Question to be addressed

The FSA is seeking your opinion on the following specific issues relating to this review of the Code of Practice, and it would be helpful if you could address these points specifically in your response.

Section 1: General Consultation Questions

- 1. Will the use of the proposed interventions be an effective tool to drive up business compliance with Food Law?
- 2. Is there sufficient information and examples relating to each monitoring category (see table at annex H) to clarify how the interventions should be reported, and have we successfully differentiated between the types of interventions?
- 3. Should premises which are given a risk rating score of A or B be subject to inspection only, or should these premises be subject to the introduction of interventions?
- 4. The agency has proposed that enforcement officers will now have the flexibility to change the risk rating of premises following an official control. What are your views on this proposal?
- 5. The Agency invite your views on any anticipated difficulties in insuring that the intervention policy is applied consistently between different officers in food establishments?
- 6. In measuring 'broad compliance' the new performance system requires establishments to achieve a minimum of ten on all three criteria: structure, food safety management systems and confidence in management to prevent food establishments with significant non compliances been judged broadly complaint. Are you supportive of this change?
- 7. Should establishments requiring approval under Regulation (EU) 853/2004 be subject to the proposed inspection frequency as laid down within section 4.3.4 of the existing code of practice?
- 8. Will the movement of premises requiring approval under Regulation (EU) 853/2004 back within the risk rating system free up resources by removing prescriptive inspection frequencies without endangering public health?
- 9. Is the application form for approval set out in Annex 11 of the Practice Guidance sufficiently flexible for use in relation to small businesses in a proportionate way?

- 10. The Agency is considering the need to provide additional guidance on the requirements for approval and the scope of exemptions, particularly in relation to small-scale establishments. . We would welcome views on issues relating to approval where additional guidance would be helpful.
- 11. We would welcome the views of business and Local Authorities on the proposed changes to the registration form. Will the proposed changes to the registration form reduce the administration burden placed upon new businesses, (estimated currently at 25 minutes per registration form) without endangering public health? [Note: see comments and questions at para 5.8 and 5.9. in RIA]
- 12. Is the level of information required from businesses when completing the registration form appropriate and if not please provide the supporting evidence/justification.
- 13. Do the proposals contained in this consultation impose any new burdens, or remove existing burdens, on business or Local Authorities other than those identified in the RIA?

Section 2: Specific Question for stakeholders groups

We are particularly interested in hearing the views of Local Authorities in relation to the following points:

- 14. Do you feel as a food authority enforcing Food Law, confident in how to apply the suite of interventions, and can you see circumstances where different interventions will be appropriate?
- 15. Alternative Enforcement Strategies (AES) are not an intervention, rather a method of monitoring compliance at low risk premises, What are your views on the proposal and please state the value and use you would make of AES?
- 16. Interventions give Local Authorities the discretion to direct resources at food establishments that present most risk to public health. Will this policy assist in protecting resources at a local level?
- 17. The changes in the Code have been introduced to complement the Local Authority Enforcement Monitoring System (LAEMS). The next inspection or type of intervention must be entered as a bring forward action at the conclusion of each intervention. What is your view on its practical application?

SUMMARY OF MAIN CHANGES BETWEEN EXISTING CODE OF PRACTICE AND PRACTICE GUIDANCE ISSUED IN 2006 AND DRAFT CODE OF PRACTICE AND DRAFT PRACTICE GUIDANCE ISSUED ON 12 SEPTEMBER 2007

	СНА	ANGES
CHAPTER	CODE OF PRACTICE	PRACTICE GUIDANCE
TITLE		
PREFACE	Para 4 – Reference to primary production added. Also reference to the Food Hygiene Reg. 2006 deleted.	
	SECTION 1: ADMINISTRA	TION
CHAPTER 1.1: INTER-AUTHORITY MATTERS	 1.1 – Reference to Devolved regions removed. 1.1.2 - Reference to primary production and local authorities added. 1.1.3 - Reference to primary production and contamination added. 1.1.4 - Reference to primary production and contamination added. 1.1.5 - Reference to primary production and RPA added. 1.1.6 - The date on the title has been amended from 1990 to 2007. Footer also amended to delete reference to the Regulation. 1.1.8 - Reference to primary production and food hygiene visits added. 	
CHAPTER 1.2: QUALIFICATIONS AND EXPERIENCE	 1.2.1 – reference made to official controls and interventions. 1.2.2 – DTI replace with BERR 1.2.4 – the hours of training required for authorised officers added. Reference to primary 	

	· · · · · · · · · · · · · · · · · · ·	
	production added.	
	1.2.8.1 - Reference to	
	primary production added.	
	Also Paragraph added on the	
	qualifications required for	
	lead officers on primary	
	production.	
	1.2.9.1.1. – Reference to	
	Reg. 853/2004 deleted.	
	1.2.9.1.4. – Qualifications	
	required enforce the reg. at	
	primary production premises	
	added.	
	1.2.9.1.5 – Qualifications	
	required to serve HIN on	
	farms.	
	1.2.9.1.7 – reference to	
	qualifications for officers	
	serving EPNs at primary	
	producers.	
	1.2.11 – Table detailing	
	qualification required for	
	interventions added.	
CHAPTER 1.3:		
CONFLICTS OF		
INTEREST		
CHAPTER 1.4:		
FOOD BUSINESS		
RECORDS		
CHAPTER 1.5:	1.5.1 – Reference to Food	
REGISTRATION OF	Hygiene Reg. 2006 deleted,	
FOOD BUSINESS	the word "including" and a	
ESTABLISHMENTS	reference to Annex X added.	
	1.5.4.1 – The words "From 1	
	January 2006" deleted.	
	1.5.8.1 – Reference to the	
	operation of a fleet of	
	vehicles added.	
	1.5.9 – Three paragraphs	
	added on EC requirements	
	for premises to be registered.	
CHAPTER 1.6:		
CROWN AND		
POLICE PREMISES	National Oriminal Intelligence	
CHAPTER 1.7:	National Criminal Intelligence	
FOOD INCIDENTS	Service replace with Serious	
AND HAZARDS	Organised Crime Agency	

		7.01
	SECTION 2: COMMUNICA	ATION
CHAPTER 2.1:		
FOOD ALERTS		
CHAPTER 2.2:		
AGENCY COMMUNICATIONS		
AND GUIDANCE		
CHAPTER 2.3:		
INFORMATION TO		
BE SUPPLIED TO		
THE AGENCY		
CHAPTER 2.4:	2.4.9 – section removed	
LIAISON WITH		
OTHER MEMBER		
STATES		
CHAPTER 2.5: LIAISON WITH	2.5.1 – The words "From 1 April 2006" deleted.	
OTHER MEMBER	2.5.2.3 – Fourth Bullet	
STATES	removed	
	Tomovou	
	SECTION 3: GENERAL ENFO	RCEMENT
CHAPTER 3.1:	3.1.10 – The word "formal"	
APPROACH TO	deleted.	
ENFORCEMENT	3.1.3 – Removed reference to	
	Regulatory reform act 2001	
CHAPTER 3.2:	3.2.3.1 – Entire Para	
IMPROVEMENT	replaced	
NOTICES		
CHAPTER 3.3:	3.3.1 – Introduction revised	
PROHIBITION	3.3.2.2.2. – Para added on	
PROCEDURES	the cleanliness of Primary	
	products storage facilities and	
	transporters. 3.3.3.4 – Reference to	
	primary products added.	
CHAPTER 3.4:	3.4.3 – Reference to section	
SEIZURE AND	9 addded	
DETENTION		
CHAPTER 3.5:	3.5.3 – Reference to the	
REMEDIAL ACTION	detention of process/handled	
NOTICES /	food added.	
DETENTION		
NOTICES		
CHAPTER 3.6:		
TEMPERATURE CONTROL		
REQUIREMENTS		
	l	

CHAPTER 3.7:	3.7.1 – Reference to the	
QUICK FROZEN	regulation amended and brief	
FOODSTUFFS	summary of contents added.	
	The words "as amended",	
	"92/1/EEC", "in Great Britain"	
	and reference to footnotes 35	
	and 36 deleted.	
	3.7.2 - Reference to	
	footnotes 36 and 37 added	
	andd reference to the 1990	
	reg. deleted. A paragraph	
	with a summary of the Reg.	
	added.	
	Footnotes 33, 35, 36, 37 and	
	38 are amended.	
	3.7.3 – Reference to	
	Schedule one and Regs. 6	
	and 7 deleted.	
	Reference to Regulations	
	increased to add others.	
	Reference to schedules 1	
	and 2, Reg. 4 and 6A are	
	deleted.	
	3.7.4 – Reference to	
	checking documents added.	
	Reference to regulations amended.	
CHAPTER 3.8:	-	
WASTE FOOD	Chapter Deleted	
CHAPTER 3.9:	Chapter Deleted	
	Chapter Deleted.	
DISTANCE SELLING		
/ MAIL ORDER		
CHAPTER 3.10:	Chapter Deleted	
BOTTLED WATERS		
CHAPTER 3.11:	Chapter Deleted	
MICROBIOLOGICAL		
CRITERIA CHAPTER		
CHAPTER 3.12:	Chapter moved to 3.8	
IMPORT OF FOOD		
FROM THIRD		
COUNTRIES		
	•	
SECTION 4: INSPECTIONS		
CHAPTER 4.1:	4.1 – Entire Chapter has	4.1.1 – insertion of text detailing
INSPECTIONS	been rewritten	the use of interventions and
		insertion of a table detail types
		of interventions
		4.1.2 – Alternative Enforcement
		Strategies added
L		

		4.1.3 – Other enforcement
		activities added
	122 – Reference to the	
CHAPTER 4.2: THE INSPECTION	4.2.2 – Reference to the recording the scope of inspections deleted. section on Article 5 move to 4.1 4.2.3.1 – Sections on handling and Primary production added. 4.2.4 – "Primary" deleted from Title. 4.2.5 - "Secondary Inspections" amended to read "Enforcement Action and Revisits –" 3 rd Para "Secondary" amended to "Subsequent". 4 th Para ""secondary inspection" amended to "revisit" 5 th Para "inspection" amended to "revisit" 6 th Para "secondary inspections" amended to "revisits and enforcement action".	4.2 – Title amended to matter relating to inspection
CHAPTER 4.3: INSPECTION OF PRODUCT- SPECIFIC ESTABLISHMENTS – ADDITIONAL REQUIREMENTS	 4.3.1 – Last sentence on Secondary inspections deleted. 4.3.2 – Reference to interventions added. Brackets and contents removed. 4.3.3.1 - A 7 deleted. 4.3.4 – Reference to Annex 5 added. A reference to Annex 5 added. A reference to competent authorities added. The rest of this section has been deleted including the table. 4.3.5 Section deleted. 4.3.6 – Section and footnote deleted. 	4.3 – New section added on matter relating to primary production assurance schemes.
CHAPTER 4.4: INSPECTION OF SHIPS AND AIRCRAFT	Lsa	
CHAPTER 4.5:	References to primary and	
ACTION	secondary inspections	
FOLLOWING	removed and replaced with	

INSPECTION	intervention and official		
	controls		
SECTION 5: PRODUCT- SPECIFIC ESTABLISHMENTS			
CHAPTER 5.1: APPROVAL OF PRODUCT- SPECIFIC ESTABLISHMENTS SUBJECT TO APPROVAL UNDER REGULATION 853/2004 CHAPTER 5.2: ENFORCEMENT OPTIONS IN PRODUCT- SPECIFIC ESTABLISHMENTS SUBJECT TO APPROVAL UNDER REGULATION 853/2004	5.1.4.2 – reference to minimum amount of plant origin removed and a reference to exempt establishments References to primary and secondary inspections removed		
CHAPTER 5.3: MATTERS RELATING TO LIVE BIVALVE MOLLUSCS	Reference to permanent transport authorisation included.		
CHAPTER 5.4: MATTERS RELATING TO FRESH MEAT			
SECTION 6: SAMPLING AND ANALYSIS			
CHAPTER 6.1: SAMPLING AND ANALYSIS			
SECTION 7: MONITORING OF INSPECTIONS			
CHAPTER 7.1: MONITORING OF INSPECTIONS	7.1.2 – Reference to Category A added. Inspection replaced with intervention	7.1 – Changed title to monitoring interventions.	

DRAFT CODE OF PRACTICE: ANNEXES

ANNEX	CHANGES
ANNEX 1: GLOSSARY OF TERMS	Refernce to SVS removed
ANNEX 2: HACCP EVALUATION COMPETENCIES	1 st Para reference to Primary Production added
ANNEX 3: FOOD INCIDENT FLOW DIAGRAM	
ANNEX 4: FOOD INCIDENT REPORT FORM (FOOD AUTHORITIES)	5. – "Local" replaced with "food".
ANNEX 5: INSPECTION RATING SCHEMES	Inspections replace with interventions were appropriate Table Score 30 – "system" changed to "procedures" Score 10 – Reference to "food safety management system" deleted. Score 5 – "and systems" and "documented system" deleted. The word "procedures" added. Score 0 – "management system" deleted and the word "procedure" added twice. A5.3.4 – table amended
ANNEX 6: FOOD BUSINESS ESTABLISHMENT / FOOD BUSINESS PREMISES INSPECTION REPORT	
ANNEX 7: MODEL FORMS OF NOTICE	Minor amendments to wording within forms 7.7, 7.9, 7.15, 7.17, 7.18

ANNEX 8: MODEL APPLICATION FORM FOR THE REGISTRATION OF A FOOD BUSINESS ESTABLISHMENT	Section 3, 4, 6, 7, 8, 9, 10, 11, 12, 13 and final signature deleted.
ANNEX 9: MODEL TEMPORARY	
PROHIBITION ORDER	
ANNEX 10: MODEL CERTIFICATE OF	

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ANNEX 8: RAW MILK	

AND DAIRY PRODUCTS	
ANNEX 9: EGG PRODUCTS AND LIQUID EGG	
ANNEX 10: EGG PACKING CENTRES	
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Food Law

Code of Practice (England)

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Amendment No. 8		
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Amendment No. 13		
Amendment No. 14		
Amendment No. 15		
Amendment No. 16		
Amendment No. 17		
Amendment No. 18		
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Amendment No. 20		

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

PREFACE

This Code of Practice is issued under Section 40 of the Food Safety Act 1990 (the Act), Regulation 24 of the Food Hygiene (England) Regulations 2006¹, and Regulation 6 of the Official Feed and Food Controls (England) Regulations 2006² which empower the Secretary of State to issue codes of practice concerning the execution and enforcement of that legislation by Food Authorities. It relates to England only. For the purposes of this Code the terms enforcement authority, port health authority and Food Authority are interchangeable, subject to the specific enforcement responsibilities.

Food Authorities are required under that legislation to have regard to this Code when discharging their duties. This means, in effect, that Food Authorities must follow and implement the provisions of this Code that apply to them.

Food Authorities that do not have regard to relevant provisions of this Code may find their decisions or actions successfully challenged, and evidence gathered during a criminal investigation being ruled inadmissible by a court.

In addition, the Food Standards Agency (the Agency) may, after consulting the Secretary of State, give a Food Authority a direction requiring them to take any specified steps in order to comply with this Code.

If a Food Authority finds that complying with this Code might compromise public health or food safety they should discuss the matter with the Agency at the earliest opportunity.

Food Authorities have statutory duties to enforce legislation relating to food, including the primary production of food.

The purpose of enforcement is to ensure compliance with legislation relating to food in each Food Authority's area in the United Kingdom. Every Food Authority must therefore discharge its duty as effectively as possible, using means that are most appropriate to the circumstances.

The effective discharge of this duty relies on authorised officers being familiar with the law they are appointed to enforce, referring to the law itself as well as to this Code and other guidance, understanding what the law actually states and requires, and seeking guidance when either it, or they, are unclear.

The Agency may, from time to time, issue Practice Guidance for Food Authorities. Food Authorities should take account of such guidance, as well as any appropriate Guidance issued by the European Commission.

Food Authorities must also have regard to the Framework Agreement on Local Authority Food Law Enforcement³, which reflects the requirements of

¹ SI 2006 No. 14

² SI 2006 No. 15

³ "The Framework Agreement on Local Authority Food Law Enforcement", published and updated by The Agency, Aviation House, 125 Kingsway, London, WC2B 6NH, www.food.gov.uk

this Code. The Framework Agreement is also consistent with the principles of the Enforcement Concordat⁴.

Food Authorities should be aware that law relating to food is not necessarily made under the Food Safety Act 1990. Law that applies to food is also contained in and/or made under the Animal Health Act 1981, the European Communities Act 1972, the Consumer Protection Act 1987, the Trade Descriptions Act 1968, and directly under EC Regulations.

Food Authorities should be aware that Article 8(5) of Regulation 852/2004⁵ stipulates that guides to good practice drawn up pursuant to Directive 93/43/EEC (known in the UK as "Industry Guides to Good Hygiene Practice") shall continue to apply provided that they are compatible with its objectives.

In this Code, references to live bivalve molluscs also include live echinoderms, tunicates and marine gastropods, in line with Annex III, Section VII(1) of Regulation 853/2004⁶, with the exception of the parts of this Code which deal with purification of live bivalve molluscs.

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

SECTION 1: ADMINISTRATION

CHAPTER 1.1: INTER-AUTHORITY MATTERS

1.1.1: Introduction

This Chapter deals with liaison arrangements between Food Authorities, and the division of enforcement responsibilities. It requires the timely exchange of information on food business establishment registration, the adoption, where possible, of the "Home Authority Principle", and the appropriate representation of Food Authorities in liaison groups. It also sets out ground-rules for the exercise of powers of entry by authorised officers in other Food Authorities' areas.

1.1.2: Liaison between two-tier Food Authorities

Lead food officers of District and County Council Food Authorities should ensure that effective day-to-day liaison arrangements between their respective authorities are in place, documented and operating satisfactorily. It

⁴ "The Enforcement Concordat", published by The Cabinet Office, Better Regulation Unit, 22 Whitehall, London, SW1A 2WH, <u>www.cabinetoffice.gov.uk</u> which will be subject to review in the Regulatory Enforcement Sanctions Bill 2007

⁵ Regulation (EC) No. 852/2004 on the hygiene of foodstuffs

⁶ Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin

should be noted that in parts of England where there are two tiers of local government and both are food authorities the Agency has not specified whether investigations and enforcement action in relation to primary production are undertaken at District or County level. However, it is anticipated that most of this work will be undertaken by TSOs who are already active on farms in relation to enforcement of animal welfare and feed legislation.

1.1.3: Microbiological quality and contamination by microorganisms or foreign matter

In the parts of England in which there are two tiers of local government and each tier is a Food Authority, District Council Food Authorities should investigate and take enforcement action in cases relating to the microbiological quality of food, contamination by micro-organisms and their toxins and contamination by foreign matter, except where contamination by chemical contaminants is found during an inspection of a primary production premises in which case 1.1.4 should apply as appropriate.

1.1.4: Composition, chemical contamination, adulteration and labelling

In the parts of England in which there are two tiers of local government and each tier is a Food Authority, County Council Food Authorities should investigate and take enforcement action in cases relating to chemical contamination.

