry the additional labelling requirements or health mark information prescribed in the Regulations. Reference should be made to the Food Labelling Regulations 1996⁴⁵ (the labelling Regulations) for details of labelling requirements of such products at retail level.

However, the labelling and health marking requirements will apply to milk and milk products that are delivered to such retail premises.

Part I

Labelling

Details regarding the enforcement responsibilities in single and two-tiered Food Authorities can be found in Chapter 1.1 of the Code of Practice.

In Paragraph 1 the lot mark or 'use by' or 'best before' date could be used to establish the date of heat treatment required under sub paragraph (b). There is an exemption from these requirements for reusable glass bottles. Note that in this Paragraph and in Paragraph 3 the labelling particulars need only be indicated on packaging (i.e. the outer box).

Part II

Health mark

Paragraph 2 means that in the case of small portions e.g. triangles of cheese in a circular box, the health mark need only be applied to the box itself. Where this product is subsequently put in further packaging e.g. a larger cardboard box, the health marks must also be applied to that box. Reference to small packaged units is interpreted to mean products the largest surface of whose packaging has an area of less than ten square centimetres, in accordance with provisions in the labelling Regulations. Individual ice creams e.g. choc ices would not need to be health marked.

In Paragraph 3, it should be noted that packaging does not include crates, wheeled trolleys or plastic trays. Also if the packaging is of a shrink wrap type and the health mark on the wrapping is visible through the shrink wrap, it is not necessary for the packaging to be health marked.

⁴⁵ as amended, SI1996/1499

In Paragraph 4, "UK" would be acceptable instead of United Kingdom in option (b) when a product is sold in the UK market. Under option (c) the approval number can be placed outside the oval health mark provided there is a reference in the mark to the place where the number can be found e.g. "for approval number - see base". "EEC" should be replaced by "EC" when new packaging is ordered.

In Paragraph 5 the abbreviated form of health mark allowed for here would apply to small packages or bottles of 10 cm² or less.

The health mark may be applied directly to the product, the wrapping or the packaging, be printed on a label affixed to the product, the wrapping or the packaging, or be pre-printed on the wrapping or packaging. The health mark may also be on an irremovable tag. For products in transport containers, intended for further processing and products that are not wrapped and packaged, but are sold in bulk directly to the retailer, the approval number may be on the external surface of the container. It would be acceptable to place a health mark on any part of a product e.g. the base provided it is visible for inspection purposes. In the case of operations that arrange packaging centrally it would also be acceptable for a number of approval numbers to be pre-printed within a health mark and for the numbers that are not applicable to be deleted. Health marks can be of any size or produced in any form e.g. embossed provided they and the details they contain are indelible and legible.

A.6.28: Schedule 11 Methods of Analysis

Schedule 11 lays down the reference methods of analysis for the standards given in the Regulations. It can be seen that there are no reference methods for the peroxidase test or phosphatase test for non-bovine milks. This is because reference methods are not available. Where no reference methods have been laid down, internationally accepted methods should be used.

Occupiers and purchasers can continue to use other methods of analysis that are not internationally recognised for routine quality purposes. (For example the goat milk industry uses the modified phosphatase test as published by D J Williams in 1986 "A modification to the Aschaffenburg and Mullen Alkaline Phosphatase Test suitable for Goats' Milk; Australian Journal of Dairy Technology 41, 28").

Authorised officers may also use routine methods of analysis that are not internationally recognised. However any legal action taken by Food Authorities should be based on the results of reference methods laid down in Schedule 11 or other internationally accepted methods of analysis. For cream, the test described in AOAC Official Method 950.41: Official Methods of Analysis, 16th edition should be used for detection of phosphatase (residual) in the first instance. In the case of a positive result being obtained AOAC Official Method 965.27: Official Methods of Analysis, 16th edition should be used for confirmation purposes.

However, the test for detection of phosphatase (residual and reactivated) AOAC Official Method 965.27: Official Methods of Analysis, 16th edition shall be used for products heat-treated by unconventional methods, those with high fat contents or

when reactivated phosphatase is otherwise suspected of being present. In relation to milk, the test for the detection of phosphatase specified in Decision 91/180/EEC may not be suitable for goats', ewes' and buffaloes' milk without undertaking prior evaluation of the method.

When undertaking analysis and testing of milk-based products Food Authorities should take account of International Dairy Federation (IDF) standard 122B: 1992 Milk and Milk Products method of preparation of samples and dilutions and IDF standard 5OB: 1985 Milk and Milk Products - method of sampling.

A.6.29: APPENDIX

Indicator organisms: guidelines

Type of micro-organism	Product	Standard (ml/g)
- Coliforms 30°C	Liquid milk-based products	m = 0 M = 5 n = 5 c = 2
	Butter made from pasteurised milk or cream	m = 0 M = 10 n = 5 c = 2
	* Soft cheese (made from heat-treated milk)	m = 10,000 M = 100,000 n = 5 c = 2
	Powdered milk-based products	m = 0 M = 10 n = 5 c = 2
	Frozen milk-based products (including ice-cream)	m = 10 M = 100 n = 5 c = 2
- Plate count 30°C	Frozen milk-based products (including ice-cream)	m = 100,000 M = 500,000 n = 5 c = 2

* It is a commonly held view of both cheesemakers and the dairy industry in general that 'fresh' cheese is a sub-category of 'soft cheese' as defined in Dairy Industry Federation guidelines i.e. 'Fresh' cheese is a soft cheese which is not subject to a maturation period (i.e. unripened) and, in this sense, is classed as fresh whilst other 'soft' varieties are ripened, usually by the growth of micro-organisms or surface moulds (e.g. Brie, Camembert).

Ripened varieties of soft cheese do not necessarily have to be matured for months to be classed as 'soft' and the ripening may, typically, be only of 3-4 weeks duration e.g. Camembert can be ripened in just four weeks.