However, in situations where the presence of chemical contaminants may pose an imminent risk to public health, the District Council Food Authority should investigate and take enforcement action, but should liaise closely with the County Council Food Authority except where contamination by microorganisms or foreign matter is found during an inspection of a primary production premises in which case 1.1.2 should apply as appropriate

In cases where a clearly identified risk to health has been notified by means of a Food Alert issued by the Agency, either the District Council Food Authority, the County Council Food Authority or both may be required to investigate and take enforcement action; such responsibility will be defined in the Food Alert.

The County Council Food Authority may also be required to investigate and take enforcement action when a clearly identified risk to health has been notified by a Public Analyst as a result of sampling.

Medical and other expert advice, including advice from the Public Analyst or Food Examiner, should be sought in order to establish whether contamination by chemicals is likely to pose an imminent risk to health. County Council Food Authorities should investigate and take enforcement action in cases that involve the adulteration, composition, advertisement, presentation and labelling of food, apart from:

- The identification marking requirements of the EU food hygiene regulations which are enforced by District Council Food Authorities;
- The provisions of the Food Labelling Regulations⁷ relating to the sale of food after the "use by" date, and the removal or alteration of "best before" or "use by" dates which are enforced jointly by County and District Council Food Authorities.

1.1.5: Timely Exchange of Information on Food Business Registration

District Council Authorities in two tier Food Authority areas receiving initial registration information under Article 6(2) of Regulation 852/2004, should supply this information to the County Council Food Authority within 28 days of receipt. District Council Authorities in two tier Food Authority areas approving establishments subject to approval under Regulation 853/2004, either fully or conditionally, should inform the County Council Food Authority of a food business establishment's approval or conditional approval within 28 days of the approval being granted.

Food Authorities should pass information they receive which indicates a change in the operations within a food business establishment, and information on any withdrawal, suspension or reinstatement of an establishment's approval, to other relevant Food Authorities within 28 days.

It should be noted, however, that primary production premises that have been registered with the Rural Payments Agency prior to 1 December 2006 are considered registered for the purposes of Article 6(2) of Regulation 852/2004.

1.1.6: Quick-Frozen Foodstuffs Regulations⁸ 2007

The primary responsibility for enforcement in two tier Food Authority areas therefore lies with County Council Food Authorities.

However, as District Council Food Authorities enforce other temperature control requirements, they should also enforce relevant parts of the Regulations including the verification of temperatures in stores, vehicles and at the point of sale (see Chapter 3.6).

1.1.7: The Home Authority Principle

⁷ SI 1996 No. 1499, as amended

⁸ SI 2007 No. 191, as amended

The Agency endorses the Local Authorities Co-ordinators of Regulatory Services (LACORS) Home Authority Principle and Food Authorities should where possible adopt and implement its provisions⁹.

A Food Authority that is unable to adopt, implement, or adhere to the Home Authority Principle must firstly discuss the matter with LACORS and, if the matter cannot be resolved, with the Agency.

The co-ordination of Food Authority advice and enforcement is essential to ensure uniformity of enforcement and consistency in dealing with food businesses, especially those that have more than one branch or unit situated in different Food Authority areas.

Food Authorities considering giving advice or taking enforcement action in relation to food businesses which have a Home Authority should consider whether they need to contact the Home Authority before doing so. This would normally be necessary, for example, where the advice or enforcement action relates to centrally agreed policies or procedures of a food business. It might not be necessary, however, where such action relates to matters of an exclusively local nature.

1.1.8: Operating in other areas

A Food Authority should normally deal with matters arising in its area of jurisdiction. However, Regulation 14(1)(b) of the Food Hygiene (England) Regulations 2006 in respect of food hygiene and Section 32(1)(b) of the Food Safety Act 1990 in respect of food standards, permit authorised officers from a Food Authority to exercise their powers of entry in another Food Authority's area insofar as food business establishments are concerned in order to ascertain whether there is in those establishments any evidence of contraventions of provisions of the Hygiene Regulations, or of the Food Safety Act or regulations or orders made under it within their own Food Authority's area.

For food hygiene visits relating to primary production; officers can be authorised by more than one authority, and therefore conduct inspections on behalf of adjoining authorities.

When exercising these powers authorised officers should liaise with the relevant Food Authority for the area they are visiting, in advance wherever possible. This applies whether or not the business being visited is a food business. If it is not possible to give prior notice to the Food Authority in which the business is located, for example in an emergency or out of hours, the Food Authority should be notified as soon as practicable thereafter.

Authorised officers exercising these powers should not give advice or recommend changes to a company's systems or procedures. Such matters should be passed to the Food Authority for the area for appropriate action.

⁹ "The Home Authority Principle - Guidelines for Home Authorities", and LACORS Home Authority Principle Standards' Document are both available from LACORS: www.lacors.gov.uk

Authorised officers exercising powers of entry in food businesses outside their own area must not exercise any enforcement powers other than those associated with their powers of entry, which include the taking of samples in connection with the investigation of suspected offences within their own area. Other enforcement powers, which include the seizure or detention of food, must only be exercised by authorised officers of the Food Authority in which the business is located

1.1.9: Regional and Local Liaison Groups

Food Authorities should be represented at an appropriate level of seniority, normally by the relevant lead food officer or officers, at meetings of regional or local food liaison groups, to help maintain enforcement consistency with other Food Authorities.

Food Authorities should ensure that regional or local liaison groups include appropriate representation from each Food Authority in two-tier Food Authority areas, and from Food Examiners and Public Analysts. Representation from the Meat Hygiene Service, the Dairy Hygiene Inspectorate, the CCDC¹⁰/CPHM (CD/EH)¹¹ and other experts or specialists should be considered as the need arises.

Matters of legal interpretation and consistency should be discussed with colleagues in the appropriate regional or local food liaison group and the home or originating authority if appropriate. Food authorities should avoid taking unilateral decisions on interpretations without seeking the views of other Food Authorities or LACORS.

Groups of home authorities serving food businesses trading in the same sector of the industry should undertake regular liaison to ensure that the advice given by home authorities across a sector is consistent. LACORS is able to facilitate the development of these liaison arrangements.

Food Authorities where there are commercial shellfish harvesting activities should refer to Paragraph 5.3.2 for liaison arrangements (see also Paragraph A.6.6 of the Practice Guidance).

¹⁰ Consultant in Communicable Disease Control

¹¹ Consultant in Public Health Medicine (Communicable Disease/Environmental Health)

CHAPTER 1.2: QUALIFICATIONS AND EXPERIENCE

1.2.1: Introduction

This Chapter concerns the qualifications of authorised officers of Food Authorities who carry out interventions including official controls which ensure compliance with food law.

It implements the qualification and training provisions of Regulation 882/2004¹².

This Chapter does not apply to staff who have only indirect managerial responsibility for the Food Authority's food law enforcement service such as Chief Executives, Directors or Chief Officers, or to those employed in a support role such as administrative and legal staff.

If a Food Authority needs to engage expertise in an area listed in Chapter I of Annex II to Regulation 882/2004, it should ensure that any expert it engages has a recognised qualification and experience in the area for which the expertise is required.

1.2.2: General Qualification and Experience Requirements

Food Authorities should set up and implement a documented procedure¹³ for the authorisation of officers. The Food Safety Act 1990 allows for the authorisation of officers, in writing, either generally or specially to act in matters arising under the Act or Regulations made under the Act. However, Officers performing duties under the Food Hygiene (England) Regulations 2006 and the Official Feed and Food Controls (England) Regulations 2006, need to be separately authorised in writing to deal with matters arising under these implementing Regulations, e.g. issues under the "specified community provisions". With regard to other specific food Regulations made under the European Communities Act 1972, where appropriate, relevant officers should be specially authorised for each of those Regulations.

Food Authorities should ensure that officers they authorise in accordance with their documented procedure to carry out enforcement under the food law are:

- Suitably qualified;
- Experienced, and;
- Competent to carry out the range of tasks and duties they are required to perform.

This applies equally to those who are directly employed, to temporary staff, and to those employed by or as contractors.

 ¹² Regulation (EC) No. 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
 ¹³ See Chapter 2, Paragraph 5.1 of the Framework Agreement

There may be other qualifications that are equivalent to those specifically set out in this Code. The Agency should be approached to consider such cases.

Existing or prospective Food Authority officers may also have a range of qualifications, additional training and experience that together indicate their competence to undertake specific enforcement activities identified in this Code. In such cases the relevant professional and awarding bodies should be approached directly by either the existing Food Authority employer or prospective officer for an assessment of equivalence.

Nationals from other countries in the European Economic Area have a right under Community law to the recognition of qualifications and experience gained outside the UK. This situation may arise if an individual seeks employment in Great Britain as a Public Analyst, Food Examiner or food law enforcement officer, having acquired relevant qualifications and work experience in their home country. Food Authorities should accept suitable non-UK qualifications and experience in order to give effect to these Community rights. The equivalence of non-UK qualifications will be determined by organisations recognised by the Department of Business Enterprise and Regulatory Reform for the purposes of Directive 89/48/EEC¹⁴ (The Mutual Recognition of Professional Qualifications). Food Authorities should make enquiries with the relevant professional and awarding bodies if they have any doubts in this area before confirming an appointment.

1.2.3: New Appointments

Food Authorities should not authorise new officers, or extend the duties of currently employed officers, unless they are qualified in accordance with the relevant provisions of this Chapter and they meet any relevant additional requirements relating to specific duties or enforcement responsibilities.

1.2.4: Training

Food Authorities should ensure that authorised officers receive relevant structured on-going training. Such training should explain new legislation and procedures and technological developments relevant to food businesses subject to their inspection.

The minimum ongoing training should be 10 hours per year based on the principles of continuing professional development.

Authorised officers engaged on on-farm food hygiene enforcement should receive a minimum of 4 hours per year ongoing training in relation to these responsibilities. These 4 hours can be included within the minimum training required either in relation to food hygiene enforcement or feed hygiene enforcement or animal health.

¹⁴ Directive 89/48/EEC on a General System for the Recognition of Higher Education Diplomas Awarded on Completion of Professional Education and Training of at Least 3 Years' Duration (The Mutual Recognition of Professional Qualifications)

Officers whose knowledge or practical experience of food law enforcement is out of date should receive structured revision training and be monitored by the lead officer or another experienced food law enforcement officer during the period of training.

The extent of the revision training will vary according to the previous experience of the officer and the period that the officer has not been undertaking food law enforcement duties. The minimum revision training should be 15 hours based on the principles of continuing professional development.

Officers that are newly qualified or are returning to food law enforcement duties after an absence of more than three years should be monitored for at least three months or for the duration of their revision training period, whichever is longer, unless food law enforcement duties are at the level of primary production only and are in addition to current on farm experience in relation to animal welfare or feed hygiene legislation.

1.2.5: Training Records

Food Authorities should keep copies of certificates of registration, qualifications and documents required by this Chapter and record on-going and revision training undertaken by their authorised officers, including contract and temporary staff.

1.2.6: Contracted or Temporary Staff

Food Authorities should be satisfied that contracted or temporary enforcement staff meet the qualification and experience requirements set out in Paragraph 1.2.9 below that are relevant to the enforcement duties they are engaged to perform. This includes the training referred to above.

Food Authorities should also be satisfied that such staff are competent to undertake the duties required and are familiar with the Food Authority's enforcement and other policies and procedures.

Food Authorities must ensure that persons employed by contractors to undertake inspection or other enforcement activities on behalf of the Food Authority are duly authorised to do so by the Food Authority in writing.

1.2.7: Sampling

Samples for microbiological examination or chemical analysis should be taken by authorised officers who are properly trained in the appropriate techniques and competent to carry out the duties assigned to them. Sampling in accordance with the provisions of the Food Hygiene (England) Regulations 2006 or the Food Safety (Sampling and Qualifications) Regulations 1990¹⁵ and this Code of Practice should only be undertaken by officers meeting the relevant requirements described in Paragraph 1.2.9 below. These

¹⁵ SI 1990 No. 2463

requirements do not apply where an adverse report following analysis/examination would not result in formal action.

1.2.8: Lead Officers

The Food Authority should notify the Agency of the name(s) of their lead officer(s) and notify the Agency of changes.

1.2.8.1: Food Hygiene and Safety

Food Authorities with responsibility for food hygiene and safety at any stage in the food chain after primary production and those associated operations listed in Annex 1 of Regulation 852/2004 should appoint a suitably qualified and experienced lead environmental health officer to take lead operational and management responsibility for these matters. The officer appointed should meet the requirements set out in Paragraph 1.2.9.1.1 and have a technical understanding of the food production processes carried out within the Food Authority's area. In addition to the lead officer, other appropriately authorised officers may inspect, and take any necessary enforcement action in respect of the establishments in which these processes are carried out.

Food authorities with responsibility for the enforcement of food hygiene at the level of primary production should appoint a suitably qualified lead officer to take lead operational and managerial responsibility in this area. Local authorities can determine the most appropriate area for this representative to be based, whether this is in animal health, feed or food. The officer appointed should meet the requirements set out in 1.2.9.1.4 and in addition have specific training in the identification and analysis of hazards.

1.2.8.2: Food Standards

Food Authorities with responsibility for food standards should appoint a suitably qualified and experienced lead officer who holds the qualifications stipulated in Paragraph 1.2.9.2.2, and has a technical understanding of the food production processes used in the Food Authority's area, to take lead operational and management responsibility for these matters.

1.2.9: Specific Qualification and Experience Requirements

1.2.9.1: Section A: Food Hygiene and Safety

1.2.9.1.1: Officers Appointed to Carry out Food Hygiene Official Controls

Officers authorised to undertake food hygiene and safety Official Controls should hold one of the qualifications, or equivalent qualifications (see Paragraph 1.2.2) as set out in Paragraph 1.2.9.1.4 and be competent to carry out these functions .

Officers who are inspecting food business operators' procedures based upon HACCP principles should also possess the competencies set out in Annex 2.

Officers authorised to undertake food hygiene and safety inspections of food business establishments should have a detailed knowledge of the following:

- The nature and types of food businesses in their area and the technology utilised by the businesses that the officer is required to inspect;
- Relevant food hygiene and safety legislation;
- Requirements in Regulation 882/2004 on official controls for competent authorities with responsibility for enforcement of food law;
- This Code of Practice;
- The Practice Guidance accompanying this Code;
- The Food Authority's Enforcement Policy;
- UK and EU Guides to Good Practice¹⁶;
- Relevant guidance issued by the Agency and by LACORS;
- Relevant industry codes of practice¹⁷.

The following establishments should be inspected <u>only</u> by environmental health officers or officers holding the Higher Certificate in Food Premises Inspection:

- All establishments which attract a minimum intervention frequency of 12 months or less under the intervention rating scheme at Annex 5.
- All establishments that, under the intervention rating scheme at Annex 5, are in the "substantial" category of the Consumers at Risk section (A5.3.1.3).

Those who do not hold the required qualifications may assist qualified officers to carry out inspections.

1.2.9.1.2: Inspection of Specialist or Complex Processes

Officers undertaking the inspection of specialist or complex manufacturing processes should have received additional training and have demonstrated their competence to undertake such inspections. These will include the following:

• The canning, aseptic packing or thermal processing of low-acid foods;

¹⁶ References to "Guides to Good Practice" in this Code mean Guides developed in accordance with Article 8 of Regulation 852/2004 and recognised by UK Government as such

¹⁷ The Institute of Food Science and Technology (IFST) publishes a comprehensive list of Guides and industry codes of practice issued by a variety of bodies – "Listing of Codes of Practice Applicable to Foods". Details of additional Guides and industry codes can be found in the IFST publication "Good Manufacturing Practice"

- The manufacture of cook-chill, ready to eat food which may be consumed without further preparation other than re-heating;
- The manufacture of meat, fish, egg or dairy products;
- Vacuum packaging (including butchers' shops that vacuum-pack meat).

1.2.9.1.3: Inspection of Establishments Subject to Approval under Regulation 853/2004

Inspections for the purposes of the approval of establishments subject to approval under Regulation 853/2004 may only be undertaken by authorised officers of the Food Authority who have a detailed knowledge of enforcement in approved establishments.

An authorised officer who has no previous experience of a particular process that is the subject of an approval application must be accompanied, during the inspection of that process, by an appropriately qualified and experienced officer, who may be from another Food Authority if necessary.

1.2.9.1.4: Qualifications and Awarding Bodies – Food Hygiene

For the purposes of this Code an **environmental health officer** is a person holding a

- Certificate of Registration of the Environmental Health Registration Board (EHRB) or
- the Diploma in Environmental Health (or its antecedents) awarded by EHRB or the Royal Environmental Health Institute of Scotland (REHIS).

The Higher or Ordinary Certificate in Food Premises Inspection may be awarded by any one of the following:

- EHRB;
- The Scottish Food Safety Officers' Registration Board (SFSORB);
- The Institute of Food Science and Technology (IFST).

All officers undertaking inspections are required to undertake a period of structured practical training as part of the preparation for the award of these qualifications.

Food authority officers undertaking food hygiene enforcement at the level of primary production, if they do not already hold the qualifications listed above, should hold a

- Diploma in Trading Standards or
- Diploma in Consumer Affairs and/or
- Certificate of Competence in Animal Health and Welfare,

or have equivalent professional experience, or undertake to achieve such qualifications, and are authorised to enforce all relevant legislation.

Officers must be able to recognise and respond to food hygiene hazards during the course of inspection.

In addition officers authorised to undertake food hygiene inspections on farms should have a detailed knowledge of the following:

- The nature and types of primary production premises in their area and the technology utilised by the business that the officer is required to inspect,
- Relevant food hygiene and safety legislation;

1.2.9.1.5: Service of Hygiene Improvement Notices

(See also Chapter 3.2)

Hygiene Improvement Notices served under Regulation 6 of the Food Hygiene (England) Regulations 2006 may only be signed by officers who have been authorised to do so by the Food Authority. To maintain a consistent approach, Food Authorities should arrange that these notices are signed only by qualified officers with experience in food law enforcement, who are properly trained and competent. These will be one of the following:

- Environmental health officers enforcing food hygiene or food processing regulations;
- Holders of the Higher Certificate in Food Premises Inspection who are authorised to carry out food hygiene inspections;
- Holders of the Ordinary Certificate in Food Premises Inspection in relation to the premises they are authorised to inspect (see Paragraph 1.2.9.1.1).

The officer who signs the notice must have witnessed the contravention and be satisfied that it constitutes a breach of the Food Hygiene (England) Regulations 2006.

Authorised officers undertaking food hygiene enforcement activity on farms must have the qualifications and experience specified in 1.2.9.1.4.

1.2.9.1.6: Service of Improvement Notices

(See also Chapter 3.2)

Improvement Notices served under Section 10 of the Food Safety Act 1990 may only be signed by officers who have been authorised to do so by the Food Authority. To maintain a consistent approach, Food Authorities should arrange that these notices are signed only by qualified officers with experience in food law enforcement, who are properly trained and competent.

These will be one of the following:

• Environmental health officers enforcing food standards regulations;

- Holders of the Higher Certificate in Food Premises Inspection who are authorised to carry out food standards inspections;
- Holders of the Ordinary Certificate in Food Premises Inspection in relation to the premises they are authorised to inspect (see Paragraph 1.2.9.1.1).

The officer who signs the notice must have witnessed the contravention and be satisfied that it constitutes a breach of the relevant legislation.

1.2.9.1.7: Service of Hygiene Emergency Prohibition Notices / Emergency Prohibition Notices

(See also Chapter 3.3)

Hygiene Emergency Prohibition Notices under Regulation 8 of the Food Hygiene (England) Regulations 2006 or Emergency Prohibition Notices under Section 12 of the Food Safety Act 1990 should be signed only by environmental health officers (see Paragraph 1.2.9.1.4) who

- have two years' post qualification experience in food safety matters,
- are currently involved in food law enforcement and who
- are properly trained, competent and duly authorised, or,

in relation to primary production, officers who are suitably qualified and experienced (see 1.2.9.1.4) and are properly trained, competent and duly authorised.

1.2.9.1.8: Service of Remedial Action Notices / Detention Notices (See also Chapter 3.5)

Remedial Action Notices or Detention Notices under Regulation 9 of the Food Hygiene (England) Regulations 2006 should be signed only by environmental health officers (see Paragraph 1.2.9.1.4) who

- have two years' post qualification experience in food safety matters,
- are currently involved in food law enforcement and
- who are properly trained, competent and duly authorised.

1.2.9.2: Section B: Food Standards

1.2.9.2.1: Officers Appointed to Carry out Food Standards Official Controls

Officers authorised to undertake food standards Official Controls should hold one of the qualifications, or equivalent qualifications (see Paragraph 1.2.2) as set out in Paragraph 1.2.9.2.2, and be competent to carry out the duties.

Officers authorised to undertake such Official Controls in food business establishments should have a detailed knowledge of the following:

- The nature and types of food business in their area and the technology utilised in those establishments the officer is authorised to inspect;
- Relevant food standards and marketing legislation;
- Requirements in Regulation 882/2004 on official controls for competent authorities with responsibility for enforcement of food law;

- This Code of Practice;
- The Practice Guidance accompanying this Code;
- The Food Authority's Enforcement Policy;
- Relevant guidance issued by the Agency and by LACORS;
- Relevant industry codes of practice.

1.2.9.2.2: Qualifications and Awarding Bodies – Food Standards

- Diploma in Trading Standards (DTS) or its antecedents;
- Certificate of Registration of EHRB, the EHRB or REHIS Diploma in Environmental Health (or its antecedents);
- Diploma in Consumer Affairs (DCA) provided it includes the Food and Agriculture Paper of Part II, or its antecedents;
- A DCA Certificate of Competence in relation to Food and Agriculture issued by the TSI (or its antecedents);
- Food Certificate in Consumer Affairs and Trading Standards;
- Certificate of Competence in Food Standards;
- A Higher Certificate in Food Premises Inspection issued by EHRB or the IFST with an endorsement to include Food Standards Enforcement;
- The Higher Certificate in Food Standards Inspection issued by SFSORB.

All officers undertaking inspections are required to undertake a period of structured practical training as part of the preparation for the award of these qualifications.

1.2.9.2.3: Quality Assurance Systems

Before being authorised to undertake food standards inspections of establishments risk rated Category A as in Annex 5, and which are engaged in the manufacture and processing of foodstuffs with documented quality assurance systems, an officer should have been appropriately trained and be able to demonstrate that they are competent to assess quality assurance systems.

1.2.9.3: Section C: Food Hygiene and Food Standards

1.2.9.3.1: Inspection, Detention and Seizure of Foodstuffs (See also Chapter 3.4)

The inspection of food and any decision to detain or seize food through the application of Section 9 of the Food Safety Act 1990 (including as directed by Regulation 27 of the Food Hygiene (England) Regulations 2006) should only be taken by appropriately authorised officers. Such officers will be either

- authorised environmental health officers and, where relevant,
- authorised Official Veterinarians,
- appropriately authorised trading standards officers (see Paragraph 3.4.3) and,
- in respect of fresh meat only, officers qualified in accordance with the Authorised Officers (Meat Inspection) Regulations 1987¹⁸.

As regards official controls in relation to the import of food from third countries, Regulation 29 of the Official Feed and Food Controls (England) Regulations 2006 stipulates that, as well as the Competent Authority, enforcement authorities also have the power to take action under Articles 18 to 21 and 24(3) of Regulation 882/2004 if the conditions set out in those Articles are fulfilled. These Articles relate to the detention, destruction, special treatment, re-dispatch and other appropriate measures in respect of food imported from third countries.

1.2.10: Alternative Enforcement Strategies

(See also Paragraph 4.1.5.4 and Annex 5, Paragraphs A5.2 (food hygiene) and A5.5 (food standards))

Officers undertaking alternative enforcement strategies are not required to meet the qualification requirements set out in this Chapter, but they should, however, be appropriately authorised. Any visits by such unqualified, but appropriately authorised, officers undertaken as part of an alternative strategy, must be confined to information collection and reporting back. The overall management of alternative enforcement strategies must remain in the hands of a food law enforcement officer qualified in accordance with this Chapter, and decisions to take other enforcement action and/or intervene further must also be made by such an officer.

1.2.11: Qualification Requirements for interventions

In assessing who can carry out which type of intervention to undertake at a food establishment, the Food Authority must have regard to the following qualification requirements, please see section 4.1.2 of the practice guidance for further details of intervention types.

Intervention Type

Qualification level required to carry out the action

Inspections and audits	A appropriately qualified officer with experience in food law enforcement, See section 1.2.9 of the Code of Practice
Verification and surveillance	A appropriately qualified officer with experience in food law enforcement, See section 1.2.9 of the Code of Practice
Sampling visits	An officer appointed under Section 1.2.7 (and, where appropriate, Section 1.2.9) of the Code of Practice
Advice and education	An appropriately authorised officer under Section 1.2.10 of the Code of Practice
Information/ intelligence gathering	An appropriately authorised officer under Section 1.2.10 of the Code of Practice

CHAPTER 1.3: CONFLICTS OF INTEREST

1.3.1: Introduction

This Chapter deals with issues to be considered in ensuring that Food Authorities and their authorised officers are impartial and free from conflicts of interest.

1.3.2: Avoiding Potential Conflicts of Interest

Article 4(2)(b) of Regulation 882/2004 requires that staff carrying out official controls are free from any conflict of interest. Food Authorities should ensure that their officers are aware of potential conflicts of interest that may arise in an enforcement situation through promotion of the Food Authority's services.

Officers should not provide their own services, e.g. training, in their own time within their Food Authority area.

Food Authorities should ensure that potential or actual conflicts of interest do not arise as a result of home or originating authority responsibilities and contracting in services for enforcement purposes.

Food Authorities and their officers should avoid promoting the Food Authority's services exclusively if other providers of those services exist in the area or the services offered by a particular organisation

Pest control and food hygiene training are examples of local Food Authority services that may be provided in competition with those supplied by other organisations.

Where a Food Authority delegates enforcement to an independent third party (control body¹⁹) then that authority must obtain proof that the control body is impartial and free from any conflict of interest as regard the tasks delegated to it.

1.3.3: Enforcement within Local Authority-run Establishments

The Food Authority's food law Enforcement Policy (see Paragraph 3.1.4) should detail the Food Authority's arrangements for ensuring compliance with food law in establishments where the Authority is itself the food business operator and that steps are taken to ensure enforcement decisions are free from any conflict of interest.

Any serious breaches of food law that may be detected in such establishments should be brought to the attention of the Chief Executive, without delay.

Contract caterers that operate within local authority establishments should be assessed in accordance with Annex 5 and be inspected accordingly.

¹⁹ See Article 2(5) of Regulation 882/2004

CHAPTER 1.4: FOOD BUSINESS ESTABLISHMENT RECORDS

1.4.1: Introduction

This Chapter requires, in line with Article 31 of Regulation 882/2004, Food Authorities to maintain an up-to-date database of registered and approved food business establishments in their area, and confirm that this data may be divulged for the purposes of ensuring public health and the effective enforcement of food law.

1.4.2: Database of Food Business Establishments

Food Authorities should maintain an up-to-date database of food business establishments which have been registered with them and food business establishments which have been approved or conditionally approved by them. Food Authorities should liaise as necessary to ensure that information is made available to all authorities that require it in accordance with Paragraph 1.1.5 (see also Chapter 4.5). The database should include a comprehensive record of:

- Food business establishments registered with the authority;
- Food Business establishments that are the decision-making base of businesses for which the Food Authority acts as Home Authority for food matters;
- Food business establishments which have been approved by the Food Authority.

In the parts of England in which there are two tiers of local government and each tier is a Food Authority, County Council Food Authorities should keep a database of information supplied to them by District Council Food Authorities in accordance with Paragraph 1.1.5.

Each Food Authority should have a documented procedure for ensuring that its database is up-to-date and protected against corruption and loss of information, including the use of the information supplied on registration or approval application forms to update the database.

1.4.3: Access to information

Food Authorities should provide details of relevant food business establishment records if requested by the HPA²⁰, the CCDC/CPHM (CD/EH), the Agency or other similar enforcement or surveillance body to facilitate the investigation of an outbreak or suspected outbreak of disease, the investigation of a food hazard or other food-related emergency or criminal investigation. Such requests should be handled with due regard to Freedom of Information and Data Protection legislation

²⁰ Health Protection Agency

Requests for information other than from the above bodies should be handled with due regard to Freedom of Information and Data Protection legislation (see also Paragraph 1.4 of the Practice Guidance) and to Paragraph 1.5.4 in connection with requests for information on registered food business establishments.

CHAPTER 1.5: REGISTRATION OF FOOD BUSINESS ESTABLISHMENTS

1.5.1: Introduction

Under Article 6(2) of Regulation 852/2004, food business operators must register their establishments (i.e. each separate unit of their food businesses) with the appropriate Food Authority, except establishments which:

- Are subject to approval under Regulation 853/2004 (see Section 5), or;
- Fall outside the scope of the Regulation 852/2004 (see Paragraph 1.5.2).

Responsibility rests with Food Authorities for recording and maintaining details of food business establishments which have been registered with them under Regulation 852/2004 (see Chapter 1.4). including establishments producing raw milk intended for direct human consumption other than raw cows' milk (Regulation 5(4)(b) of the Food Hygiene (England) Regulations 2006 refers). For the registration of establishments undertaking primary production see Annex 5.

1.5.2: Exemptions

In respect of food business establishments subject to Regulation 852/2004 only i.e. establishments which are not subject to approval under Regulation 853/2004, there are no specific exemptions from the requirement to be registered.

In determining whether or not a particular establishment is subject to Regulation 852/2004 only (and is hence required to be registered) consideration should be given to whether the business concerned is a 'food business' as defined in Regulation $178/2002^{21}$, and to both Recital (9), and Article 1(2), of Regulation 852/2004 which set out the circumstances under which the Regulation, and hence the requirement to register under Article 6(2), would not apply.

1.5.3: Registration of New Food Business Establishments

1.5.3.1: Applications for Registration: General

Under Article 31(1)(a) of Regulation 882/2004 the Competent Authority is required to establish procedures for food business operators to follow when applying for the registration of their establishments. The following paragraphs set out these procedures.

²¹ Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

1.5.3.2: Time Frame for Registration

Food business operators should register their food business establishments with the appropriate Food Authority at least 28 days before food operations commence.

1.5.3.3: Registration Form

Food business operators must provide the relevant Food Authority with full details of the activities undertaken when registering their establishments. A model registration form as at Annex 8 should be made available to, and completed by, food business operators for each establishment under their control and submitted to the relevant Food Authority.

1.5.3.4: Sites on which there is more than one Food Business Establishment

1.5.3.4.1: Establishments under the control of the same Food Business Operator

Sites will exist on which there are two or more food business establishments under the control of the same food business operator. For example, in the case of a shopping centre in which there are two or more food business establishments under the control of the same food business operator, such operators must ensure that each establishment under their control is registered separately. Food business operators should therefore complete a registration form for each separate establishment.

1.5.3.4.2: Establishments under the Control of Different Food Business Operators

Sites will also exist on which there are two or more food business establishments under the control of different food business operators. For example, a supermarket may have a coffee shop on site under the control of a different food business operator such as a coffee shop chain. In such cases, the coffee shop will not be covered by the supermarket's registration and must be registered in its own right by its operator. Coffee shops, snack bars etc. operated by the supermarket itself would be covered as part of the supermarket's registration.

1.5.4: Lists of Food Business Establishments

1.5.4.1: Requirements of Regulation 882/2004

Article 31(1)(b) of Regulation 882/2004 requires the appropriate Competent Authority to draw up a list of food establishments that have been registered and permits the use of existing lists to be used for this purpose.

The register of food business establishments held by each Food Authority in accordance with the now revoked Food Premises (Registration) Regulations 1991, as amended, in the authority's database (see Chapter 1.4) satisfy this requirement and may be carried forward. Food business operators will not, therefore, need to re-register food business establishments under their control which have already been registered with a Food Authority. Food Authorities

must maintain their lists in accordance with the requirements of Article 31(1)(b) of Regulation 882/2004.

1.5.4.2: Separate List of Registered Food Business Establishments

Unitary Authorities and District Council Food Authorities should also ensure that a separate, up-to-date, list of food business establishments registered with them is available for inspection by the general public at all reasonable times. The list should contain the following information about each food business and should be consistent with the information held in the Food Authority's database:

- 1. Name of the food business
- 2. Address of the food business establishment
- 3. Particulars and nature of the food business

These authorities may give or send a copy of their list or any entry on it to any person who makes a request for such information.

County Council Food Authorities should refer requests from the general public for information on registered food business establishments in their area to the relevant District Council Food Authority.

1.5.5: Action on Receipt of Completed Registration Form

On receipt of a completed registration form, Food Authorities should record the date of receipt on the form. They should ensure that if there are any activities indicated on the form outside their enforcement remit, a copy of the form is sent without delay to the relevant Competent Authority.

Food Authorities should enter relevant information from the registration form on to the database (see Chapter 1.4) and lists (see Paragraph 1.5.4) of registered food business establishments. The registration form should then be placed on a file prepared in respect of that food business establishment.

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

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

On receipt of a completed application form, Food Authorities should also give consideration to carrying out an inspection of the establishment in accordance with Paragraph 4.1.3.2

1.5.6: Registration Certificates / Confirmation of Receipt

Certificates of Registration for food business establishments should not be issued to food business operators because of their potential to mislead consumers into believing that a food business establishment has "official approval". Food Authorities may, however, choose to confirm safe receipt of registration forms and the entry of an establishment on to the list of registered food business establishments. Any such confirmation should remind the food business operator to advise the Food Authority of any subsequent changes to the business, in accordance with Article 6(2) of Regulation 852/2004 (see Paragraph 1.5.7).

1.5.7: Changes to Activities after Registration

Under Article 6(2) of Regulation 852/2004, food business operators must ensure that the appropriate Competent Authority always has up-to-date information on their food business establishments and must notify the relevant Competent Authority of any significant changes of activities, or closure.

Any changes to the details previously supplied e.g. a change of food business operator, a change to the activities carried out in relation to food, the closure of an establishment etc. should be notified by the food business operator to the relevant Food Authority. Notification of a change to the operator of a food business establishment should be made by the new food business operator.

On receipt of a notification of a change of activities Food Authorities should update the list of registered food business establishments as appropriate, and place or record the details on the file relating to that food business establishment.

1.5.8: Moveable Establishments

1.5.8.1: Ships, Aircraft, Trains and Coaches

Although ocean-going ships, aircraft, trains and long distance coaches are subject to the provisions of Regulation 852/2004, their movable nature generally means that there is little practical value in the registration of individual ships, aircraft, trains and coaches with the Food Authority in whose area they are be based as they are not always present in that authority's area of jurisdiction. See enforcement approaches set out at Paragraph 4.1.12 (trains and coaches) and Chapter 4.4 (ships and aircraft).

However, food business operators must register vessels under their control which are permanently moored such as floating restaurants etc. with the relevant Food Authority. Food business operators must also register vessels under their control which ply their trade on inland waterways e.g. pleasure craft, with the Food Authority in the area in which they are ordinarily kept.

Where a food business operator is engaged solely in the operation of a fleet of vehicles for the purposes of the distribution of food to other food business operators, then registration is required.

1.5.8.2: Vending Machines

Vending machines are subject to the relevant provisions of Regulation 852/2004. However, there is little practical value in the registration of individual vending machines or the premises on which they are sited if the only food related activity on those premises relates solely to vending machines. However, distribution centres where food for stocking vending machines is stored and/or from which food is transported to vending machines for stocking should be registered with the relevant Food Authority. The delivery vehicles used for the transport of food for stocking vending machines should be covered in the interventions at such establishments.

1.5.8.3: Markets

In the case of vehicles and stalls (whether or not these stalls are provided by the controller of the market) used for transporting or preparing food or the sale of food to consumers within the area of a market, the food business operator should register the establishment in which their stocks of food to be sold are ordinarily kept with the relevant Food Authority.

If the controller of a market is the provider of permanent units (establishments) (and not simply stalls) within a market, the food business operators operating their food businesses from those establishments should register each such establishment with the relevant Food Authority.

1.5.8.4: Movable establishments other than those which form part of a market operating within the area of a market

Moveable establishments other than those which form part of a market or operate within the area of a market e.g. ice cream vans, hot dog vendors etc. should be registered by the food business operator with the Food Authority in the area in which they are ordinarily kept.

1.5.9: Non-registered establishments thought to be engaged in activities subject to Regulation 852/2004

In such circumstances the Food Authority should ask the food business operator to complete a registration form as soon as possible and should satisfy itself that the food business establishment is operating in compliance with the other provisions of Regulation 852/2004 as appropriate.

EU food hygiene legislation requires primary producers to notify the Competent Authority of establishments under their control with a view to those establishments being registered. The details of the registration process for food business operators are detailed in EC Regulation No. 852/2004 while the Official Feed and Food Control (OFFC) Regulations 2006 enforcing regulation (EC) No. 882/2004 provides requirements for Competent Authorities, defined as the central authority of a member state competent for the organisation of official controls to register and list those businesses.

The purpose of registration is to enable the Competent Authorities to have the business details available, from external sources if necessary, so businesses can subsequently be factored into official controls.

Regulation (EC) No. 882/2004 states in Article 31 (1)(b) states that 'where such a list already exists for other purposes, it may also be used for the purposes of this Regulation'. The option to use existing lists is also detailed in the Commission's guidance document on the implementation of 852/2004 where specific examples of suitable alternative registration information sources are made e.g. environmental or animal health data. A new dedicated food hygiene registration system at primary production level is **not** therefore required

Officers are directed to Section 3 for general guidance on enforcement.

Officers should be careful to ensure that:

- Such establishments are subject to Regulation 852/2004;
- Such establishments are not subject to approval under Regulation 853/2004 (see Section 5).

CHAPTER 1.6: CROWN AND POLICE PREMISES

1.6.1: Introduction

This Chapter 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. For information on military ships and aircraft refer to Chapter 4.4. Home Authority contacts for the Army, Royal Navy and Royal Air Force are given in Paragraph 4.4.4.