ANNEX 7: SHELLFISH

A.7.1: Introduction

This Annex provides specific guidance to Food Authorities on the application and enforcement of the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998 as amended (the Regulations) as they apply to live shellfish. The Regulations implement Council Directives 91/492/EEC (as amended by Council Directive 97/61/EC), 91/493/EEC (as amended by Council Directive 95/71/EC), and 92/48/EEC, which lay down the health rules for the production and placing on the market of live bivalve molluscs, fish caught by fishing vessels, and fishery products intended for human consumption, and Council Directive 96/43/EC relating to the financing of hygiene inspections of fishery products.

Guidance on fishery products, wholesale & auction markets, and fish caught by fishing vessels is contained in Annex 3.

A.7.2: 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.7.3: The Local Market Exemption

Regulation 20 exempts coastal fishermen from the requirement of parts of Regulation 19, if they only deal with small quantities of molluscs or other shellfish harvested from Class A areas. This exemption only applies when the coastal fisherman has provided the Food Authority with the information required by Regulation 20(2). A coastal fisherman may include a farmer or grower of shellfish.

Products which are exempt from the requirements of part of Regulation 19 because of the 'local market' provision must still meet the end product standard set out in Chapter V of Schedule 2 to the Regulations.

A.7.4: 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 the Regulations 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 Schedule 2 Chapter 1, Parts 2 and 3 of the Regulations.

A.7.5: Classification of Harvesting Areas

Classifications are made in accordance with Regulation 3 and Schedule 32, Chapter I of the Regulations. Areas may be designated “Class A areas”, “Class B areas” or “Class C areas”. Live bivalve molluscs may only be produced from designated bivalve production areas. Marine gastropods, echinoderms, tunicates and scallops that are not farmed, are not subject to the classification requirements and may be taken from any waters, providing the waters have not been designated as prohibited areas under Regulation 4 or, depending on the terms, subject to Temporary Prohibition Orders. They are subject to the end product standard in Schedule 2, Chapter V.

Live bivalve molluscs taken from Class A areas may be placed directly on the market through approved dispatch centres. Special controls exist for molluscs taken from Class B or C areas and the details are given in the Regulations.

Chapter VI Schedule 2 also requires a Food Authority to undertake periodic monitoring of relaying and production areas. Providing the data from this sampling to the Food Standards Agency will assist in the continuing review of classifications.

A.7.6: Shellfish Liaison Arrangements

The Food Authority’s shellfish liaison officer will be the Food Standards 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 Public Health Laboratory Service (or a representative of the microbiology laboratory used by the Food Authorities if it is not a PHLS 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.7.7: Notification of Production Areas and Relaying Areas

The Food Standards 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.

Some information issued to Food Authorities by Central Government about production areas may be sensitive commercial information and this should be treated in strict confidence. In England and Wales, DEFRA will indicate to Food Authorities information that is likely to be commercially sensitive.

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 Food Standards 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.7.8: Monitoring of Relaying Conditions and Procedures

The primary responsibility for monitoring relaying conditions rests with operators, having regard to conditions for relaying that have been laid down by the Food Authority. Operators of relaying areas are required to keep records detailing the source of the molluscs, relaying periods, relaying areas used and the subsequent destination of batches after relaying. After harvesting from the relaying area, batches of molluscs must be accompanied by a movement document during transport to the approved dispatch centre, purification centre or processing plant. A permanent transport authorisation (PTA) may be used where the same staff operate both the relaying area and the approved centre or establishment to which the molluscs are transported.

A.7.9: Monitoring of Movement 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.

Since it is an offence for a gatherer to include false or misleading information on a movement document, Food Authorities may find that an appropriate system of monitoring is to take samples and to consider the test results against the standards prescribed in Schedule 2, Chapter V of the Regulations.

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.7.10: Sampling by Operators

Regulations 13 and 19 with Chapters IV and V of Schedule 2 to the Regulations requires operators of purification centres to undertake microbiological tests on shellfish and water entering purification tanks.

Operators of approved dispatch centres must also have adequate laboratory arrangements to ensure that the shellfish comply with the microbiological standards of Chapter V of Schedule 2.

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 Central Government or contained in voluntary guidelines produced by relevant trade associations.

A.7.11: Laboratories Used in Connection with Dispatch or Purification Centres

Laboratories used by operators of dispatch or purification centres to examine samples to meet their obligations under Schedule 2, Chapter IV Sections III and IV of the Regulations must be recognised by the Food Authority. The laboratory may be directly associated with the approved centre, or may be a PHLS, Food Examiner, or any other appropriate laboratory.

However, recognition by the Food Authority will be dependent on the laboratory using methods for microbiological examination that are acceptable to the Food Standards 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.

A.7.12: 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.7.13: Information on Standards to be Applied

Information on the standards required by the Regulations may be found in “Guidelines for the facilities required for Handling Bivalve Molluscs from Harvesting through to Distribution to Retail Outlets” published by the Sea Fish Industry Authority (SFIA). These guidelines have been drawn up with the co-operation of various sections of the trade, enforcement bodies and Government Departments. They 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 guidelines make recommendations for good industry practice which go beyond the requirements of legislation.

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.7.14: Molluscs and Other Shellfish Which Fail to Satisfy Requirements

Regulation 57 enables a Food Authority to certify any live shellfish that have not been handled etc in accordance with the Regulations as failing to meet the requirements of the Regulations. Products that have been certified under Regulation 57 may be treated as failing to comply with Section 9 of the Food Safety Act 1990 and may be seized and taken before a magistrate 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.7.15: 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.7.16: Areas Prohibited for Bivalve Mollusc Production

Any production area which has not been designated "Class A area", "Class B area" or "Class C area" may not be used for commercial bivalve mollusc production for human consumption (see also Regulation 19). The Agency may also designate any area as prohibited for shellfish production (Regulation 4).

A.7.17: Temporary Prohibition Orders

A Food Authority may make a temporary prohibition order under Regulation 7 to prohibit the collection of any live shellfish from that 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 (Schedule 2 Part I, Chapter V refers).

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 PHLS.

The procedure the Food Authority should adopt after making a temporary prohibition order varies according to whether the area affected by the order is a private or public laying (Regulation 7(3)).