1.6.2: Powers of Entry (Food Hygiene (England) Regulations 2006)

The powers of entry under Regulation 14 of the Food Hygiene (England) Regulations 2006 may be used in relation to Crown premises.

As there are no specific exemptions for certain members of the Royal Family or certain Royal residences afforded by the Food Safety Act 1990 (see Paragraph 1.6.3 below), Food Authorities should use discretion when exercising their powers in respect of Crown premises.

In practice, Food Authorities should adopt the same approach to the enforcement of the Food Hygiene (England) Regulations 2006 in respect of Crown premises as they do in respect of the Food Safety Act 1990.

1.6.3: Powers of Entry (Food Safety Act 1990)

The powers of entry under Section 32 of the Food Safety Act 1990 may be used, in respect of food standards issues, in relation to Crown premises (subject to exemptions for certain members of the Royal Family and certain Royal residences). However, a national security certificate may have been issued by a Secretary of State certifying that powers of entry under the Food Safety Act 1990 cannot be exercised. If an authorised officer seeks entry to Crown premises and is informed that such a certificate has been issued, the officer may ask to see the certificate or a copy of it.

1.6.4: Obtaining Entry to Crown Premises

For the purposes of obtaining entry, Crown premises fall broadly into 3 categories, although premises may move from one category to another between inspections.

<u>Group 1</u> - includes premises situated on Crown land where there are normally no security implications, e.g. restaurants in museums or Royal Parks. These premises should be treated like any other food business.

Group 1 premises should normally be visited without prior arrangement.

<u>Group 2</u> - includes premises with controlled entry but normally minimal security implications. Most government and police premises fall within this category. They are similar to many private businesses with security systems.

First visits to Group 2 premises should be by prior arrangement. Future visits may be unannounced, but arrangements for subsequent visits should be agreed at the first inspection and confirmed in writing.

<u>Group 3</u> – includes premises where unannounced entry is not possible because of security implications and/or for the personal safety of the authorised officer, e.g. HM Forces, defence and national security establishments, prisons and remand centres, and parts of police premises that accommodate prisoners.

Group 3 premises should always be visited by prior arrangement with the appropriate contact at the establishment concerned, e.g. the defence establishment security officer, the commanding officer or nominated representative of an HM Forces establishment, the Governor of a prison service establishment, or the officer in charge of police premises. This will enable the authorised officer to obtain entry without undue delay. The contact may be reminded of the power of entry if an authorised officer considers that the suggested appointment is too far in advance.

Authorised officers who have not been security cleared will be subject to visitor control procedures and escorted at all times. Officers should carry an identity card that incorporates their photograph.

Authorised officers should bear in mind that there may be times when it will not be possible for an inspection to take place or continue in Group 3 premises. Any such reasonable restriction should not be regarded as obstruction.

The authorised officer's name, date of birth, card or pass number (if any), and the registration number of the officer's motor vehicle should be given in advance of a visit to Group 3 premises, if required.

If the Food Authority is in doubt as to how to classify particular premises to which this Chapter applies, they should be treated as Group 3 premises and reviewed at a later stage, if necessary.

An incident such as a food poisoning outbreak may require an authorised officer to visit premises at short notice even though prior notice would normally be required. A telephone notification that the officer is on the way is essential in Group 3 premises, and may save time in gaining entry to Group 2 premises. It should not normally be necessary in such circumstances to give more than the briefest notice of such a visit.

1.6.5: Conduct of Inspections

Authorised officers should be aware of matters of confidentiality when inspecting those parts of premises that accommodate prisoners. Such matters may be discussed when the visit is arranged.

Inspections should be confined to areas used by the food business or where records relating to it are held, unless the inspection is connected with the

investigation of an outbreak of foodborne disease and it is necessary, as part of the investigation, to inspect other areas.

Military activities should not be impeded or interrupted by an inspection.

Authorised officers should conform to the security requirements of the establishment concerned, including baggage inspections and identity checks.

1.6.6: Photographs

Before taking any photographs, making sketches or taking measurements on Group 3 premises, the authorised officer should discuss such matters with the escorting officer and take account of any requirements. Unless absolutely necessary to illustrate a possible contravention of the legislation, photographs on Group 3 premises should not include individuals. It should not be possible to identify any individual from any photograph taken within a prison or remand establishment.

1.6.7: Liaison with the Home Authority / Agency

Food Authorities should report any difficulties encountered in the enforcement of food law in premises to which this Chapter applies to the appropriate home authority or, if there is no home authority, to the Agency.

CHAPTER 1.7: FOOD INCIDENTS AND HAZARDS

1.7.1: Introduction

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

A schematic representation of the process that Food Authorities should follow when dealing with a food incident or hazard is included at Annex 3.

1.7.2: Food Incidents / Food Hazards

1.7.2.1: Food Incident: Definition

A "food incident" occurs when a Food Authority or the Agency becomes aware that food or its labelling (e.g. in relation to the presence of undeclared allergens) fails or appears to **fail to meet food law requirements**. A food incident can be a relatively minor matter or a major food hazard.

1.7.2.2: Food Hazard: Definition

A "food hazard" is a food incident involving a biological, chemical or physical agent in, or condition of, food with the potential to cause an **adverse effect** on the health or safety of consumers.

1.7.2.3: Documented Procedure

Food Authorities should set up and implement a documented procedure for dealing with food incidents that are identified within their area.

1.7.3: Categories of Food Hazard

Food Authorities should categorise food hazards according to the following criteria:

- A localised food hazard one in which food is not distributed beyond the boundaries of the Food Authority and is NOT deemed to be a serious localised food hazard;
- A serious localised food hazard one in which food is not distributed beyond the boundaries of the Food Authority but which involves *E. coli* O157, other VTEC, *C. botulinum, Salmonella typhii or Salmonella paratyphi* or which the Food Authority considers significant because of, for example, the vulnerability of the population likely to be affected, the numbers involved or any deaths associated with the incident;
- A non-localised food hazard one in which food is distributed beyond the boundaries of the Food Authority.

A Food Authority should seek the advice of the Agency if it is in doubt as to whether a food incident amounts to a food hazard.

1.7.4: Deliberate Contamination and Malicious Tampering

Food may be contaminated deliberately. If such an incident occurs, Food Authorities should follow the arrangements in this Chapter, except where the deliberate contamination is thought to be due to malicious tampering. For the purposes of this Code, "malicious tampering" means the deliberate contamination of food by terrorist activity, or with a view to blackmail or extortion.

Arrangements for dealing with malicious tampering incidents have been established between the Agency and the police forces throughout the UK and if necessary the Serious Organised Crime Agency will be involved in the investigation.

Food Authorities should contact the Food Standards Agency at the earliest opportunity if malicious tampering is suspected and hand over responsibility for dealing with such incidents to the police if requested by them to do so.

Food Authorities should co-operate fully with police investigations into incidents of malicious tampering and respect police requests for confidentiality whenever possible, although there may be occasions when the need to alert consumers to the existence of a food hazard outweighs the need to maintain confidentiality.

1.7.5: Food hazards associated with outbreaks of foodborne illness

If a food hazard has resulted in an outbreak of foodborne illness, the Food Authority should consider, with their CCDC/CPHM (CD/EH), the activation of their Outbreak Control Plan.

Serious localised outbreaks should immediately be notified to the appropriate contacts at HPA CDSC in England, the National Public Health Service in Wales, and the Agency²².

Food Authorities should arrange with their Public Analyst and Food Examiner to be notified promptly if they identify a food hazard during the course of the analysis or examination of a food sample.

1.7.6: Action by the Food Authority – Food Hazards

Once a food hazard has been identified, the Food Authority should immediately carry out an assessment to determine the likely scale, extent and severity of the risk to public health or safety of the hazard, involving other agencies as appropriate. These other agencies may include home, originating and neighbouring authorities, medical specialists, Food Examiners, Public Analysts and microbiologists.

²² A list giving contact details is issued as a separate document and is available from the Food Incident Team at the Agency, Room 715B, Aviation House, 125 Kingsway, London, WC2B 6NH, tel: 020 7276 8448/8453.

Food Authorities should have procedures in place to call the appropriate agencies together at short notice, to implement urgent control measures whenever they are required and to identify a lead authority if necessary.

The assessment should include the following:

- The nature of the hazard;
- The toxicity of the contaminant, the allergenicity of an undeclared ingredient/constituent, or the virulence and pathogenicity of the organism;
- The type of injury which might be caused by a physical contaminant;
- The population likely to be affected and its vulnerability;
- The likely quantity and distribution of the food in the food chain up to the point of consumption;
- The ability and willingness of the producer or distributor to implement an effective withdrawal of the product;
- The ability to identify accurately the affected batch(es) or lot(s);
- The accuracy and extent of records held by the producer or distributor;
- The likely effectiveness of any trade withdrawal at all stages of the food chain;
- The stage(s) at which the fault is likely to have occurred (for example in processing, packaging, handling, storage or distribution) and its likely significance to the problem;
- Whether other products produced in the same establishment may have been affected;
- Whether the food has been imported;
- Whether any of the food has been exported;
- Whether there are wider implications for others in the same industry or for establishments using similar processes in other food industries;
- The possibility that the complaint or problem has been caused by a malicious act (see Paragraph 1.7.4).

When a Food Authority becomes aware of a food hazard it should take action to protect public health and safety at the earliest opportunity, including, if necessary, detaining or seizing the food concerned if it is located within the Food Authority's area (see Chapter 3.4). Food Authorities should also consider the use of other powers under the Food Hygiene (England) Regulations 2006 or the Food Safety Act 1990 as appropriate, relevant to the circumstances involved.

Localised food hazards should be dealt with locally by the Food Authority, in conjunction with other relevant agencies and need not be reported to the Agency.

Serious localised food hazards and **non-localised food hazards** should be notified by the Food Authority to the Agency and other relevant agencies at the earliest opportunity and by the quickest available means²³ and confirmed in writing using a copy of the incident report form at Annex 4. This form is also available on the Agency's website and can be submitted directly to the Food Incidents Team via the website.

However, where a Food Authority becomes aware that a food business operator in their area has withdrawn or recalled food from the market in accordance with Article 19 of Regulation 178/2002 due to non-compliance with the food safety requirements of that Regulation, the Food Authority should confirm that the Agency is also aware.

Responsibility for action at local level remains with the Food Authority unless the Agency notifies the Food Authority otherwise.

1.7.7: Localised Food Hazards – Media Relations

In the event of a localised food hazard, the Food Authority may issue a local press statement to alert the public to the hazard. The relevant food business operators should be consulted before the identity of a named business or branded food is discussed with, or released to, the media. Such media releases should be sent to the Agency without delay. The Food Authority should notify the Agency immediately if the food business operator raises objections to the release of such information.

1.7.8: Action by the Food Authority – Food Incidents

Food incidents that are contraventions of food law, but not food hazards should normally be resolved by the Food Authority and the food business operator, through the home or originating authority if appropriate.

²³ A list giving contact details is issued as a separate document and is available from the Food Incident Team at the Agency, Room 715B, Aviation House, 125 Kingsway, London WC2B 6NH. Tel: 020 7276 8448 / 8453.

SECTION 2: COMMUNICATION

CHAPTER 2.1: DISCLOSURE OF INFORMATION

CHAPTER 2.2: FOOD ALERTS

2.2.1: General

(See also Chapter 1.4 of the Practice Guidance)

There will be circumstances in dealing with communications when confidentiality, data protection and human rights issues arise. In such circumstances, the Food Authority must apply the law and general principles set out in relevant legislation and case law to the specific facts with which they are dealing. This is best done at a local level, and local administrators should consult their own Legal Department.

2.2.2: Introduction

A "food alert" is a communication from the Agency to a Food Authority concerning a food hazard or other food incident, and a "food alert update" should be read accordingly. A food alert or a food alert update may or may not require the Food Authority to take action and any action/responses required by the Agency will be clearly specified.

The Agency may also issue information to Food Authorities on product recalls or food incidents.

2.2.3: Responding to Food Alerts

Food Authorities should ensure that their documented procedure for dealing with food safety incidents²⁴ includes the effective response to food alerts issued by the Agency.

This documented procedure should be developed in consultation with:

- Members of the relevant Food Liaison group;
- HPA;
- Public Analyst;
- CCDC;
- Relevant officers of the Food Authority, e.g. Emergency Planning Officer.

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

- Details, including contact details, of the Lead Officer for such matters;
- Liaison arrangements between County Council and District Council officers in two-tier Food Authority areas;

²⁴ See Chapter 2, Section 14, of the Framework Agreement.

- Any arrangements for the reception of and response to alerts received outside office hours;
- Arrangements to ensure that food alerts and updates are brought to the attention of an officer with authority to initiate appropriate action without undue delay;
- Arrangements for the liaison with other relevant bodies, including neighbouring Food Authorities, both within and outside normal office hours;
- Arrangements to provide adequate staff resources to allow effective response to alerts;
- Arrangements to provide adequate equipment, including access to Council Offices out of hours, to allow an effective response to be made.

2.2.4: Facilities for Receiving Food Alerts and Updates

Food Authorities should have facilities to receive food alerts and updates from the Agency by an electronic mail system that is acceptable to the Agency. Food Authorities should put in place systems to ensure that food alerts can be responded to outside normal working hours.

Food Authorities should advise the Agency of their electronic mail address and of any changes to these details at the earliest opportunity.

2.2.5: Out-of-hours Services

Food Authorities should advise the Agency of emergency telephone numbers on which responsible officers may be contacted outside the Food Authority's normal office hours and of any changes to these details at the earliest opportunity.

2.2.6: Action by Food Authorities

Food Authorities must ensure that any action specified by the Agency in a food alert is undertaken promptly and in accordance with any risk assessment carried out by the Agency. If Food Authorities propose to take alternative actions, they should agree these with the Agency before implementing them. Where a Food Authority anticipates difficulties in complying with a request for action given in an alert, they must contact the Agency's Food Incident Team immediately.

2.2.7: Media Relations – Food Alerts

Food Authorities wishing to enhance local publicity may, where permitted by the Agency, use a press release/media statement issued by the Agency as a basis for a local press release. In such cases, the Food Authority must ensure that the local statement is accurate, relevant and consistent with the Agency statement. If Food Authorities wish to display food alerts on their websites they should ensure that any material from Agency food alerts or press/media releases is edited so as to specify what local action has been taken in response to the alert. It should also include local contact information.

CHAPTER 2.3: AGENCY COMMUNICATIONS AND GUIDANCE

2.3.1: Introduction

This Chapter requires Food Authorities to take appropriate action on Agency guidance on the effective enforcement of food law.

2.3.2: Guidance Issued to Food Authorities

The Agency will, from time to time, need to issue enforcement guidance or communicate with Food Authorities to ask them to take action, to pass on information, or for other reasons connected with the effective enforcement of food law.

Such communications may be by letter, fax or e-mail and will be clearly identified as communications to which this Chapter applies. They will be sequentially referenced and include details of any action required to be taken by the Food Authority.

Food Authorities should have arrangements to determine what action is appropriate locally on receipt of such communications and to bring them to the attention of their authorised officers if necessary.

2.3.3: Enforcement Consistency

The consistent application and enforcement of food law by Food Authorities is essential to ensure the protection of consumers and the fair treatment of food businesses.

Food Authorities should therefore have due regard to enforcement guidance issued by, jointly with, or on behalf of the Agency.

The Food Authority should have regard to centrally issued guidance, including that from LACORS.

CHAPTER 2.4: INFORMATION TO BE SUPPLIED TO THE AGENCY

2.4.1: Introduction

This Chapter deals with the information required by the Agency in relation to:

- Food hazards
- Approvals and other matters under the EU food hygiene Regulations;
- Matters relating to European liaison arrangements;
- Lead officers; electronic mail addresses;
- Emergency telephone numbers.

2.4.2: Matters Relating to Food Hazards

Food Authorities must notify the Agency as soon as they become aware of a:

- Serious localised food hazard;
- Non-localised food hazard;
- Serious localised outbreak of foodborne illness;
- Withdrawal or recall of food by a food business operator due to noncompliance with the food safety requirements of Regulation 178/2002 (Article 19).

2.4.3: Matters Relating to Product-Specific Establishments Subject to Approval under Regulation 853/2004

Food Authorities must notify the Agency:

- When an establishment has been approved or conditionally approved;
- Where an approved establishment ceases activities that are the subject of the approval or conditional approval;
- Where an approval or conditional approval has been withdrawn or suspended;
- Where a live bivalve mollusc purification centre or modification to an existing centre is proposed (see Paragraph 5.1.9);
- Where they have designated a live bivalve mollusc relaying area (see Paragraph 5.1.10). The notification should include the relevant details of the area and any specified operating conditions;

• Where consideration is being given to the issue of a Closure Notice to restrict the harvesting of live bivalve molluscs (see Paragraph 5.3.5).

2.4.4: Quality of Live Bivalve Mollusc Production and Relaying Areas

Food Authorities responsible for live bivalve mollusc production or relaying areas must notify the Agency where sample results suggest a significant variation in the quality of such areas (see Paragraph 4.3.3.2).

2.4.5: Matters Relating to the Delegation of Tasks Related to Official Controls

Food Authorities responsible for the delegation of specific tasks to independent third parties (control bodies²⁵) must provide the Agency with details of the control body and the tasks delegated to it.

2.4.6: Matters Relating to Liaison Arrangements with Other Member States

Food Authorities must notify the Agency whenever they become aware of a trans-border matter that should be referred directly to the Agency (see Paragraph 2.5.2.1).

2.4.7: Lead Officers

Food Authorities must notify the Agency of the name of their appointed lead officer who has operational and management responsibility for food hygiene and safety matters and / or for food standards matters, and notify any changes to these details (see Paragraph 1.2.8).

2.4.8: Electronic Mail Addresses

Food Authorities must notify the Agency of their electronic mail address and notify any changes to these details (see Paragraph 2.2.3).

²⁵ As defined in Article 2(5) of Regulation 882/2004

CHAPTER 2.5: LIAISON WITH OTHER MEMBER STATES

2.5.1: Introduction

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

Trans-border matters that may have policy implications, matters relating to outbreaks of foodborne disease and matters connected with food hazards are dealt with by the Agency. Food Authorities must therefore notify the Agency of all such matters at the earliest opportunity.

Detailed provisions on administrative assistance and co-operation with other Member States are set out in Articles 34 to 38 of Regulation 882/2004.

2.5.2: Trans-border Issues

Trans-border matters fall into three broad categories:

- A. Trans-border matters that need to be referred directly to the Agency;
- B. Trans-border matters reported to the Agency after liaison has taken place;
- C. Routine liaison between Food Authorities and food control authorities in other Member States.

2.5.2.1: A. Trans-border Matters to be referred directly to the Agency

- The identification of foods which appear to pose a risk to public health or safety;
- Enquiries about a particular product which has been examined and the microbiological condition of which gives cause for concern;
- The identification of foods which relate to previously identified food warnings, frauds or hazards;
- Cases where malicious tampering of food is suspected;
- Circumstances in which food products have been removed from the UK market with or without the agreement of the retailer or supplier;
- Cases in which the authorised officer suspects that other significant national or EC policy matters are at issue.
- Where repeated non-compliance has been identified in connection with <u>different</u> batches, lots or consignments from the same source.