A.7.18: Control of Shellfish Disease – Movement of Shellfish

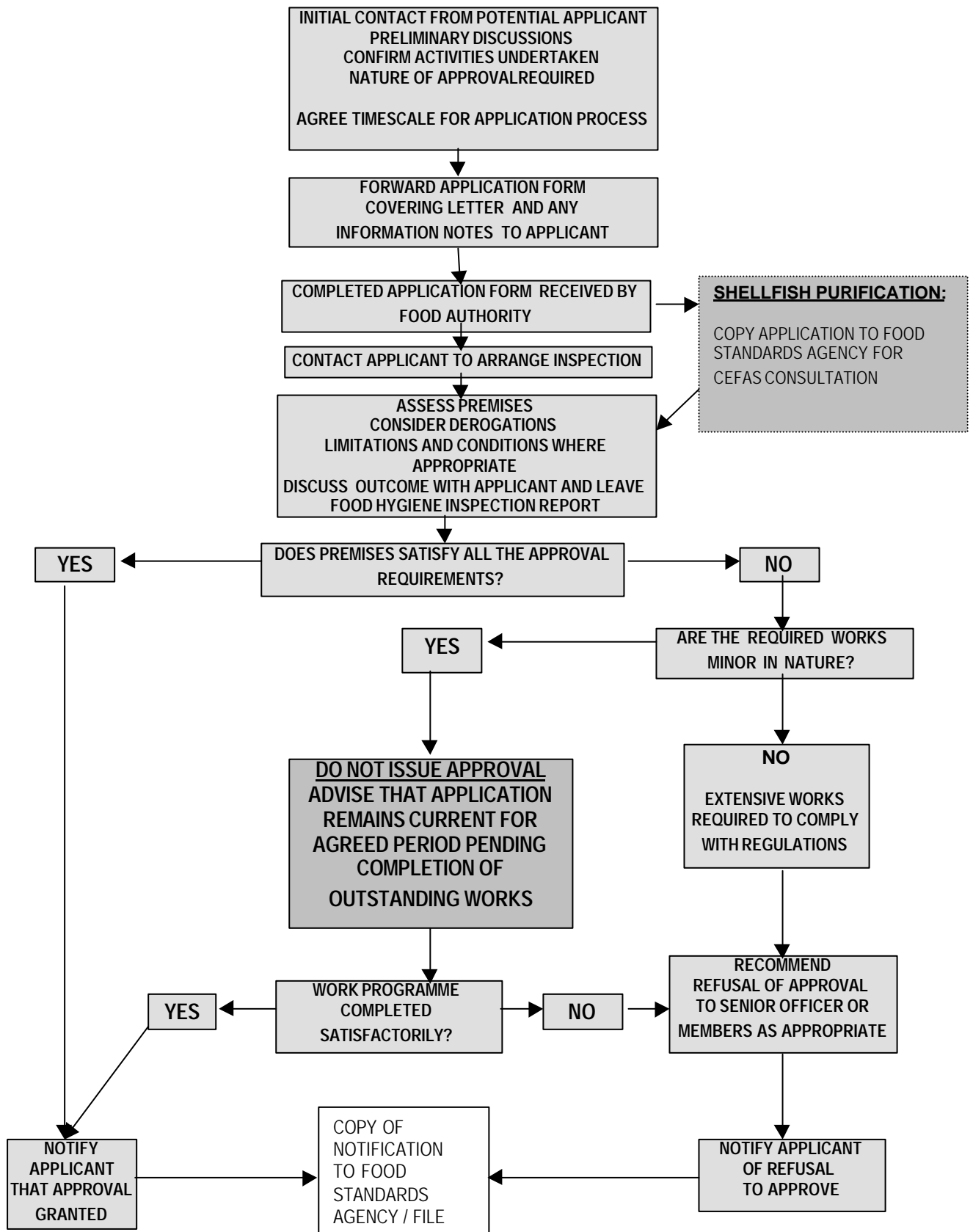
The Fish Health Regulations 1997⁴⁶ are designed to prevent the introduction into Great Britain of serious molluscan shellfish disease, and therefore prohibit the movement of certain shellfish species for relaying in Great Britain from areas that do not have equal or higher shellfish health status.

These Regulations also prevent the relaying of any live molluscs originating from coastal areas in Cornwall, Dorset, Hampshire, Suffolk and Essex. CEFAS enforces these Regulations on behalf of DEFRA.

⁴⁶ SI 1997/1881

ANNEX 8: APPROVAL PROCESS

A.8.1: APPENDIX 1 - Flow Chart for Approval of Product-specific Premises



A.8.2: APPENDIX 2 - Approval Application Templates⁴⁷

[NAME OF FOOD AUTHORITY]

Meat Products (Hygiene) Regulations 1994, as amended

Application for Approval of Stand Alone Meat Products Establishment

Please complete this form in BLOCK LETTERS and return it to the approval authority at the address given at the end of the form.

PART 1 - DETAILS OF PREMISES

1.	Trading name of premises			
	Full postal Address			
		Postcode:		
	Tel. No.		Fax No.	
	Name of applicant			
	Position in business			
	Name of contact			
	Position in business			
2.	If appropriate, Name and full Address of parent Company			
		Postcode		

PART 2 - MANAGEMENT DETAILS (Continue on separate sheet if necessary)

3.	Names of Directors	1.	2.	3.
	Full postal Address			
	Postcode:			
4.	Names of Managers	1.	2.	3.
	Job Title			

⁴⁷ For the purposes of consultation, comments on the content of these templates are welcome, but they will be redesigned prior to publication so comments on the format are unnecessary

5. Names of Controllers	1.	2.	3.
Job Title			

PART 3 - TYPE OF PREMISES

6. Please indicate by ticking the appropriate box(es), **all** the activities which apply to your business, and giving the approximate quantities handled in kilograms per week

- (a) Handling meat products
- (b) Handling meat products containing 10% or less meat
- (c) Handling meat products in hermetically sealed Containers which have been heat-treated (e.g. cans)
- (d) Handling meat-based prepared meals
- (e) Re-wrapping or assembling meat products
- (f) Ambient store for the storage of unpackaged meat products
- (g) Handling Other Products of Animal Origin ie Tripe
- (h) Detached cold store for the storage of unpackaged meat products

PART 4 – TRADING DETAILS

7. Which of the following best describes your business?

- a) Retailer
- b) Market Stall
- c) Manufacturer
- d) Cash and Carry
- e) Distributor
- f) Other

8. Who do you (or intend to) supply with meat products?

- a) Members of the public direct from the premises where meat products are manufactured
- b) Retail premises (including ones in your own ownership).....
- c) Caterers.....
-

d) Distributors.....

d) Other (Please specify.....)

9. Please indicate the total volume of meat products that you intend to produce:

> 7.5 tonnes/week < 7.5 tonnes/week

10. Other activities carried out on the same site

	YES	NO	EC APPROVED	APPROVAL NUMBER
(a) Are premises licensed for Slaughter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Fresh meat cutting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Storage of fresh meat?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Are the following products handled				
(b) on the premises? meat preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
(c) Fishery products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
(d) Milk products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
(e) Egg products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

11. How are meat products transported from the premises?

- (a) Own transport
- (b) Haulier
- (c) Purchaser's own vehicle
- (d) Other

12. In order to assist the approving authority in its determination of your application you are required to provide relevant documentation (see accompanying information notes). Please indicate in the Schedule attached those documents which accompany this application.

Signature	<input type="text"/>	Date	<input type="text"/>
Name in BLOCK LETTERS	<input type="text"/>	Position in Company	<input type="text"/>

Please advise the authority of any subsequent changes to the information given on this form

Please send the completed form to: **[Chief Environmental Health Officer/ Director of Environmental Health]**
[Name and address of Food Authority]

Meat Products (Hygiene) Regulations 1994, as amended

Application for Approval of Stand Alone Meat Products Establishment

SCHEDULE – DOCUMENTS SUBMITTED WITH APPLICATION

Please indicate, by ticking the appropriate box(es), which of the following documents accompany this application:

- A scale plan of the (proposed) premises
- A description of the (proposed) meat product operations
- A description of the (proposed) arrangements for the maintenance of premises and Equipment
- A description of the (proposed) arrangements for cleaning of premises, equipment , utensils And transport
- A description of the (proposed) arrangements for the collection and disposal of solid waste ---
- A description of the (proposed) water supply to be used in the premises
- A description of the (proposed) arrangements for testing the quality of the water supply -----
- A description of the (proposed) arrangements for testing product
- A description of the (proposed) arrangements for controlling pests
- A description of the (proposed) arrangements for monitoring staff health
- A description of the (proposed) arrangements for the hygiene training of staff
- A description of the (proposed) arrangements for record keeping
- A description of the (proposed) arrangements for applying the health mark or regional mark to product, wrapping and packaging as appropriate
- Other documents, please specify:
-
-
-
-
-

[NAME OF FOOD AUTHORITY]

Minced Meat and Meat Preparations (Hygiene) Regulations 1995, as amended

Application for Approval of Stand Alone Minced Meat or Meat Preparation Establishment

Please complete this form in BLOCK LETTERS and return it to the approval authority at the address given at the end of the form.

PART 1 - DETAILS OF PREMISES

1.	Trading name of premises			
	Full postal Address			
		Postcode:		
	Tel. No.		Fax No.	
	Name of applicant			
	Position in business			
	Name of contact			
	Position in business			
2.	If appropriate, Name and full Address of parent Company			
		Postcode		

PART 2 - MANAGEMENT DETAILS (Continue on separate sheet if necessary)

3.	Names of Directors	1.	2.	3.
	Full postal Address			
	Postcode:			
4.	Names of Managers	1.	2.	3.
	Job Title			
5.	Names of Controllers	1.	2.	3.
	Job Title			

PART 3 - TYPE OF PREMISES

6. Please indicate by ticking the appropriate box(es), **all** the activities which apply to your business, and giving the approximate quantities handled in kilograms per week

<input type="checkbox"/>	(a)	Production of minced meat	<input type="checkbox"/>
<input type="checkbox"/>	(b)	Production of meat preparations	<input type="checkbox"/>

Please indicate other types of foodstuffs, including fresh meat, handled or stored at your premises

PART 4 – TRADING DETAILS

7 Where will your products be sold?

a) National market only	<input type="checkbox"/>
b) To EEA States (15 countries of the European Union, plus Iceland, Norway and Liechtenstein)	<input type="checkbox"/>

8 Trading activities: which of the following best describes the customer base for your products (tick more than one box if appropriate)?

(a) Wholesale/Cash & Carry	<input type="checkbox"/>
(b) Retail supply	<input type="checkbox"/>
(c) Sales direct from your premises	<input type="checkbox"/>
(d) Catering supply	<input type="checkbox"/>
(e) Sales direct to takeaway premises	<input type="checkbox"/>
(f) Other (please specify)-----	<input type="checkbox"/>

PART 4 - CONTINUED

9. Please indicate the total volume of Minced Meat, Meat Preparations and Meat Products that you intend to produce:

> 7.5 tonnes/week	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
-------------------	--------------------------	--------------------------	--------------------------

10. Other activities carried out on the same site.

	YES	NO	EC APPROVED	APPROVAL NUMBER
(a) Are premises licensed for				
Slaughter,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Fresh meat cutting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
storage of fresh meat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
(b) Are the following products handled on the premises?				
Fishery products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Milk products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Egg products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

Signature	<input type="text"/>	Date	<input type="text"/>
Name in BLOCK LETTERS	<input type="text"/>	Position in Company	<input type="text"/>

Please advise the authority of any subsequent changes to **the information given on this form**

Please send the completed form to:

[Chief Environmental Health Officer/ Director of Environmental Health]
[Name and address of food authority]

Minced Meat and Meat Preparations (Hygiene) Regulations 1995, as amended
Application for Approval of Stand Alone Minced Meat and Meat Preparation Establishments

SCHEDULE – DOCUMENTS SUBMITTED WITH APPLICATION

Please indicate, by ticking the appropriate box(es), which of the following documents accompany this application:

- A scale plan of the (proposed) premises
- A description of the (proposed) minced meat/meat preparations operations
- A description of the (proposed) arrangements for the maintenance of premises and Equipment
- A description of the (proposed) arrangements for cleaning of premises, equipment , utensils and transport
- A description of the (proposed) arrangements for the collection and disposal of solid waste ---
- A description of the (proposed) water supply to be used in the premises
- A description of the (proposed) arrangements for testing the quality of the water supply -----
- A description of the (proposed) arrangements for compositional testing of product -----
- A description of the (proposed) arrangements for controlling pests -----
- A description of the (proposed) arrangements for monitoring staff health -----
- A description of the (proposed) arrangements for the hygiene training of staff -----
- A description of the (proposed) arrangements for record keeping -----
- A description of the (proposed) arrangements for applying the health mark or regional mark to product, wrapping and packaging as appropriate -----
- Other documents, please specify:
- _____
- _____
- _____
- _____
- _____

A.8.3: APPENDIX 3 - Local Authority Files

List of Contents

The following guidance is offered to approval 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 approval/enforcement 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 authority in demonstrating its competence.