2.5.2.2: B. Trans-border Matters Reported to the Agency After Liaison has Taken Place

- Any issue when, after investigation, liaison or inquiry, it appears that circumstances set out in Paragraph 2.5.2.1 above apply;
- Cases involving enforcement authorities in other EC Member States where there is undue delay, equivocation or a refusal to undertake action which appears to be warranted;
- Circumstances in which it appears that elements of the national food law of one Member State conflicts with that of another;
- Any issue listed for information which, after investigation, liaison or enquiry, appears to have such implications or is of such a serious nature that the Agency should be informed of it.

2.5.2.3: C. Routine Liaison between Local Food Control Authorities of Member States

Food Authorities should only deal directly with "For Information" matters. Other issues requiring action should be referred without delay to the Agency. Food Authorities should seek advice from the Agency if there is doubt as to the appropriate procedure for dealing with a particular trans-border matter.

Matters of routine liaison between local food control authorities of Member States under Category C would include:

- Enquiries about a particular product which has been analysed and found to have no food safety implications;
- Enquiries about a product label or description which appears to be in breach of requirements;
- Enquiries about sampling records, company history or control systems likely to support legal action;
- Enquiries to establish the integrity of documents, problem source and to avoid duplicating sampling or inspections;
- Enquiries into the particular circumstances surrounding the rejection of, or cause for enforcement action relating to, a specific UK food product;
- Notification of other faults and infringements unlikely to require UK action, but which are for note or action by the authority in another EC Member State.

2.5.3: Enquiries to Other Member States

Food Authorities should address enquiries about food law enforcement issues in other Member States to the appropriate liaison body or authority in the Member State concerned either via the Agency or direct. The Agency can provide assistance in identifying the relevant liaison body or authority if necessary.

Food Authorities should carry out a full investigation prior to referring a matter to the Agency with full supporting documentation.

2.5.4: Enquiries from Other Member States

Food Authorities should comply with any reasonable request for information or administrative assistance from another Food Authority, food control body, another Member State (or the Agency). In doing so they should take the following action:

- Acknowledge receipt of the request and advise the originating party that it is being dealt with;
- Investigate if necessary;
- Take appropriate enforcement action, if necessary;
- Inform the originating party of the results of any enquiries, inspections, or other enforcement action, either directly or through the Agency;
- Ensure that responses to requests are open, helpful and provided without undue delay;
- Keep the originating party updated on progress when action is ongoing and the outcome will not be known for some time.

Any request for information which, after investigation, liaison or enquiry, appears to be of a serious nature should be referred to the Agency.

2.5.5: Disclosure of Information to Other Member States

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

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

SECTION 3: GENERAL ENFORCEMENT

CHAPTER 3.1: APPROACH TO ENFORCEMENT

3.1.1: Introduction

This Chapter

- Lists reference materials of which Food Authorities should take account.
- Requires each Food Authority to document its food law Enforcement Policy and keep it up-to-date.
- Also requires that direct communication with multi-site food businesses should normally be with the head office unless the business has agreed other arrangements.

A clear distinction between statutory requirements and good practice must be made in all communications with food businesses. Where appropriate, decisions to prosecute should be taken at the earliest opportunity. Where, on the other hand, it is decided to adopt an informal approach, it should be explained to the food business operator what action is needed to secure compliance.

3.1.2: Enforcement Information

Food Authorities should ensure that authorised officers have up-to-date information readily available to enable them to carry out their duties competently.

This includes

- relevant legislation,
- this Code of Practice,
- UK Guides to Good Practice where appropriate,
- guidance issued by the Agency and LACORS,
- relevant industry codes of practice, and
- appropriate technical literature.

3.1.3: Reasonableness, Proportionality and Consistency

Food Authorities should ensure that enforcement action taken by their authorised officers is reasonable, proportionate and consistent with good practice.

Authorised officers should take account of the full range of enforcement options. This includes educating food business operators, giving advice, informal action, sampling, detaining and seizing food, serving hygiene improvement notices / improvement notices, hygiene prohibition procedures / prohibition procedures and prosecution procedures.

Except where circumstances indicate a significant risk, officers should operate a graduated and educative approach (the *hierarchy of enforcement*) starting at the bottom of the pyramid i.e. advice/education and informal action and only move to more formal action where the informal does not achieve the desired effect. This should lessen the likelihood of a legal challenge.

In considering whether to initiate enforcement action, Food Authorities should take account of the following:

- The Code for Crown Prosecutors;
- The Enforcement Concordat;
- The Food Authority's Enforcement Policy.

3.1.4: Food Law Enforcement Policies

Each Food Authority should have an up-to-date, documented Food Law Enforcement Policy²⁶ which is readily available to food business operators and consumers.

The Policy should cover all areas of food law that the Food Authority has a duty to enforce and include criteria for the use of all the enforcement options that are available.

Food Authorities should have regard to any advice issued by the Agency and by LACORS when drafting their Food Law Enforcement Policies.

A Food Authority's Food Law Enforcement Policy may be part of a generic policy, or combined with other enforcement policies, e.g. feeding stuffs, providing the applicability of the Policy to the enforcement of food law is clear.

Authorised officers should implement their Food Authority's food law Enforcement Policy, which should reflect all the factors set out in Paragraph 3.1.3.

Departures from the Policy should be exceptional and the reasons for any departure should be recorded.

In deciding the type of enforcement action to take, an authorised officer should have regard to

• the nature of the breach and

²⁶ See Chapter 2, Paragraph 15.1 of the Framework Agreement

- the history of compliance of the food business operator or,
- in the case of new businesses, an assessment of the food business operator's willingness to undertake the work identified by the officer.

It is important that the full range of enforcement options remains open to an authorised officer. A Food Authority should **not** adopt policies where the number of (hygiene) improvement notices served or the number of other legal processes such as prosecution or formal caution is an indicator of performance.

3.1.5: Communication with Multi-site Food Businesses

Communications between Food Authorities and multi-site food businesses should where possible be in accordance with the Home Authority Principle.

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

Documents that are left with on-site personnel should also be copied to the relevant head office or other address unless the business indicates otherwise.

3.1.6: Mandatory Requirements and Advice

A clear distinction between action needed to meet statutory requirements and recommendations about good practice should be made in all communications with food businesses.

All correspondence should identify each contravention and the measures which, in the opinion of the officer, could be taken in order to secure compliance. Correspondence should contain an indication of the time scale suggested for achieving compliance.

Standard documents, circulars, booklets and other publications issued by the Food Authority should be accurate and reflect current practice. Food Authorities should be prepared to discuss letters, circulars, etc with any food business operator to whom they have been sent.

3.1.7: Use of Food Safety Act 1990, as Amended and Regulations Made Under the Act

Food Authorities should deal with food hygiene matters under the Food Hygiene (England) Regulations 2006 and food standards matters under the Food Safety Act 1990. However, those who handle food for sale or supply which, by virtue of Recital (9) and Article 1(2) of Regulation 852/2004, fall outside the scope of that regulation remain subject to the provisions of the Food Safety Act 1990 and Regulation 178/2002, and appropriately authorised officers may use enforcement powers under the Act and Regulations made under the Act to enforce in respect of such activities. An example would be

enforcement action taken under the General Food Regulations 2004²⁷ (made under the Food Safety Act 1990) in respect of a one-off event, such as a wedding reception that resulted in an outbreak of food poisoning i.e. the sale or supply of unsafe food in contravention of Article 14(1) of Regulation 178/2002.

3.1.8: Powers of Entry, Search and Seizure: Human Rights Act 1998 / Police and Criminal Evidence Act 1984 (PACE)

(See also Chapter 3.1 of the Practice Guidance)

The right to privacy and respect for personal property are key principles of the Human Rights Act 1998. Powers of entry, search and seizure should be fully and clearly justified before use because they may significantly interfere with the occupier's privacy. Officers should consider if the necessary objectives can be met by less intrusive means.

Section 32(4) of Food Safety Act 1990 and Regulation 14(5) of the Food Hygiene (England) Regulations 2006 permit an authorised officer to take with them such other persons as they consider necessary. This would include, for example, any suitably qualified or skilled person or an expert in a particular field whose presence is needed to help accurately identify the material sought or to advise where certain evidence is most likely to be found and how it should be dealt with. It does not give an authorised officer any right to force entry to search or seize property but it does give the *other person* the right to be on the premises during the search without the occupier's permission.

In all cases authorised officers should:

- exercise their powers courteously and with respect for persons and property,
- in circumstances where a warrant has been obtained and is appropriate only use reasonable force when this is considered necessary and proportionate to the circumstances.

If the provisions of Sections 15 and 16 of PACE, PACE Code of Practice B, the Food Safety Act 1990, the Food Hygiene (England) Regulations 2006 and this Code are not observed, evidence obtained from a search may be open to question.

3.1.9: Informal Approach

An authorised officer who decides to adopt an informal approach in accordance with the Food Authority's Enforcement Policy to secure compliance with food law should, where appropriate, follow the procedures set out in the LACORS Home Authority Principle.

Any subsequent correspondence with the food business operator concerned by the home, originating or enforcing authority, should contain sufficient

²⁷ SI 2004 No. 3279

information to enable the food business operator to understand exactly what action they are expected to take, and why the action is necessary.

Correspondence should be treated as outlined in Paragraph 3.1.6. This should be discussed and, if possible, agreed with the food business operator.

3.1.10: Prosecution

The decision to initiate a prosecution should be taken at the earliest opportunity.

Before deciding whether a prosecution should be taken Food Authorities should consider a number of factors:

• Whether there is a sufficiency of the evidence (the test for which is set out in the Code for Crown Prosecutors).

Of particular note are:

1. The likely cogency of any important witness, and their willingness to cooperate;

- 2. The alleged person or persons responsible have been identified;
- 3. Any explanation offered by the suspect;
- 4. The likelihood of the suspect being able to establish a defence in particular a due diligence defence;
- Whether the public interest test has been satisfied (again, the test is set out in the Code for Crown Prosecutors). Prosecutors must note that unless the Evidential Test is satisfied, the Public Interest Test is irrelevant. If the evidence is not present, no amount of argument in favour of it being in the public interest will suffice to justify launching the prosecution, as the Prosecutor will already have decided that it is more likely than not that it will fail in Court on the available evidence.
- Using the hierarchy of enforcement structure, whether a prosecution is more appropriate as opposed to the use of, say, informal action or an enforcement notice. (Officers should be aware, however, that if a Hygiene Improvement Notice or similar is used, it too is a matter which can go before the Court, and the Officer should be able to justify his actions. The criteria below will be of assistance).
- That the Enforcement Policy has been adhered to.
- Whether any other action, such as issuing a caution in accordance with Home Office Circular 30/2005²⁸ would be more appropriate.

Factors favouring prosecution include:

²⁸ Home Office Circular 30/2005 on The Cautioning of Offenders

- The seriousness of the offence;
- The prevalence of that type of offence in the area in which it was committed (if the offence is not serious in itself);
- The suspect's previous convictions or cautions.

There are various factors against prosecution including:

- The likelihood of a nominal penalty;
- The offence was committed as a result of a genuine mistake or misunderstanding (this must be balanced against the seriousness of the offence);

It is important that the authorised officers brief their legal advisers fully on the public health aspect of the case in hand, including the public health basis for the legal requirements which have been breached, so that they can, in turn, impress upon the Court the seriousness of the charges.

Officers should explain the reason for bringing a prosecution and record that reason, which may later be referred to in open Court.

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3.2.1: Introduction

This Chapter deals with the use of Hygiene Improvement Notices under Regulation 6 of the Food Hygiene (England) Regulations 2006. It then deals with the use of Improvement Notices under Section 10 the Food Safety Act 1990²⁹.

A model form for use in connection with Regulation 6 of the Food Hygiene (England) Regulations 2006 can be found at Annex 7. Food Authorities must continue to use the prescribed forms set out in the Food Safety (Improvement and Prohibition - Prescribed Forms) Regulations 1991³⁰ when using powers under Section 10 of the Food Safety Act 1990.

3.2.2: Hygiene Improvement Notices (Food Hygiene (England) Regulations 2006, Regulation 6) (See also Paragraph 1.2.9.1.5)

3.2.2.1: When to Use Hygiene Improvement Notices

Hygiene Improvement Notices may be appropriate in any of the following circumstances or a combination thereof:

- Where formal action is proportionate to the risk to public health;
- Where there is a record of non-compliance with breaches of the food hygiene regulations;
- Where the authorised officer has reason to believe that an informal approach will not be successful.

3.2.2.2: When Hygiene Improvement Notices are Inappropriate

The Hygiene Improvement Notice procedure would be inappropriate in the following circumstances:

- Where the contravention might be a continuing one, for example, personal cleanliness of staff and a notice would only secure an improvement at one point in time;
- In transient situations, and it is considered that swift enforcement action is needed, for example, a one day festival or sporting event. A Hygiene Emergency Prohibition Notice would be the only formal remedy which would have immediate effect;

 ²⁹ Reference should be made to LACORS Guidance on the Use of Improvement Notices
 ³⁰ SI 1991 No. 100

• Where there is a breach of good hygiene practice but no failure to comply with an appropriate regulation.

3.2.3: Improvement Notices (Food Safety Act 1990, Section 10) (See also Paragraph 1.2.9.1.6)

3.2.3.1: When to Use Improvement Notices

Food authorities should deal with breaches of the Food Hygiene (England) Regulations 2006 by using the enforcement powers provided by those regulations (such as hygiene improvement notices under regulation 6). However, where legislation such as the Animal By-products (Identification) Regulations 1995 is involved, they should issue an improvement notice under section 10 of the Food Safety Act 1990.

3.2.3.2: When Improvement Notices are not Appropriate

The improvement notice procedure would be inappropriate where breaches exist in respect of food standards which pose a potential and imminent risk of injury to health and it is considered that swift enforcement action is needed. An Emergency Prohibition Notice would be the only formal remedy which would have immediate effect.

CHAPTER 3.3: PROHIBITION PROCEDURES

(See also Paragraph 1.2.9.1.7)

3.3.1: Introduction

This Chapter deals with

- the use of hygiene emergency prohibition procedures under Regulation 8 of the Food Hygiene (England) Regulations 2006 and the associated voluntary closure procedures
- the prohibition of persons under Regulation 7.
- the use of emergency prohibition procedures under Section 12 of the Food Safety Act 1990 and associated voluntary closure procedures,
- the prohibition of persons under Section 11 of the Act.

Model forms for use in connection with Regulations 7 and 8 of the Food Hygiene (England) Regulations 2006 can be found at Annex 7.

Food Authorities must continue to use the prescribed forms set out in the Food Safety (Improvement and Prohibition - Prescribed Forms) Regulations 1991 when using powers under Sections 11 and 12 of the Food Safety Act 1990.

3.3.2: The Food Hygiene (England) Regulations 2006 Procedures

3.3.2.1: When to Use Hygiene Emergency Prohibition Notices (Regulation 8)

Unless the use of voluntary procedures is more appropriate in the circumstances, hygiene emergency prohibition procedures should be used if an authorised officer has evidence that the health risk condition is fulfilled. If the appropriate evidence is found, a Hygiene Emergency Prohibition Notice may be served on the food business operator, followed by an application to a Magistrates' Court for a Hygiene Emergency Prohibition Order.

3.3.2.2: Health Risk Conditions Where Use of Hygiene Prohibition Procedures May be Appropriate

The following paragraphs provide examples of circumstances that may show that the health risk condition as defined by Regulation 7(2) / Regulation 8(4) i.e. there is an imminent risk of injury to health, where an authorised officer may therefore consider the use of such prohibition powers. These examples are in no way prescriptive or exhaustive and are for illustrative purposes only.

3.3.2.2.1: Health Risk Conditions Where Prohibition of Premises May be Appropriate

 Infestation by rats, mice, cockroaches, birds or other vermin, serious enough to result in the actual contamination of food or a significant risk of contamination;

- Very poor structural condition and poor equipment and/or poor maintenance or routine cleaning and/or serious accumulations of refuse, filth or other extraneous matter resulting in the actual contamination of food or a significant risk of food contamination;
- Drainage defects or flooding of the establishment, serious enough to result in the actual contamination of food or a significant risk of food contamination;
- Premises or practices which seriously contravene food law and have been or are implicated in an outbreak of food poisoning;
- Any combination of the above, or the cumulative effect of contraventions which, taken together, represent the fulfilment of the health risk condition.

3.3.2.2.2: Health Risk Conditions Where the Prohibition of Equipment may be Appropriate

- Use of defective equipment, e.g. a pasteuriser incapable of achieving the required pasteurisation temperature;
- Use of equipment for the processing of high-risk foods that has been inadequately cleaned or disinfected or which is grossly contaminated and can no longer be properly cleaned.
- Use of storage facilities or transport vehicles for primary produce where the storage facilities or transport vehicles have been inadequately cleaned or disinfected.

3.3.2.2.3: Health Risk Conditions Where Prohibition of a Process May be Appropriate

- Serious risk of cross contamination;
- Failure to achieve sufficiently high processing temperatures;
- Operation outside critical control criteria, for example, incorrect pH of a product which may allow *Clostridium botulinum* to multiply;
- The use of a process for a product for which it is inappropriate.

3.3.2.3: Health Risk Condition No Longer Exists: Certificate (Regulation 7(6)(a) and Regulation 8(8)) / Health Risk Condition Remains in Existence: Certificate (Regulation 7(7)(b) and Regulation 8(9)(b

In respect of Hygiene Emergency Prohibition Notices and Hygiene Emergency Prohibition Orders the Food Authority should issue a certificate to the food business operator within three days, if it is satisfied that the health risk condition no longer exists

If the food business operator applies for such a certificate, the Food Authority must determine the position as soon as is reasonably practicable and within a

period of no longer than fourteen days. If the Food Authority is satisfied that the health risk condition no longer exists it must issue a notice that determination to the food business operator and must do so within three days. If the Food Authority determines that the health risk condition remains in existence, it must issue a notice of that determination to the food business operator and should do so within three days.

3.3.2.4: Voluntary Procedures (Food Hygiene)

Voluntary procedures to remove a health risk condition may be used, at the instigation of the food business operator, when the food business operator agrees that a health risk condition exists as defined by Regulation 7(2) / Regulation 8(4) i.e. there is an imminent risk of injury to health. An officer may suggest this option to the food business operator, but only when they are able to use Regulation 8. If in doubt, the food business operator should be advised to take legal advice.

Any voluntary closure agreement should be **confirmed in writing** by the food business operator or manager and the authorised officer, with an undertaking by the food business operator or manager not to re-open without the officer's prior approval.

If the manager of a food business offers to close voluntarily, the officer should confirm that the manager has the authority of the food business operator to agree to such voluntary action.

The officer should ensure that frequent checks are made on the establishment to ensure that it has not re-opened.