Each file should contain:

- A plan or plans of the establishment indicating:
 - the layout of the establishment;
 - the location of equipment;
 - work flows for each product line;
 - water distribution system within the establishment including all outlets and sampling points;
 - drainage layout;
 - pest control - baiting and/or trapping points within the establishment and external areas;
- a synopsis of the establishment which briefly describes what type of establishment it is, products produced, volume of product, type of trade, number of employees, approval number and what it is approved for. This synopsis should be no more than one side of an A4 sheet;
- pre-approval inspection report;
- planned programme of works to achieve approval;
- approval notification document specifying:
 - details of activities to which the approval relates;
 - approval number;
 - classification;
 - special hygiene direction(s);
 - any derogations that have been granted;
 - any other conditions or limitations specified by the approval authority;
 - any arrangements acceptable to the Food Authority;

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

- labels (printed, reprinted and use of) and commercial documents bearing the health mark;
- letter indicating the enforcing 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 including names, telephone numbers, etc., of key personnel within the company;
- results of all samples taken by the approval authority;
- hazard rating of the premises to determine inspection frequency;
- location of any off-site facilities.

A.8.4: APPENDIX 4 - Approval Notification Templates

Reference No

FP2
MP02

NOTIFICATION TO APPLICANT OF APPROVAL OF STAND ALONE MEAT PRODUCTS PREMISES

[NAME OF FOOD AUTHORITY]

Notification to Applicant of Approval of Meat Products Premises

[Insert name and address of applicant]

Meat Products (Hygiene) Regulations 1994, as amended

[Insert business name and address of meat products premises]

Further to the application for approval made on [date of application], this is to notify you that [name of Food Authority] grants approval to the above-mentioned premises in accordance with the Meat Products (Hygiene) Regulations 1994, as amended, as follows:

The premises have been classified as:

[insert, as appropriate

Industrial - This classification is based on an estimated output of finished meat products from the premises of [insert amount] tonnes per week.

Or

Non-industrial - This classification is based on an estimated output of finished meat products from the premises of [insert amount] tonnes per week. Should the volume of output exceed 7.5 tonnes per week, other than for a short temporary period, you must inform the local authority as this may lead to a re-classification of the premises with attendant changes in structural/operational requirements.]

Part(s) of Premises that are subject of approval: (Specify whole, or identify area/room attach scale plan with approved area hatched, Specify whether on-farm establishment)

The meat product activities to which the approval relates are:

[Insert as appropriate:

- the handling of meat products, namely – [insert appropriate description – e.g. manufacture of sausage rolls and meat pies];
- the handling of meat products containing 10% or less meat, namely – [insert appropriate description – e.g. 'X' pizzas];

- the handling of meat products in hermetically sealed containers which have been heat-treated, namely – [insert appropriate description – e.g. canned minced meat];
- the handling of meat-based prepared meals, namely – [insert appropriate description – e.g. manufacture of meat, potato and vegetable meals];
- the rewrapping of meat products, namely – [insert appropriate description – e.g. slicing and wrapping of cured meats];
- the storage at ambient temperature of unpackaged meat products, namely – [insert appropriate description – e.g. storage of canned meat products];
- the cold storage of unpackaged meat products, namely – [insert appropriate description – e.g. storage of wrapped cooked meats];

[and, where appropriate, insert

‘This approval is subject to the **special hygiene direction**. As such, the requirements for “Industrial Premises” apply to these premises even though the average weekly output is less than 7.5 tonnes.’]

This **special hygiene direction** has been applied with respect to your premises for the following reason(s):

[Insert Details]

If you consider that this **special hygiene direction** has been unfairly applied, you may appeal to the Magistrates Court at the following address:

[Insert address of Magistrates Court]

[and, where appropriate, insert

The approval also includes:

- the alternative method of disinfecting equipment and utensils by – e.g. ‘chemical disinfection’;
- the method of applying the United Kingdom EC Health Mark/Northern Ireland Regional Mark by – e.g. ‘hot branding’;
- the use of [specify room(s)] for the storage of meat products at ambient temperature;
- the requirement that pasteurised products in hermetically sealed containers, namely: [insert a description of relevant meat products], must satisfy the following safety criteria – [insert as appropriate];
- the use of recirculated water for cooling heat-processed containers which has been purified and treated as follows: [insert description of the method of treatment];

The approval code of the premises will be [insert approval number]

[and, where appropriate, insert

The following arrangements are acceptable to the Council, as the enforcement authority, namely:

- the use of the off-site facilities for the cleaning and disinfecting means of transport;
- the alternative cleaning and disinfecting processes provided where the treatment of meat products requires the absence of water;
- the use of working areas, instruments and working equipment may also be used for work on other foodstuffs;
- the manufacture and wrapping of meat products may be carried out in the same room, namely, [specify room];
- the alternative time/temperature combinations for the incubation tests to be carried out to ensure that sterilised products have undergone effective treatment;
- the laboratory, namely, [insert name and address of laboratory], used to carry out microbiological examination of the contents and containers, to ensure that sterilised products have undergone effective treatment;
- the derogation from the requirement that meat-based prepared meals be cooled to an internal temperature of 10°C or less within not more than 2 hours after the end of cooking for reasons connected with the production technology.]