If the food business operator offers to close voluntarily, the officer should:

- Consider whether there is a risk of the establishment being re-opened without the officer's knowledge and/or agreement (if this were to cause food poisoning, the Food Authority could be criticised for not having used statutory powers);
- Recognise that there is no separate legal sanction against a food business operator who re-opens for business after offering to close, although enforcement action for the actual breaches e.g. unsafe food, similar processing as before, etc, remains available;
- Explain to the food business operator that, by making the offer to close, any right to compensation is lost.

3.3.2.5: Action When a Hygiene Prohibition Order Has Been Made Against a Person (Regulation 7(4))

A Hygiene Prohibition Order issued by a Court can only be fully effective if other Food Authorities are notified, as the individual concerned may try to start a business in another area.

The Food Authority should notify the Chartered Institute of Environmental Health (CIEH) as soon as possible after a hygiene prohibition order is made against a person prohibited from running a food business, provided the order is not the subject of an appeal and the period allowed for appeal has expired, supplying the following information:

- Case number
- Court details
- Date of prohibition order
- Date(s) of offence
- Nature of offence(s)
- Regulation/section number under which offence was made
- Penalties
- Name of food business operator or manager
- Name of the business
- Food business establishment address including post code
- Business type/main activity (e.g. catering, retail etc)
- Details of assumed names.

3.3.2.6: Lifting of Hygiene Prohibition Orders Against Persons (Regulation 7(6)(b) and Regulation 7(8))

Hygiene Prohibition Orders against persons imposed under Regulation 7(4) by a Court may only cease to have effect if, on an application by the food business operator, the Court gives such a direction, in accordance with the provisions at Regulation 7(8). Note should be paid that no application will be entertained within 6 months of the date of the order begin made.

The Food Authority should also notify CIEH at the earliest opportunity after they learn that a Hygiene Prohibition Order against a person has been lifted in their area.

3.3.3: Food Safety Act 1990 Procedures

3.3.3.1: When to Use Emergency Prohibition Procedures (Section 12)

Unless the use of voluntary procedures is more appropriate in the circumstances, emergency prohibition procedures should be used if an authorised officer has evidence of an imminent risk of injury to health. If the appropriate evidence is found, an Emergency Prohibition Notice may be served on the proprietor, followed by an application to a Magistrates' Court for an Emergency Prohibition Order.

3.3.3.2: Imminent Risks of Injury to Health where the Use of Emergency Prohibition Procedures May be Appropriate

The following are examples of circumstances that may involve an imminent risk of injury to health and in which an authorised officer may therefore consider the use of prohibition powers. These examples are in no way prescriptive or exhaustive and are for illustrative purposes only.

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

3.3.3.3: Voluntary Procedures (Food Standards)

Voluntary procedures to remove an imminent risk of injury to health may be used, at the instigation of either the proprietor or the manager of the business, when the proprietor or manager of the business agrees that an imminent risk of injury to health exists. An officer may suggest this option to the proprietor or manager, but only when they are able to use Section 12 of the Food Safety Act 1990. If in doubt, the proprietor or manager should be advised to take legal advice.

Any voluntary closure agreement should be confirmed in writing by the proprietor or manager and the authorised officer, with an undertaking by the proprietor or manager not to re-open without the officer's prior approval.

If the manager of a food business offers to close voluntarily, the officer should confirm that the manager has the authority of the proprietor to agree to such voluntary action.

The officer should ensure that frequent checks are made on the establishment to ensure that it has not re-opened.

If the proprietor of a food business offers to close voluntarily, the officer should:

- Consider whether there is a risk of the establishment being re-opened without the officer's knowledge and/or agreement (if this were to cause food poisoning, the Food Authority could be criticised for not having used statutory powers);
- Recognise that there is no separate legal sanction against a food business operator who re-opens for business after offering to close, although enforcement action for the actual breaches e.g. unfit food, unclean establishment etc, remains available;
- Explain to the food business operator that, by making the offer to close, any right to compensation if a Court subsequently declines to make an Emergency Prohibition Order is lost.

3.3.3.4: Action When a Prohibition Order has Been Made Against a Person (Section 11(4))

A prohibition order issued by a Court can only be fully effective if other Food Authorities are notified, as the individual concerned may try to start a business in another area.

The Food Authority should notify the CIEH as soon as possible after a prohibition order is made against a person prohibited from running a food business, provided the order is not the subject of an appeal and the period allowed for appeal has expired, supplying the following information:

- Case number
- Court details
- Date of prohibition order
- Date(s) of offence
- Nature of offence(s)
- Regulation/section number under which offence was made
- Penalties
- Name of food business proprietor or manager
- Name of the business
- Food business establishment address including post code
- Business type/main activity (e.g. catering, retail etc)
- Details of assumed names.

3.3.3.5: Lifting of Hygiene Prohibition Orders Against Persons (Section 11(6)(b) and Section 11(8))

Prohibition Orders against persons, imposed under Section 11 by a Court may only cease to have effect if, on an application by the proprietor, the Court gives such a direction, in accordance with the provisions at Section 11(8).

The Food Authority should also notify CIEH at the earliest opportunity after they learn that a Prohibition Order made against a person has been lifted in their area.

CHAPTER 3.4: SEIZURE AND DETENTION

(See also Paragraph 1.2.9.3.1)

3.4.1: Introduction

This Chapter describes the circumstances when the use of detention and seizure powers under Section 9 of the Food Safety Act 1990, as amended, is appropriate including after food has been certified in accordance with Regulation 27 of the Food Hygiene (England) Regulations 2006. It also covers the procedures for serving and withdrawal of notices; voluntary surrender; and the destruction or disposal of food.

Food Authorities must continue to use the forms set out in the Detention of Food (Prescribed Forms) Regulations 1990³¹ when using powers under Section 9 of the Food Safety Act 1990, including after food has been certified in accordance with Regulation 27 of the Food Hygiene (England) Regulations 2006.

3.4.2: The Food Hygiene (England) Regulations 2006, Regulation 27

When food has not been produced, processed or distributed in compliance with the "Hygiene Regulations" as defined in Regulation 2 of the Food Hygiene (England) Regulations 2006, an authorised officer may use Regulation 27 (see also Regulation 23 in this regard) of those Regulations to seize the food by the use of Section 9 of the Food Safety Act 1990. Following the certification required by Regulation 27, the authorised officer should follow the advice set out in this Chapter in connection with the use Section 9 of the Food Safety Act 1990.

A model certificate to certify, where appropriate, that food has not been produced, processed or distributed in compliance with the Hygiene Regulations for use in connection with Regulation 27 of the Food Hygiene (England) Regulations 2006 can be found at Annex 7.

3.4.3: Specific Powers of Seizure and Detention for County Council Food Authorities

County Council Food Authorities have been given powers of seizure and detention under certain regulations. These regulations are listed Paragraph 3.4.4 of the Practice Guidance.

In addition, officers appropriately authorised under the Food Safety Act 1990 may seize and detain food when directed by the Agency by means of a food alert, or when a risk to health is identified through analysis and notified to the County Council Food Authority by a Public Analyst, provided they are satisfied that the statutory thresholds set out in Section 9 as appropriate are met eg that in the case of detention it appears to them that the food fails to comply with food safety requirements.

³¹ SI 1990 No. 2614

3.4.4: Detention of Food

Unless the circumstances require immediate action, a decision to detain food should only normally be taken if it has been discussed with the owner or person in charge of the food and, if appropriate, with the manufacturer.

Where the authorised officer has served a detention of food notice, professional judgement should be used to determine whether food should be detained where it is, or moved elsewhere. If the officer has any doubts about the security or physical care of the food, the detention notice should specify a place to which the food is to be moved.

If food is to be removed to another Food Authority's area the officer should notify that Food Authority and make any necessary arrangements for the food to be checked while it is being detained.

In all cases, but especially with highly perishable food, the officer should act expeditiously at every stage and provide full information to those required to carry out analysis or examination of samples of the food.

If food is to be detained where it is found, the authorised officer should be satisfied that adequate arrangements can be made to ensure its security and prevent tampering. The officer should organise periodic monitoring of the food throughout the period of detention. Before making such arrangements regard should be had to the nature of the food, the quantity, any health hazard that it represents and the ownership of the establishment where it is located. The officer should generally avoid leaving it in the charge of, or in an establishment owned by, any person who may be prosecuted for an offence under food law.

3.4.5: Seizure of Food

When considering whether to seize food that has been detained, authorised officers should consider whether the food in question can be treated or processed before consumption and if so, whether the food, after treatment or processing, would be sound and wholesome and satisfy food safety requirements.

Arrangements for the treatment or processing of food in these circumstances should be agreed by the authorised officer and the owner or the person in control of the food and be subject to a signed, written undertaking.

Any arrangement that involves food being moved to the area of another Food Authority for treatment or processing should be accepted by the receiving Food Authority before the agreement is concluded.

Arrangements should be made for that Food Authority to take steps to ensure the processing or treatment is carried out, including the service of a Detention of Food notice if appropriate. If the receiving Food Authority is unable to accept responsibility for ensuring that the food is properly processed or treated, the arrangement should not proceed.

Unless the preceding paragraphs of this section apply, or the use of voluntary procedures is more appropriate, food should be seized if an authorised officer has evidence that it does not satisfy food safety requirements.

If evidence indicates that food that has already been detained should be seized, the officer should serve a food condemnation notification, warning of the intention to take the food before a Justice of the Peace and apply for its condemnation.

Food that has been seized should be dealt with by a Justice of the Peace as soon as is reasonably practicable, normally within 2 days, but if necessary longer to ensure that parties attend and be represented should they so choose. Highly perishable food should be dealt with by a Justice of the Peace at the earliest opportunity.

The person in charge of the food, or the owner should be given the opportunity of being present and represented should they so choose, when the food is dealt with by the Justice of the Peace, although action should not be delayed if the owner cannot be traced or contacted. It is important the owner or the person who is in charge of the food has the opportunity of attending, and good service of notice of the hearing should be documented and retained to show the Court that was the case.

The authorised officer should ensure continuity of evidence whether or not there may be a subsequent prosecution and should make every attempt not to leave the food which has been seized unattended.

3.4.6: Notices of Detention and Seizure

A Detention or seizure of Food Notice should be signed by the officer who takes the decision to detain the food.

When food is seized, written notification of the seizure should be issued as soon as is reasonably practicable. This notification should include details of the type and quantity of the food seized, including any distinguishing marks, codes, dates etc.

A food condemnation notification should be given to the person in charge of the food when the officer intends to have the food dealt with by a Justice of the Peace. The notification should, where possible also be given to the owner of the food.

3.4.7: Withdrawal of Detention of Food Notice

The authorised officer should act as quickly as possible when evidence or information indicates that detained food can be released, and in any case within 21 days. A Withdrawal of Detention of Food Notice should be served.

The decision to issue a Withdrawal of Detention of Food Notice should be taken either by the officer who originally issued the notice or initiated the action or by another officer with the relevant experience.

A Withdrawal of Detention of Food Notice should be served as soon as possible to prevent possible deterioration of the food. The notice need not be served by the officer who made the decision, but may be served by any authorised officer.

3.4.8: Dealing with Batches, Lots or Consignments of Food

Article 14(6) of Regulation 178/2002 stipulates that where "any food which is unsafe forms part of a batch, lot, or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe".

If a quantity of food of different types or batches is being detained, the authorised officer should issue a separate Detention of Food Notice in respect of each type or batch.

When considering whether to seize or detain a batch, lot or consignment the authorised officer should take into account the following:

- The evidence available;
- The nature of the contamination;
- The nature and condition of any container holding the food;
- The risk to health;
- The quantity of food involved in relation to any sampling which has been undertaken.

3.4.9: Voluntary Procedures

Voluntary procedures to remove food that is not suitable for human consumption from the food chain **may** be used, either at the instigation of the owner of the food or at the suggestion of the authorised officer when the owner of the food agrees the food is not suitable for human consumption.

A receipt should be issued for food that is voluntarily surrendered to the Food Authority for destruction. The receipt should indicate that the food has been voluntarily surrendered to the Food Authority for destruction and be signed and counter-signed by the authorised officer and the person surrendering the food respectively.

The receipt should include space for recording the time, place and method of destruction of the food, and these details should be recorded on the office copy by the authorised officer in due course and retained by the Food Authority.

If the Food Authority does not secure, as part of the voluntary surrender, an agreement by the owner to pay the reasonable expenses of destruction or disposal, then it may have to bear the expenses itself.

3.4.10: Destruction or Disposal of Food

The Food Authority is responsible for ensuring the destruction of food that has been seized or voluntarily surrendered, and arrangements should be made for the food to be supervised until it can be dealt with in the appropriate manner. If possible and if there is likely to be some delay before destruction, the food should be disfigured so as to prevent any possibility of it being returned to the food chain.

The Food Authority should ensure the total destruction of the food by incineration or some other appropriate method, or if total destruction is not possible, such a degree of disfigurement that the food could never re-enter the food chain, e.g. by flattening tin cans for disposal in a suitably licensed landfill site, having regard to the requirements of relevant waste disposal legislation.

A copy of the waste transfer note must be obtained and kept on file for any food that has been disposed of by a licensed waste disposal contractor under these arrangements.

CHAPTER 3.5: REMEDIAL ACTION NOTICES / DETENTION NOTICES

3.5.1: Introduction

Powers to issue Remedial Action Notices and Detention Notices in respect of establishments subject to approval under Regulation 853/2004 are provided by Regulation 9 of the Food Hygiene (England) Regulations 2006. A model Remedial Action Notice, a model Detention Notice and a model Notice of Withdrawal of a Remedial Action Notice / Detention Notice can be found at Annex 7.

3.5.2: Approach to Enforcement

Authorised officers should seek to remedy non-compliance in establishments subject to approval under Regulation 853/2004 by a graduated approach to enforcement (see paragraph 3.1.3). When necessary, the Hygiene Improvement Notice provisions in Regulation 6 or (see Chapters 3.2 and 3.3). Authorised Officers should consider these options before commencing any other enforcement action. However, Remedial Action Notices and/or Detention Notices as provided for by Regulation 9 of these Regulations may be used, when appropriate.

3.5.3: Remedial Action Notices / Detention Notices

Regulation 9 provides for Authorised Officers to serve a Remedial Action Notice if any of the requirements of the "Hygiene Regulations", as defined by Regulation 2 of the Food Hygiene (England) Regulations 2006, are being breached or an inspection under the Hygiene Regulations is being hampered. More specifically, this provision provides, through the service of a Remedial Action Notice, for the prohibition of the use of any equipment or any part of the establishment, the imposition of conditions upon, or prohibiting, any process and also allows for the rate of an operation to be reduced or, stopped completely. Regulation 9 also includes the provision for the detention of any food, including the taking of samples for the purposes of examination, by the service of a Detention Notice.

Circumstances which may lead to the issue of a Remedial Action Notice in respect of an establishment include:

- The failure of any equipment or part of an establishment to comply with the requirements of the "Hygiene Regulations" as defined by Regulation 2 of the Food Hygiene (England) Regulations 2006;
- The need to impose conditions upon or the prohibition of the carrying on of any process breaching the requirements of the Regulations or hampering adequate health inspection in accordance with the Regulations;
- Where the rate of operation of the business is detrimental to its ability to comply with the Regulations;

Circumstances which might lead to the issue of a Detention Notice include:

• Where there are indications or suspicions that food at an establishment is unsafe and therefore examination is necessary, including the taking of samples.

Such action should be proportionate to the risk to public health and where immediate action is required to ensure food safety. A Remedial Action Notice may be used if a continuing offence requires urgent action owing to a risk to food safety or when corrective measures have been ignored by the food business operator and there is a risk to public health.

As soon as the Authorised Officer is satisfied that the action specified in a Remedial Action Notice has been taken, the notice must be withdrawn by means a further notice in writing. Similarly, in respect of a Food Detention Notice, if the Authorised Officer is satisfied that the food need no longer be detained, the relevant notice must also be withdrawn by means a further notice in writing.

The use of Remedial Action Notices and Detention Notices is governed by Regulation 9 of the Food Hygiene (England) Regulations 2006. If an Authorised Officer considers it necessary to serve a Remedial Action Notice owing to the conditions or practices found on the inspection of an establishment subject to approval under Regulation 853/2004, the officer should also consider whether food at the establishment should be detained for the purposes of examination by means of a Detention Notice under Regulation 9.

CHAPTER 3.6: TEMPERATURE CONTROL REQUIREMENTS

3.6.1: Introduction

This Chapter concerns the enforcement of Regulation 30 and Schedule 4 of the Food Hygiene (England) Regulations 2006 (the Regulations), which are concerned primarily with the safety of food that needs to be stored under chilled conditions.

3.6.2: General Approach to Temperature Checks

Schedule 4 does not apply to any food business operation on ships and aircraft and those businesses to which Regulation 853/2004 applies. Where applicable, the Schedule requires certain types of perishable food to be maintained within specified temperature ranges. The purpose of checking the temperature of such foods for enforcement purposes is to establish whether these requirements are being met, taking account of any exemptions or tolerances that may apply.

Where appropriate, regard must be given to any relevant temperature requirements of Annex II of Regulation 852/2004.

Authorised officers should normally adopt a staged approach to verifying compliance with the temperature requirements of the Regulations as follows:

Stage 1 – a check of any temperature monitoring equipment used by the business, including any logs or records derived from it, and verification of the accuracy of temperature monitoring equipment by air temperature measurement if necessary;

Stage 2 – measuring between-pack temperature of food without disturbing the state of the food or its individual packaging, although cases may be opened (non-destructive temperature checks);

Stage 3 – measuring the temperature of the product itself (destructive testing).

If an authorised officer is satisfied after "stage 1" or "stage 2" that the relevant temperature requirements are being met, there is no need to move to the next stage and enforcement action should cease.

If there is no temperature monitoring system, or the officer has reasonable doubt about the information derived from the system where there is one, the officer should carry out a "stage 2" check.

If the temperature measured at "stage 2" gives the officer reasonable doubt that the relevant temperature requirements are being met, the officer should move on to "stage 3" and measure the temperature of the food itself.

"Stage 3" product testing (destructive) methods must always be used to produce evidence for prosecution.

The food business operator or manager should, if present, be invited to witness temperature measurement. This is especially important when evidence is being gathered with a view to possible legal proceedings.

3.6.3: Food that is Warmer than Prescribed Chill Holding Temperature

When measuring the temperature of food itself, authorised officers should be aware that the Schedule allows the temperature of a food subject to chill holding temperatures, whilst it is for service or on display for sale, to rise above 8°C for one period only of less than 4 hours (Schedule 4, Paragraph 5(1)(b) and (c)).

The officer should be satisfied that the food business operator has measures in place, as appropriate, to ensure that the chill holding tolerance described above is not exceeded.

3.6.4: Food that is Cooler than Prescribed Hot Holding Temperature

When measuring the temperature of food itself, authorised officers should be aware that the Schedule allows the temperature of a food subject to hot holding temperatures, whilst it is for service or on display for sale, to fall below 63°C for one period only of less than 2 hours. (Schedule 4, Paragraph 7(2)(a) and (b)).

The officer should be satisfied that the food business operator has measures in place, as appropriate, to ensure that the hot holding tolerance described above is not exceeded.