Signature _____ Date _____
Full name _____
Position _____

Any changes to the activities to which this approval relates must be notified to the Council immediately.

MP02

Meat Product Establishment Approval

Schedule of Arrangements Acceptable to the Approving Authority

Premises Address.....

Approval Code

Arrangement	Agreed Arrangement	Authorising Officer
<i>Example:</i> Method of Cleaning & Disinfection		
Training		

Appeal Information

**NOTIFICATION TO APPLICANT OF
APPROVAL OF STAND ALONE MINCED MEAT AND MEAT
PREPARATIONS ESTABLISHMENT**

[NAME OF FOOD AUTHORITY]

**Notification to Applicant of Approval of Minced Meat and Meat Preparations
Premises**

[Insert name and address of applicant]

Minced Meat and Meat Preparations (Hygiene) Regulations 1995, as amended

[Insert business name and address of minced meat/meat preparations
establishment]

Further to the application for approval made on [date of application], this is to notify you that [name of Food Authority] grants approval to the above-mentioned premises in accordance with the Minced Meat and Meat Preparations (Hygiene) Regulations 1995, as amended, as follows:

The premises have been classified as:

[insert, as appropriate

Industrial - This classification is based on an estimated output of finished meat products from the premises of [insert amount] tonnes per week.

Or

Non-industrial - This classification is based on an estimated output of finished meat products from the premises of [insert amount] tonnes per week. Should the volume of output exceed 7.5 tonnes per week, other than for a short temporary period, you must inform the local authority as this may lead to a re-classification of the premises with attendant changes in structural/operational requirements.]

Part(s) of Premises that are subject of approval: (Specify whole, or identify area/room attach scale plan with approved area hatched)

The activities to which the approval relates are [Insert as appropriate:

- the production of minced meat for consignment to a relevant EEA State for human consumption];

- The production of meat preparations for human consumption in a relevant EEA State namely – [insert appropriate description e.g. haggis, burgers];

[and, where appropriate, insert

The approval also includes:

- the alternative method of disinfecting equipment and utensils by – e.g. ‘chemical disinfection’;
- the method of applying the United Kingdom EC Health Mark/Northern Ireland Regional Mark by – e.g. ‘hot branding’;

The approval code of the premises will be [insert approval number]

[and, where appropriate, insert

The following arrangements are acceptable to the Council, as the enforcement authority, namely:

- the use of the off-site facilities for the cleaning and disinfecting means of transport;
- the alternative cleaning and disinfecting processes provided where the treatment of meat products requires the absence of water;
- the laboratory, namely, [insert name and address of laboratory], used to carry out microbiological examination and compositional testing of end product;

Signature _____ Date _____
Full name _____
Position _____

Any changes to the activities to which this approval relates must be notified to the Council immediately.

Minced Meat and Meat Preparation Establishment Approval

Schedule of Arrangements Acceptable to the Approving Authority

Premises Address.....

Approval Code

Arrangement	Agreed Arrangement	Authorising Officer
<i>Example:</i> Method of Cleaning & Disinfection		

Appeal Information

**STANDARD LETTER TO ACCOMPANY NOTIFICATION TO APPLICANT
OF REFUSAL TO APPROVE PREMISES**

[FOOD AUTHORITY LETTERHEAD]

[Insert name and address of applicant]

Dear Sir/Madam,

[Insert as appropriate] Regulations

[Insert business name and address of premises]

Please find attached official notification of the **refusal to approve** your premises under the above Regulations. The reasons for refusing the application are given in the Schedule to the notification.

You have already been provided with an opportunity to discuss this matter with an Officer. However, should you believe any of the information on the attached Schedule to be inaccurate, or you consider that you have been unfairly treated, you should contact me immediately.

You have a right of appeal to a Magistrates Court against the decision to refuse approval. If you wish to lodge an appeal, you must do so by (Date dd/mm/yy) at the following address:

[Insert Name] Magistrates Court
Address 1.
Address 2.
Post Code

You are advised that you must not undertake any activity that requires approval under the relevant Regulations unless such approval has been granted.

Should you require clarification of any of these matters please do not hesitate to contact me.

Yours faithfully,

Reference No.....

**NOTIFICATION TO APPLICANT OF REFUSAL
TO APPROVE PREMISES**

[INSERT NAME OF FOOD AUTHORITY]

Notification to applicant of refusal to approve premises

[Insert name and address of applicant]

Meat Products (Hygiene) Regulations 1994, as amended
Food Safety (Fishery Products and Live Shellfish)(Hygiene) Regulations 1998
Dairy Products (Hygiene) Regulations 1995, as amended
Minced Meat and Meat Preparations (Hygiene) Regulations 1995
Egg Products Regulations 1993

[Insert business name and address]

Further to the application for approval made on [date of application], [insert name of Food Authority] [at its meeting held on [date of meeting]] [has] decided to **refuse** your application for approval for the above-mentioned premises in accordance with the [insert as appropriate] Regulations. The decision to **refuse** approval has been made for the reasons given on the attached Schedule.

Signature _____ Date _____

Full name _____

Position _____

YOUR RIGHT OF APPEAL

Any person who is aggrieved by the decision of a Food Authority to:

- Refuse a licence or approval;
- Revoke a licence or approval;
- Serve a suspension or Prohibition Notice;
- Impose Conditions or Limitations;
- Issue a Special Hygiene Direction;
- Fail to grant a derogation

may appeal to the local Magistrates Court. The accompanying letter identifies this court and the time limit for making such an appeal

Reference No.....

SCHEDULE

[Insert as appropriate] Regulations

Your application for approval has been refused because you have failed to comply with the requirements of the Regulations identified below (Column A). The details of the non-compliance are given in Column B.

[Insert business name and address of premises]

COLUMN A Provisions of Regulations not complied with	COLUMN B Reasons for non- compliance	COLUMN C Measures needed to comply with requirements

A.8.6: APPENDIX 6 - Notification of Revocation of Approval

Reference No.....

STANDARD LETTER TO ACCOMPANY NOTIFICATION TO REVOKE AN APPROVAL

[FOOD AUTHORITY LETTERHEAD]

[Insert name and address of applicant]

Dear Sir/Madam,

[Insert as appropriate] Regulations

[Insert business name and address of premises]

Please find attached official notification of the decision to **REVOKE** the approval with respect to your premises. The reasons for the **REVOCATION** are given in the Schedule to the notification.

You have already been provided with an opportunity to discuss this matter with an Officer. However, should you believe any of the information on the attached Schedule to be inaccurate, or you consider that you have been unfairly treated, you should contact me immediately.

You have a right of appeal to a Magistrates Court against the decision to **REVOKE** your approval. If you wish to lodge an appeal, you must do so by (Date dd/mm/yy) at the following address:

[Insert Name] Magistrates Court
Address 1.
Address 2.
Post Code

You are advised that you must not undertake any activity that requires approval under the relevant Regulations unless such approval has been granted. Should you continue with any activities that are the subject of this revocation, enforcement action may be taken.

You must cease to use the approval code XXX with immediate effect.

Should you require clarification of any of these matters please do not hesitate to contact me.

Yours faithfully,

Reference No.....

NOTIFICATION TO APPLICANT OF REVOCATION OF APPROVAL

[INSERT NAME OF FOOD AUTHORITY]

[Insert name and address of applicant]

Meat Products (Hygiene) Regulations 1994, as amended
Food Safety (Fishery Products and Live Shellfish)(Hygiene) Regulations 1998
Dairy Products (Hygiene) Regulations 1995, as amended
Minced Meat and Meat Preparations (Hygiene) Regulations 1995
Egg Products Regulations 1993

[Insert business name and address of premises]

This is formal notification that the approval granted on [dd/mm/yy], by [insert name of Food Authority] with respect to the above named premises (or parts of premises or activities as identified on the attached Schedule) is hereby **REVOKED**. The reasons for the Revocation are given in the Schedule.

You must cease all activities that were the subject of the specified approval with immediate effect. Under no circumstances must the Approval Code specified in the attached Schedule be used for any products

Signature _____ Date _____
Full name _____
Position _____

YOUR RIGHT OF APPEAL

Any person who is aggrieved by the decision of a Food Authority to:

- Refuse a licence or approval;
- Revoke a licence or approval;
- Serve a suspension or Prohibition Notice;
- Impose Conditions or Limitations;
- Issue a Special Hygiene Direction;
- Fail to grant a derogation

may appeal to the local Magistrate's Court. The accompanying letter identifies this court and the time limit for making such an appeal

Reference No.....

SCHEDULE

[Insert as appropriate] Regulations

Your approval has been REVOKED because:

1. You are no longer undertaking the activities for which the approval was required. (Column A)
2. you have failed to comply with the requirements of the Regulations identified below (Column B). The details of the non-compliance are given in Column C.

[Insert business name and address of premises]

COLUMN A Details of approval that is subject of this revocation	COLUMN B Provisions of Regulations not complied with	COLUMN C Reasons for non-compliance

You must not use the following Approval Code: XXXX

The Food Standards Agency has been informed that this approval number has been revoked.

If you are handling products that are subject to a different approval, you should contact the approving authority who may issue you with a new Approval Code

Reference No.....

STANDARD LETTER TO ACCOMPANY NOTICE TO SUSPEND AN APPROVAL

[FOOD AUTHORITY LETTERHEAD]

[Insert name and address of applicant]

Dear Sir/Madam,

[Insert as appropriate] Regulations

[Insert business name and address of premises]

Please find attached official notice of the decision to **SUSPEND** the approval with respect to your premises. The reasons for the **SUSPENSION** are given in the Schedule to the notice.

Until the matters specified in the Notice have been remedied, the activities identified in the Schedule will, from the effective date, be treated as if they were not approved.

You are advised that you must not undertake any activity that requires approval under the relevant Regulations unless such an approval is in place. Should you continue with any activities that are the subject of this suspension, enforcement action may be taken.

You must cease to use the approval code XXX with immediate effect.

You have already been provided with an opportunity to discuss this matter with an Officer. However, should you believe any of the information on the attached Schedule to be inaccurate, or you consider that you have been unfairly treated, you should contact me immediately.

You have a right of appeal to a Magistrates Court against the decision to **SUSPEND** your approval. If you wish to lodge an appeal, you must do so by (Date dd/mm/yy) at the following address:

[Insert Name] Magistrates Court
Address 1.
Address 2.
Post Code

Should you require clarification of any of these matters please do not hesitate to contact me.

Yours faithfully,

Reference No.....

NOTIFICATION TO APPLICANT OF SUSPENSION OF
APPROVAL

[INSERT NAME OF FOOD AUTHORITY]

[Insert name and address of applicant]

Regulation 6A, Meat Products (Hygiene) Regulations 1994, as amended
Regulation 5A Minced Meat and Meat Preparations (Hygiene)
Regulations 1995

[Insert business name and address of premises]

This is formal notification that the approval granted on [dd/mm/yy], by [insert name of food authority] with respect to the above named premises (or parts of premises or activities as identified on the attached schedule) is hereby **SUSPENDED**. The reasons for the suspension are given in the Schedule.

You must cease all activities that are the subject of this suspension of approval [specify date][with immediate effect]. Under no circumstances must the Approval Code specified in the attached Schedule be used for any products that are the subject of this suspension

Signature _____ Date _____
Full name _____
Position _____

YOUR RIGHT OF APPEAL

Any person who is aggrieved by the decision of a Food Authority to:

- Refuse a licence or approval;
- Revoke a licence or approval;
- Serve a suspension or Prohibition Notice;
- Impose Conditions or Limitations;
- Issue a Special Hygiene Direction;
- Fail to grant a derogation

may appeal to the local Magistrates Court. The accompanying letter identifies this court and the time limit for making such an appeal

Reference No.....

SCHEDULE
[Insert as appropriate] Regulations

[Insert business name and address of premises]

The approval specified in column A has been **SUSPENDED** because:

1. you have failed to comply with the requirements of the Regulations identified below (Column B). The details of the non-compliance are given in Column C
2. An inspection of your premises by an authorised officer was hampered (details attached)
3. You have failed to comply with the terms of a notice served on you under [Regulation 19A Meat Products (Hygiene) Regulations 1994 as amended]
[Regulation 12A Minced Meat and Meat Preparations (Hygiene) Regulations 1995].