3.6.5: Temperature Deviations Resulting in a Breach of Regulation 30 / Schedule 4 of the Food Hygiene (England) Regulations 2006

Where the food business operator suggests that specified temperatures have not been complied with for unavoidable reasons, the authorised officer should discuss the reasons with the food business operator and, where possible, seek agreement on action to prevent any recurrence.

Authorised officers should always ensure that any measures taken by the food business operator with respect to food that has been exposed to temperatures in excess of, or below, those permitted by the Regulations are consistent with food safety, and take appropriate action to remove such food from the food chain if necessary.

If the food itself is at a higher temperature than the prescribed chill holding temperature or a lower temperature than the prescribed hot holding temperature and the authorised officer is of the opinion that the food has not been produced, processed or distributed in accordance with the Food Hygiene (England) Regulations 2006 the officer should normally deal with the food under Regulation 27 of the Regulations (see also Regulation 23 in this regard). Voluntary procedures to remove food from the food chain may, however, be used in appropriate circumstances (see Paragraph 3.4.9).

If food is at a higher temperature than 8°C (chill holding) or below 63°C (hot holding) but does not fail food safety requirements, the authorised officer should use professional judgement to determine the most appropriate action in the circumstances. The food may still be fit for consumption, even if it has

been maintained at temperatures higher than those specified in the Regulations beyond the time limits allowed.

Authorised officers should enquire into the history of the food, in particular to ascertain whether it could previously have been exposed to temperatures above 8°C. Enforcement decisions should take account of the history of the food and whether it is consistent with food safety. Authorised officers may adopt an educative approach as the first step towards securing compliance, and discuss the requirements of the legislation with the food business operator to ensure they understand the controls, why they are needed and how they can be achieved.

3.6.6: Checking and Calibration of Enforcement Measuring Thermometers etc

(See also Paragraph 3.6.5 of the Practice Guidance)

Thermometers and other temperature measuring devices used for inspection and / or enforcement purposes should be periodically tested and calibrated by a suitably accredited tester (e.g. the instrument manufacturer or a UKAS accredited laboratory or testing house) in accordance with any recommendations of the manufacturer or supplier, to ensure accuracy, integrity and reliability. A certificate of such calibration should be obtained.

Food Authorities should also check devices for accuracy at regular intervals between each calibration (e.g. against a reference thermometer used only for that purpose) to ensure they remain within relevant tolerances. Details of such checks should be recorded and these records retained.

Food Authorities should ensure that temperature measurements that are to be used in evidence should be taken with a thermometer or other measuring device that has a current certificate of calibration.

CHAPTER 3.7: QUICK FROZEN FOODSTUFFS

3.7.1: Introduction

This Chapter concerns enforcement of the Quick-frozen Foodstuffs (England) Regulations 2007³², , (the Regulations), which implement Directives 89/108/EEC³³, and 92/2/EEC³⁵ and provide for the enforcement and administration of Commission Regulation 37/2005³⁶ England. (Similar, parallel legislation exists in the devolved administrations)

Food is not subject to the Regulations unless it is specifically labelled or described as "quick-frozen".

The decision whether to describe food as "quick-frozen" is a matter for the manufacturer. Food authorities cannot apply the requirements of the Regulations to food that is not labelled or described as "quick-frozen".

3.7.2: Legislative Changes

Commission Directive 92/1/EEC³⁷ has been repealed and replaced by the directly applicable Commission Regulation 37/2005.³⁶

There are three main points of difference between Directive 92/1/EEC and Regulation 37/2005. First, in the case of transport there is no longer a requirement for competent authorities to approve the temperature measuring instruments used. Also, from 1 January 2006 all measuring instruments, used in transport, warehousing, or storage of quick-frozen foodstuffs must comply with the relevant CEN standards³⁴. Finally, from 1 January 2006 the legislation will apply to rail transport for the first time.

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

In summary, the Regulations:

 provide the administration and enforcement provisions for Commission Regulation 37/2005; and

³², SI 2007 No. XXXX

³³ Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption

³⁸European Committee for Standardization, <u>www.cenorm.be</u> (i.e. EN 12830: 1999; EN 13485:2001; EN 13486:2002)

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

3.7.3: Division of Enforcement Responsibilities

Both County and District Council Food Authorities may take legal proceedings under Regulation 3 of the Regulations

District Council Food Authorities should enforce Regulation 3, 4, 6 and 9(3) as read with Schedule 3 and Schedule 2 (1)(f), 2(2)(b). (They should consult and liaise with County Councils at all relevant stages. County Council Food Authorities should enforce Regulations 5 and 8.

3.7.4: Approach to Enforcement

Since the Regulations are concerned with maintaining food quality, compliance checks may be less frequent than for legislation concerned with food safety.

Authorised officers should initially adopt an educative approach and discuss the requirements of the legislation with the food business operator.

Authorised officers should, where relevant, examine all relevant documents permitting verification that the measuring instruments conform to the relevant EN standard, although not normally during every inspection.

Temperature monitoring of quick-frozen foodstuffs in cold stores and display cabinets should be carried out as part of inspection, although not normally during every inspection

The prime responsibility for monitoring delivery vehicles for compliance with the requirements of Regulations 6, 8 and 9(3) [as read with Schedule 3, paragraphs 1, 2, 3 (a, e, f and g)] rests with the Food Authority in whose area the vehicle operator is based. In the event of a problem being identified elsewhere, the inspecting Food Authority should liaise with the Food Authority that has prime responsibility.

Detailed examination and sampling of a load should only be undertaken where there is evidence that the temperature of food may have exceeded the maximum level set down in the Regulations. Transport vehicles should not be stopped en-route purely to enforce the Regulations. Inspection should normally take place only during the loading or unloading of a vehicle.

3.7.5: Temperature Requirements

After quick-freezing, the Regulations require relevant food to be kept at, or colder than, -18°C. A brief upward tolerance of 3°C (-15°C) is permitted for primary distribution and for local distribution i.e. that part of the distribution chain in which the food is delivered to the point of retail sale (including sale to a catering establishment).

Food in retail display cabinets must be kept in conditions consistent with good storage practice, and is required to comply with the temperature requirements of the Regulations, although the permitted temperature is higher (-12°C) for the warmest packs than for the rest of the "cold chain".

3.7.6: Staged Approach to Enforcement

Enforcement should comprise a staged sequence of examinations and measurements, as described in the Practice Guidance, and an authorised officer should only proceed to the next step if there is reasonable doubt that the food in question complies with the Regulations.

Article 1.2 of Directive 92/2/EEC states that the method of measuring temperature given in Annex II of the Directive may only be used when inspection leaves reasonable doubt on the threshold of temperatures provided for in Directive 89/108/EEC.

3.7.7: Sampling

If there is reasonable doubt at one step in the sequence of examinations and measurements that food is being kept at the required temperature then the authorised officer should proceed to the next step.

It is necessary to be able to identify positions where food is likely to be warmest in any particular situation in order that it can be sampled where breach of the Regulations is most likely to occur.

It is also important to ensure that whenever and wherever food is sampled in the cold chain, from cold store to retail cabinet, care is taken to avoid unnecessary rises in temperature of the food or of the samples to be tested.

Sampling and subsequent testing should be done with the minimum possible disruption to the operation, without undue delay and, where possible, in a controlled temperature environment, e.g. in a cold store.

CHAPTER 3.8: IMPORT OF FOOD FROM THIRD COUNTRIES

Significant volumes of food are routinely imported into the UK and it is important that effective arrangements are in place in Food Authorities to check imported food both at points of entry and inland. Food Authorities should have regard to the general guidance on enforcement contained in this Code of Practice in relation to their imported food enforcement control arrangements.

Further specific guidance on imported food control is provided in the Practice Guidance at Annex 14.

SECTION 4: INTERVENTIONS

CHAPTER 4.1: INTERVENTIONS

4.1.1: Introduction

This Chapter provides a definition of interventions and the circumstances in which they are applied

Interventions are activities which are designed to monitor, support and increase Food Law compliance within a food establishment. They include, but are not restricted to, Official Controls which are defined under Article 2 of Regulation (EC) No. 882/2004 as controls for the verification of compliance with food law. Methods and techniques for carrying out tasks related to Official Controls are specified in Article 10 of Regulation (EC) No.882/2004. These include monitoring, surveillance, verification, audit, inspection, sampling and analysis. In addition to the Official Controls listed above, interventions may also include the provision of targeted educational and advisory visits that take place at food establishments. Interventions may also include information and intelligence gathering.

Interventions, which are Official Controls must provide sufficient information to Food Authorities to establish that food related activities carried on at food establishments comply with food law.

An interventions programme, is central to an effective enforcement regime and food authorities must ensure that such a programme is appropriately resourced.

Interventions, which are not Official Controls should assist in supporting food businesses achieve compliance with Food Law.

Official Controls should be carried out at all stages of production, processing and distribution to establish whether the requirements of relevant food law are being met, in line with the general obligations as set out in Article 3 of Regulation 882/2004.

In each case, the authority must document the basis for the choice of intervention.

4.1.2.1: Interventions,

Interventions which **are** Official Controls include:

- Inspections
- Monitoring
- Surveillance
- Verification

- Audit
- Sampling where the analysis/examination is to be carried out by an Official laboratory. (see 4.1.4)

Interventions which are **not** deemed to be official controls include

- Education, advice and coaching provided at a food establishment.
- Information and intelligence gathering (including sampling where the analysis or examination is **not** to be carried out by an Official laboratory).

4.1.2.2 Food Standards Interventions

Food standards interventions should include checks that the food business is meeting the legal requirements relating to the quality, composition, labelling, presentation and advertising of food and of materials or articles in contact with food.

Food standards interventions are part of the system for ensuring that food meets the requirements of food standards law, including proper presentation, labelling and advertising so as not to confuse or mislead; compliance with compositional standards; and the absence of non-permitted or excessive levels of additives, contaminants and residues.

Each Food Authority should document, maintain and implement a food standards interventions programme that includes all the businesses for which the Food Authority has food standards law enforcement responsibility. The programme should be based on the food standards interventions ratings that have been determined in accordance with Annex 5.

4.1.2.3 Food Hygiene Interventions

Regulation 852/2004 defines "food hygiene" as

the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff, taking into account its intended use.

Food hygiene interventions are part of the system for ensuring that food meets the requirements of food hygiene law, including microbiological quality; absence of pathogenic micro-organisms; and safety for consumption.

Each Food Authority should document, maintain and implement a food hygiene interventions programme that includes all the establishments for which the Food Authority has food hygiene law enforcement responsibility. The programme should be based on the food hygiene interventions ratings that have been determined in accordance with Annex 5.

4.1.2.4: Definitions

Article 2 of Regulation (EC) No. 882/2004 provides the Following definitions of interventions

Inspection is defined as

the examination of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of feed and food law and animal health and welfare rules

Monitoring is defined as

Conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with feed or food law, animal health and animal welfare rules

Surveillance is defined as

The careful observation of one or more food businesses, or food business operators or their activities

Verification is defined as

The checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled

Audit is defined as

The systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Sampling is defined as

Taking feed or food or any other substance (including from the environment) relevant to the production, processing and distribution of feed or food or to the health of animals, in order to verify through analysis compliance with feed or food law or animal health

4.1.3: Inspections

4.1.3.1 Carrying out an Inspection

Any inspection will consider the appropriate elements set out in the relevant inspection form³⁵ for the business concerned. Food Authorities or their regional groups may develop and use food inspection forms, providing all the

³⁵ The relevant inspection form is the inspection form that relates to the type of business being inspected and the type of inspection being carried out. Inspection forms and aides memoire can be found on the LACORS Website

elements of an inspection that are appropriate to the type of business being inspected are included. Authorised officers must use their professional judgement in selecting which elements of the inspection form to examine in detail.

Inspections may also include

- Revisits to check on the progress of measures required after a previous intervention;
- Visits to investigate food and food establishment complaints where they include verification checks on specific aspects of the food business.
- Inspections that form part of a food award or food hygiene rating system which include the verification of specific aspects of the food business.

Following an inspection, officers should consider revising the intervention risk rating of the establishment

4.1.3.2 Initial Inspections of New Food Establishments

Food Authorities should make use of information supplied to them by food business operators in connection with the registration or application for approval of their food business establishments in accordance with Article 31 of Regulation 882/2004 (See Chapter 1.5 and Chapter 5.1 respectively) in order to determine when to carry out the initial Inspection.

New food establishments that come to the attention of the Food Authority for the first time must be subject to an initial inspection following which intervention rating(s) for the establishment should be determined.

An officer carrying out the initial inspection of a new food establishment must:

- Establish the scope of the business and the relevant food law that applies to the operations taking place;
- Thoroughly and systematically <u>gather</u> and <u>record</u> information from the observation of practices, procedures and processes, including procedures based on HACCP principles, (NB: procedures based on HACCP principles are **not** required in relation to primary production) and discussion with food handlers, contractors, food business operators and managers;
- Determine whether it is necessary to <u>collect samples</u> of raw materials, ingredients, additives, intermediates, finished products, or materials and articles in contact with food for analysis and/or examination;
- Identify any <u>actual or potential breaches of food law and</u>, if appropriate, gather and preserve evidence;
- Determine <u>relevant enforcement action and communicate to business an</u> intention to carry out such action.

<u>4.1.4</u> Samples

All samples which are sent to an Official Laboratory constitute an Official Control. ³⁶

Chapter 6 provides the definition of "formal" samples which is relevant to any possible legal proceedings in the courts relating to the results of analysis /examination of samples.

4.1.5 Establishment Intervention Ratings

<u>4.1.5.1</u> Establishments Intervention Rated Category A and B for Food Hygiene and Category A for Food Standards

In the majority of cases the appropriate intervention for an establishment that has been given an intervention rating of A or B for food hygiene, or A for food standards, will be an inspection as defined in paragraph 4.1.2.4, which should be carried out at appropriate intervals in accordance with the prescribed frequencies specified in Annex 5.

However, where an officer is satisfied that an establishment in these intervention rating categories is broadly compliant³⁷ with relevant food law, which in the case of food hygiene would include implementation by the operator of effective procedure based on HACCP principles the officer may choose to alternate between inspections and other official controls as defined above.

In such circumstances the reasons for not carrying out an inspection, the justification for and details of the official control selected must be recorded on the establishment file.

<u>4.1.5.2</u> Establishments Intervention Rated Category C for Food Hygiene and Category B for Food Standards

Establishments that have been given an intervention rating of C for food hygiene or B for food standards should receive an intervention at appropriate intervals in accordance with the prescribed frequencies specified in Annex 5. Such interventions can alternate between inspections and other official controls as defined above.

4.1.5.3 Establishments Intervention Rated Category D for Food Hygiene

Following an Initial Inspection establishments that have been given an intervention rating of D for food hygiene should receive an intervention at appropriate intervals in accordance with the prescribed frequencies specified

³⁶ Please see following web site for full list of all official laboratories http://www.food.gov.uk/enforcement/foodsampling/foodcontrollabs

³⁷ An establishment may be considered broadly compliant provided it has not been awarded a score of more than 10 under part (2), level of (current) compliance either (hygiene or structure) or part (3) Confidence in Management of Annex 5.

in Annex 5. Such interventions can alternate between interventions that are official controls and interventions that are not deemed to be official controls.

<u>4.1.5.4</u> Establishments Intervention Rated category E for food hygiene and category C for food standards

Following an initial inspection, food businesses in establishments that have been given a intervention rating of rated categories E for food hygiene and category C for food standards may be subject to an Alternative Enforcement Strategy (see Paragraph 1.2.10 and Annex 5, Paragraphs A5.2 (food hygiene) and A5.4 (food standards).

Food Authorities must ensure that these establishments continue to be monitored through investigation of complaints, any other Food Authority action or an Alternative Enforcement Strategy not less than once every three years for food hygiene and once every five years for food standards.

It is not intended to preclude inspections of such establishments where inspection is the Food Authority's preferred intervention option, in which case the minimum frequency of intervention is determined by the intervention rating.

<u>4.1.5.5</u> Revising the Intervention Type and Intervention Rating

The intervention rating(s) of a food business may be revised at the conclusion of any intervention that is an Official Control, in accordance with Annex 5 (or any amendment thereto that may be notified to food authorities by the Agency). The officer must have gathered sufficient information to justify revising the intervention rating and the reasons for revising the rating must be fully documented on the establishment file.

Officers must always satisfy themselves when revising rating scores that they have sufficient information and evidence to justify their decision in revising an intervention rating. A verification of current compliance must take place before the intervention rating of an establishment is changed. Officers must consider the potential risk posed to public health and use their professional judgement when selecting the type of intervention to use at an establishment.

Equally where new information arises, in the case for example of a justified complaint or poor sampling result, the Food Authority will need to reconsider both the intervention rating and intervention choice.

An explanation for the choice of intervention should be fully documented in the establishment file in every case.

<u>4.1.6</u> Frequency of Intervention at Establishments and Primary Production

4.1.6.1 Establishments

Intervention ratings determine

- the interval that should elapse between one intervention of a food establishment and the next and
- the priority of the next intervention of that establishment, relative to the other businesses in the Food Authority's planned intervention programme (See also Annex 5).

Intervention programmes should be planned so that establishments receive an intervention no later than 28 days after the relevant date as detailed in annex 5.4 In circumstances outside the control of the Food Authority such as seasonal business closures, food authorities have the discretion to defer the intervention (see also paragraph viii of A5.2.1 in Annex 5).. The Food Authority Food Service Plan must contain details on how it intends to include any new food establishment within its intervention programme.

4.1.8.2 Primary Production

Annex 5 does not apply to primary production.

In determining intervention frequencies at the level of primary production the Food Authority must make best possible use of evidence available. <u>Examples</u> of local or other intelligence, which the Food Authority may use to consider whether inspection is necessary, include:

- Membership of a 'recognised' farm assurance scheme <u>http://www.food.gov.uk/foodindustry/hygiene/primprodqanda/</u>
- Change of activity;
- Track record of compliance:
- Intelligence generated by other statutory inspections;
- Consumer and customer (industry) problems;
- Surveillance information on problem products and products associated with foodborne illness
- Other (to reflect local intelligence).

A current list of approved assurance schemes is also available in the Practice Guidance accompanying this Code of Practice

4.1.7 Timing of Interventions

To determine the appropriate timing of interventions, Food Authorities should have regard to all relevant and available information. This includes:

- The hours of operation of the food establishment.
- Seasonal factors (where applicable);

A Food Authority's Intervention programme should provide for food establishments to be subject to intervention at times when they are open for business, whether or not that coincides with the Food Authority's normal hours of work. Food establishments that operate at night, at weekends or in the early hours of the morning should be subject to interventions at these times. Professional judgement should be applied in respect of establishments subject to 24 hour opening in determining the most appropriate time(s) to carry out an intervention at such establishments.

The Food Authority's approach to interventions out of hours should be documented in it's Food Service Plan.

4.1.8 Need to Defer Planned Intervention

Circumstances may arise where the Agency requires Food Authorities to defer their interventions in order to take urgent action over a period of time.