[Insert business name and address of premises]

COLUMN A Details of approval that is subject of this Suspension	COLUMN B Provisions of Regulations not complied with	COLUMN C Reasons for non-compliance

You must not use the following Approval Code: XXXX

The Food Standards Agency has been informed of the Suspension of your approval

If you are handling products that are subject to a different approval, you should contact the Approving Authority who may issue you with a new Approval Code

Reference No.....

STANDARD LETTER TO ACCOMPANY NOTICE TO AMEND APPROVAL

[FOOD AUTHORITY LETTERHEAD]

[Insert name and address of applicant]

Dear Sir/Madam,

[Insert as appropriate] Regulations

[Insert business name and address of premises]

Please find attached official notification of the decision to **AMEND** the approval with respect to your premises. The reasons for the **AMENDMENT** are given in the attached notice (reference number...)

You have already been provided with an opportunity to discuss this matter with an Officer. However, should you believe any of the information on the attached notice to be inaccurate, or you consider that you have been unfairly treated, you should contact me immediately.

The attached notice will be withdrawn, in writing, once the authorised officer is satisfied that the matters specified in the notice have been remedied.

Where the notice requires you to implement additional systems or procedures, you should consider these requirements as necessary for the continued approval of your premises.

You have a right of appeal to a Magistrates Court against the decision to **AMEND** your approval. If you wish to lodge an appeal, you must do so by (Date dd/mm/yy) at the following address:

[Insert Name] Magistrates Court
Address 1.
Address 2.
Post Code

Failure to comply with the terms of this notice may result in the suspension or revocation of your approval or in you being prosecuted.

Should you require clarification of any of these matters please do not hesitate to contact me.

Yours faithfully,

Reference No.....

[INSERT NAME OF FOOD AUTHORITY]

NOTICE TO OCCUPIER OF APPROVED [MEAT PRODUCTS][MINCED MEAT AND MEAT PREPARATIONS] PREMISES TO:

- 1. prohibit the use of equipment**
 - 2. prohibit any part of an approved premises**
 - 3. impose conditions on an approval**
 - 4. prohibit the carrying out of any process**
 - 5. require the rate of operation to be reduced**
 - 6. require the rate of operation to be stopped completely**
- [Delete as appropriate]

**Regulation 19A Meat Products (Hygiene) Regulations 1994, as amended
Regulation 12A Minced Meat and Meat Preparations (Hygiene)
Regulations 1995 [delete as appropriate]**

To : [Insert name and address of Occupier]

Occupier of : [Insert business name and address of premises]

This is formal notification that the approval granted on [dd/mm/yy], by [insert name of Food Authority] with respect to the above named premises (or parts of premises or activities as identified on the attached Schedule) is hereby **amended**. The reasons for this amendment are given in the attached Schedule.

You must AMEND THE PROCESS ACCORDINGLY AS SPECIFIED WITHIN THIS NOTICE [BY dd/mm/yy] [with immediate effect].

Signature _____ Date _____
(Authorised Officer)

Full name _____
Position _____
Address _____

Telephone Number.....

Reference No.....

SCHEDULE
[Insert as appropriate] Regulations

This Notice has been served on you because at:

[Insert business name and address of premises]

1. You are no longer undertaking the activities in accordance with the original approval because:

2. You have failed to comply with the following requirements of the Regulations [specify Regulations breached] because [specify nature of the breach(es)]

3. An adequate health inspection was hampered on [dd/mm/yy] because [specify]:

REMEDIAL ACTION TO BE TAKEN

4. You must take the following remedial action to the satisfaction of the authorised officer:

[Specify the action required to comply with the notice i.e.:

- a) You must not use [details of equipment or part of premises] until [details of necessary remedial work] [further notice]

- b) You must [Details of conditions to be imposed onto the approval]

- c) You must not carry out the following process [specify]

- d) The rate of operation of [specify business, process or activity] must be reduced from the current level of [specify] to [specify level to be reduced to]

- e) The following operation should be stopped completely [specify]

5. The matters specified in this notice must be actioned:

Immediately

on : [dd/mm/yy]

[delete as necessary]

6. The matters specified in this notice must be completed by:

[Insert date]

YOUR RIGHT OF APPEAL

Any person who is aggrieved by the decision of a Food Authority to:

- Refuse a licence or approval;
- Revoke a licence or approval;
- Serve a suspension or Prohibition Notice;
- Impose Conditions or Limitations;
- Issue a Special Hygiene Direction;
- Fail to grant a derogation

may appeal to the local Magistrates Court. The accompanying letter identifies this court and the time limit for making such an appeal

A.8.7: APPENDIX 7 - Notification of Decision to the Food Standards Agency

**STANDARD LETTER TO THE FOOD STANDARDS AGENCY NOTIFYING
A DECISION OF THE FOOD AUTHORITY**

[FOOD AUTHORITY LETTERHEAD]

To: The Food Standards Agency [Insert appropriate FSA Division]
Aviation House
125 Kingsway
London
WC2B 6NH

Meat Products (Hygiene) Regulations 1994, as amended*
Food Safety (Fishery Products and Live Shellfish)(Hygiene) Regulations 1998*
Dairy Products (Hygiene) Regulations 1995, as amended*
Minced Meat and Meat Preparations (Hygiene) Regulations 1995*
Egg Products Regulations 1993*

Notification of a decision of this Food Authority to grant / amend / suspend / revoke / refuse an approval in relation to the following premises:

Trading name and address of premises:	
Telephone number:	
Name of owner:	
Approval code:	
Decision:	Approval/Amendment/Suspension/Revocation/Refusal*
Date of decision:	
Reason for decision:	
Approved for:	
Approval conditions:	
Nature of amendment*:	

* delete as appropriate

Food Authority contact:	
Telephone number:	
Fax number:	
E-mail address:	

A copy of the notification document that has been sent to the operator of the establishment is attached for information.

Food Safety Act 1990 Practice Guidance

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