Such situations may include those where there is evidence that:

- An unsafe practice is occurring or has occurred which represents a significant hazard to public health;
- A particular food handling or food preparation practice is found to entail a previously unsuspected hazard to public health;
- A foodstuff previously thought to be safe is found to be hazardous to public health;
- A food with widespread distribution is found to be contaminated and thereby presents a significant hazard to public health;
- A food with widespread distribution is the subject of fraud in labelling or presentation.

Where such a situation arises the Agency may, by means of a communication issued in accordance with Paragraph 2.2.2, require Food Authorities to take specific action. Food Authorities are required to have regard to and to act on, any such communication.

Discussions will normally take place with LACORS before Food Authorities are asked to defer their interventions. In all cases, the Agency will, before taking action under this paragraph, consider whether urgent action by Food Authorities is necessary to protect public health or the interests of consumers.

Food Authorities may be asked to provide information to the Agency about the action that they have taken, in response to requests under this paragraph and any action taken should be documented.

4.1.9 Single Tier Food Authorities

Where the same officer is responsible for enforcement of both food hygiene and food standards matters in an establishment or feed hygiene and animal welfare on farm or the officer should decide whether it is appropriate to cover both matters at a single visit, even though an intervention may not be due under one of the Food Authority's planned intervention programmes.

4.1.10 Two Tier Food Authorities

District and County Council Food Authorities should ensure, with regard to interventions, that there is co-ordination and effective liaison between their respective authorities as appropriate, in accordance with Paragraph 1.1.2.

4.1.11 Larger Food Establishment

Larger food business establishments may have smaller food business establishments on site under the control of different food business operators e.g. coffee shops. Such establishments are subject to separate registration (see Paragraph 1.5.3.4.2) and hence separate interventions are required as appropriate. Food Authorities may, however, wish to co-ordinate their activities in such a way that they may carry out programmed interventions of these smaller establishments whilst they are on site to inspect the main food business establishment (or elements thereof).

<u>4.1.12</u> Factory and Fishing Vessels – Hygiene Inspection

In addition to the planned intervention programme of land based establishments, coastal Food Authorities will need to consider the inspection of factory, freezer and fishing vessels. Such inspection will normally be carried out whilst vessels are in port.

Inspection of factory, freezer or fishing vessels whilst at sea should not normally be undertaken by officers of Food Authorities. In the case of factory vessels, there may be circumstances when inspections can only be carried out when the factory vessels are moored offshore.

When carrying out inspections of fishing vessels only, a Food Authority should use the form attached in Annex 10 to ensure that all hygiene requirements are met. This form should not be used for factory and freezer vessels, which are subject to approval and a different enforement regime.

The frequency of inspections of fishing vessels should be set out in the Food Authority's Food Service Plan or Enforcement Policy.

While a vessel may be approved by another Food Authority, there is nothing to prevent any authorised officer of any other Food Authority from inspecting the vessel, as long as they are satisfied that they have the appropriate legal authority to inspect and have contacted the Food Authority that has approved the vessel and that authority considers it necessary. Where, during an inspection, contravention of the Regulations is identified, the authorised officer should notify the Food Authority, where the vessel is normally based, of the contravention. The Food Authority receiving details of contravention should liaise with the notifying Food Authority and take whatever follow-up action is necessary.

<u>4.1.13</u> Inspection of Moveable Establishments/Premises: Trains and Long Distance Coaches

Before considering the inspection of trains or long distance coaches, relevant information should be obtained from the Home Authority and/or the train operator or coach operator, as appropriate. Inspection and visits to, such moveable establishments/premises should be carried out in liaison with the train or coach operator and should be duly recorded in accordance with the Framework Agreement.

For information on the inspection of ships and aircraft, see Chapter 4.4.

CHAPTER 4.2: INSPECTION

4.2.1: Introduction

This Chapter describes how inspections should be carried out.

4.2.2: Inspections – General

Inspections should be based on the relevant inspection form for the business concerned.

The inspection form is intended to assist officers and businesses by introducing a structured approach to the inspection process consistent with quality assurance practice. It is not necessary to inspect every aspect of a food business at every inspection, e.g. an inspection of a supermarket's instore bakery or restaurant operated by that supermarket.

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

At an appropriate point at the beginning of the inspection, the officer should discuss with the food business operator or representative the purpose and scope of the inspection, whether there have been any changes in activities since the last visit, and what the officer intends to do.

An inspection should include the identification of all the food related activities undertaken by the business, the areas of the establishment used for the preparation, production and storage of foodstuffs, any processes used and the staff involved.

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

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

Inspections may also be for purposes connected with the Home Authority Principle, for example, advising food business operators on the law and ways in which they can comply with it.

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

At the conclusion of every inspection, the officer should discuss any contravention of food law discovered,

• any corrective action necessary,

- the timescale for corrective action,
- any further action the officer intends to take and any recommendations of good practice that the officer considers appropriate.

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

The officer should, on request, advise, and discuss with the food business operator, the intervention or rating applied to the business.

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

4.2.3: Food Hygiene Inspections

The approach to inspection will depend on the legal requirements and the extent to which the business has documented its food safety management system.

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

- Assess the risk of the enterprise failing to meet food hygiene requirements;
- Assess the hazards posed by the activities of the business, the food business operator's understanding of those hazards, and the application of appropriate controls; having regard to the nature and size of the business;
- Establish whether food is being handled and produced hygienically having regard to subsequent processing;
- Assess and verify appropriate procedures based on HACCP principles appropriate to the nature and size of the business, confirming that controls are in place and operating effectively and that appropriate corrective action is taken when necessary, Other than in respect of primary production;
- Establish whether food is being handled and produced hygienically, is safe to eat, and that relevant temperature controls are being observed;
- Recommend good food hygiene practice in accordance with EU and UK Industry Guides, relevant sector specific codes, and other relevant technical standards, and promote continued improvements in hygiene standards through the adoption of good practice;
- Check the source and any health or identification marking of raw materials, and the identification marking and destination of finished products. Where deficiencies in health or identification marking are identified, officers should refer to and implement any relevant provisions of Chapters 1.7 and 2.4 of this Code and the Home Authority Principle, and consider using their powers under Regulation 27 of the Food Hygiene (England) Regulations

2006 (see also Regulation 23 in this regard) to remove affected products from the food chain;

• In relation to retail and catering businesses that sell or use live bivalve molluscs, ensure that where parcels of live bivalve molluscs are split before sale to the ultimate consumer, that information on identification marks is retained for at least 60 days.

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

- A discussion with any staff responsible for monitoring and corrective action at critical control points to confirm that control is effective;
- A physical inspection to determine whether critical controls have been identified and whether the controls are in place and to assess compliance with relevant food law;
- An assessment of compliance with the traceability requirements of Article 18 of Regulation 178/2002;
- A discussion regarding any hazards that have been identified by the officer that have not been covered by the business's systems;
- A discussion regarding any failure to implement or monitor any critical controls that have been identified by the business.

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

The full scope of the food hygiene inspection is detailed in the relevant inspection form for the business concerned.

4.2.4: Food Standards Inspections - Scope

Particular attention should be paid to relevant key control points, mixing stages when ingredients are added, monitoring and verification procedures, corrective actions and documentation.

In particular, an officer conducting a food standards inspection should:

- Assess the risk of the enterprise failing to meet food standards requirements;
- Consider the existence and effectiveness of management systems designed to ensure that food standards requirements are met and, where they exist, test their effectiveness;

- Assess compliance with composition, presentation and labelling requirements by examining advertisements, labels, descriptions, menus, claims, recipes and other records;
- Assess compliance with the traceability requirements of Article 18 of Regulation 178/2002;
- Assess compliance with supplier specifications;
- Recommend good practice in accordance with relevant industry codes and other relevant technical standards.

The full scope of the food standards inspection is detailed in the relevant inspection form for the business concerned.

4.2.5: Enforcement Action and Revisits– Food Hygiene and Food Standards

Food businesses that fail to comply with significant statutory requirements must be subject to appropriate enforcement action and revisit inspection(s).

Failure to comply with significant statutory requirements includes:

- Failure to comply with a single requirement that compromises food safety, compromises public health, or prejudices consumers;
- Failure to comply with a number of requirements that, taken together, indicate ineffective management;
- Failure to comply with the requirements of a Hygiene Emergency Prohibition Notice or Order (food hygiene);
- Failure to comply with the requirements of an Emergency Prohibition Notice or Order (food standards).

Revisit inspections under this section should be based on the relevant inspection form for the business concerned, although the inspection may focus on the significant statutory requirements that were found to be contravened at the previous intervention.

The timing of the revisit will be determined by the action taken as a result of the earlier intervention.

Such a revisit should, whenever practicable, be undertaken by the officer who undertook the original intervention.

The Food Authority's approach to revisits and enforcement actions should be part of its documented Food Service Plan or Enforcement Policy (see Paragraph 3.1.4).

4.2.6: Clothing and Equipment

Food Authorities should provide officers who carry out intervention at establishments with clean protective clothing including headgear consistent with good industry practice.

Food Authorities should require officers to wear protective clothing, give any relevant information on their health status when requested and adhere to any reasonable precautions that are required by the business where the intervention is being conducted. Officers should wear appropriate protective clothing etc if it is provided by the business.

Food Authorities should provide their officers with the equipment and facilities necessary to enable them to carry out their inspections competently and in accordance with food law and the standards in this Code.

CHAPTER 4.3: INTERVENTIONS AT APPROVED ESTABLISHMENTS - ADDITIONAL REQUIREMENTS

4.3.1: Introduction

This Chapter requires Food Authorities to identify food business establishments within their enforcement remit that are subject to approval under Regulation 853/2004 and ensure they are approved and subject to interventions as appropriate. It also sets out specific requirements on sampling at each inspection of a live bivalve mollusc dispatch or purification centre; and on following-up adverse sample results.

4.3.2: General Requirements

Food Authorities should ensure that product-specific establishments in their area that are subject to approval under Regulation 853/2004 are identified and appropriately approved, as required by the relevant legislation and subjected to regular interventions.

4.3.3: Live Bivalve Molluscs

4.3.3.1: Examination of Registration Documents

Food Authorities should carry out regular examinations of registration documents to determine their accuracy. The examination of the documents and samples should normally be carried out as part of the inspection of dispatch or purification centres (see Paragraph 5.3.3 of this Code and paragraph A.6.8 and Annex 6, Appendix 2 of the Practice Guidance).

4.3.3.2: Sampling as Part of the Inspection

Each inspection of a dispatch or purification centre should include the taking of samples for laboratory tests. The frequency of sampling should follow the advice officially recognised by, or issued by, the Agency³⁸.

The Food Authority must investigate test results that show breaches of the end product standard.

If necessary, further sampling and laboratory tests should be undertaken in the relevant harvesting area, relaying area, dispatch or purification centre to establish the cause of the non-compliance and any corrective action which is needed.

Where necessary, Food Authorities should communicate test results which do not comply with the end product standard to neighbouring Food Authorities responsible for the relevant harvesting area, relaying area, or purification centre.

Food Authorities should also communicate the results of any samples of live bivalve molluscs to the operator of the centre from where the samples were procured. The Food Authority should also notify the Agency of the results of any samples that may indicate a significant variation in the quality of production areas or relaying areas.

4.3.4: Interventions at Product-Specific Establishments Subject to Approval under Regulation 853/2004

The minimum number of food hygiene interventions at establishments subject to approval under Regulation 853/2004 should be conducted as necessary in accordance with Annex 5. The Food Authority shall keep the approval of establishments under review when carrying out official controls.

³⁸ Guidance on the Frequency of Microbiological Sampling of Purified Molluscs by Operators of Purification Centres – issued February 1995

CHAPTER 4.4: INSPECTION OF SHIPS AND AIRCRAFT

4.4.1: Introduction

The Food Hygiene (England) Regulations 2006 includes any ship or aircraft in the definition of premises. However, Schedule 4 to these Regulations which sets out specific temperature control requirements does not, by virtue of Paragraph 1(b), apply to these means of transport. The relevant temperature requirements in Annex II of Regulation 852/2004 do, however, apply.

In terms of the Food Safety (Ships and Aircraft) (England and Scotland) Order 2003, only paragraph (a) of Article 2(1) giving the definition of "the principal Hygiene and Temperature Control provisions" and Paragraph 2 (b) of the Schedule have been revoked. Hence, the definitions in this Order remain in food law for the application of the Food Safety Act 1990, where appropriate.

The range and variety of vessels, from cruise liners, passenger ferries and merchant ships to training yachts, is an important factor when planning inspection activities on board vessels. In respect of aircraft, primary consideration should be given to the origin of the food on board, including water and other drinks, and the transport to, and loading of, the aircraft.

The aim of the legislation will best be achieved by adopting a balanced approach of inspection and professional judgement.

4.4.2: Background and Relationship to Other Inspections

Authorised Officers should bear in mind that other parts of this Code and corresponding Practice Guidance are primarily designed for the inspection of fixed premises, and that there are significant differences between these and ships and aircraft. When conducting inspections of ships and aircraft, authorised officers should therefore take account of, and give precedence to, the content of this Chapter and the corresponding Chapter of the Practice Guidance.

A strategy for frequency of inspection should be adopted, based on knowledge about different types of craft, their origin and history (see also Paragraph 4.4.5.5 in relation to ships). Before considering ship or aircraft inspection, all relevant information should be obtained from the Home Authority (HA), shipping operator or airline, as appropriate. Inspections of, and visits to, ships and aircraft should be duly recorded in accordance with the Framework Agreement.

4.4.3: Enforcement Issues

Authorised officers who require access to secure areas of ports or airports to undertake their duties will need clearance under the Aviation and Maritime Security Act 1990. Food Authorities should therefore make arrangements to obtain appropriate security clearance for their staff so that they have unrestricted access, subject to compliance with the normal security procedures of the facility concerned (see Paragraph 4.4.4 regarding UK military craft). Where an HA agreement is in place, there is an obligation to inform LACORS of the agreement and to follow the LACORS guidelines.

Food hygiene standards on ships and aircraft should meet the relevant requirements of Regulation 852/2004 including those in Chapters III to X and Annex II of that Regulation.

A Hygiene Improvement Notice or a Hygiene Emergency Prohibition Notice may be served under the Food Hygiene (England) Regulations 2006 in respect of an aircraft or ship that is registered in the United Kingdom. The conditions that must be met before such a notice can be served are the same as apply in relation to fixed premises.

In the case of contraventions that do not warrant service of a notice, an enforcing Food Authority may consider liaising with the HA, and should do so if the HA has specifically requested information on inspections.

An authorised officer may also serve a Hygiene Improvement Notice or Hygiene Emergency Prohibition Notice in relation to a foreign registered ship or aircraft. In such cases, the authorised officer should contact the UK office of the company or Handling Agent. If considered necessary, in respect of ships, the officer should also contact the Maritime and Coastguard Agency (MCA) at the earliest opportunity (see Paragraph 4.4.5.4). Where there is no such UK office or Handling Agent, the Competent Authority in the country where the ship or aircraft is registered should be made aware of the defects found.

If the craft is registered in another Member State, the procedures set out in Chapter 2.4 on liaison with other Member States should be followed. Any difficulties should be discussed with the Agency.

If the craft is registered in a third country, the Agency should be given full details to allow the matter(s) to be raised with the competent authorities in the relevant country.

4.4.4: UK Military Ships and Aircraft

Authorised Officers should refer to Chapter 1.6 in relation to security considerations when visiting UK military ships and aircraft, which must be regarded as Group 3 premises. This requires prior notification before a proposed visit. Any food safety issues found on inspection, which concern UK military ships and aircraft should be brought to the attention of single Service Environmental Health leads and the relevant HA for the particular Service (see below for details). Authorised Officers must bear in mind the ultimate purpose of military ships and aircraft, and that galley design may have been constrained for operational reasons. Military policy, procedures and practices should therefore be given due consideration.

Authorised Officers should also take account of the relevant parts of "JSP 456 – Defence Catering Manual Vol. 3", which is available on the individual HA's websites and through the LACORS website.

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

Authorised Officers should contact Portsmouth City Council, the Royal Navy HA for procedural guidance prior to any proposed visit to an RN ship or submarine. Tewkesbury Borough Council, the Royal Air Force HA, should be contacted for guidance prior to any proposed visit to RAF aircraft.

Royal Navy

Home Authority: Portsmouth City Council. Tel: (02392) 834253. Environmental Health Lead: SO2 Environmental Health Policy. Tel: (02392) 722285.

<u>RAF</u>

Home Authority: Tewkesbury Borough Council. Tel: (01684) 295010. Environmental Health Lead: Command Environmental Health Officer Tel: (01452) 712612.

<u>Army</u>

Home Authority: Rushmoor Borough Council. Tel: (01252) 398398. Environmental Health Lead: SO2 Medical Intelligence. Tel: (01276) 412737.

4.4.5: Ship Inspections

4.4.5.1: Preparation

Before commencing an inspection, authorised officers should ascertain when the vessel was last inspected by requesting a copy of the previous inspection report from the Master or from another UK Food Authority.

The officer should then be able to decide whether there is a need to carry out an inspection for food safety purposes. If no previous inspection report is available, and after taking other factors into account (see Paragraph 4.4.5.5), the officer should decide whether an inspection is needed.

It might be necessary to follow up the findings of a previous inspection which are reflected in the report, and a decision can therefore be made as to the type and extent of the inspection to be undertaken.

The officer should ensure that the ship's Master is aware of the purpose of the inspection and also determine the scope of the food business activities taking place on the vessel.

Initial discussions with the ship's Master or representative should include consideration of any documentation that is available, and identification of all food and drink related activities undertaken on the vessel, including drinking water, water used in galleys, and any other areas on board where food and drink is prepared or served. Where arrangements are in place, Home Authorities (HAs) should ensure that shipping operators are aware of their responsibilities in relation to providing information. HAs should provide relevant information to other Food Authorities, when requested to do so and, where this relates to the general operating policy and procedures of the shipping operator, be afforded appropriate confidentiality.

4.4.5.2: Inspection of the Vessel

When there is an adverse report from a previous inspection, or the vessel has not been inspected for a period in excess of that set out in Paragraph 4.4.5.5, officers may need to carry out a inspection of the relevant parts of the vessel.

Items for consideration include:

- Specifications and sourcing of food and water;
- Transport to the vessel, loading and subsequent storage;
- Subject to the type of vessel, the facilities, including equipment, for food preparation/production/storage and the storage, distribution and quality of water used in the food areas or available for drinking purposes;
- Adequacy of procedures based on the HACCP principles, which will depend on the type of vessel;
- Food temperature requirements in Annex II of Regulation 852/2004;
- Commensurate with their food handling activities, the food handlers' knowledge of food hygiene/own health status;
- Food and water sampling;
- Pest control procedures;
- Any known adverse report or cases/outbreaks of gastric illness, etc.

4.4.5.3: Action on Conclusion of the Inspection

Following completion of the inspection, the findings should be discussed with the ship's Master or delegated representative, giving an indication of the expected timescale of any corrective actions found to be necessary. An inspection report³⁹ should also be prepared and given to the ship's Master before leaving the vessel. If it is not possible for a full report to be completed before the vessel's departure, this should be explained to the Master or his representative and forwarded to the Master at the first available opportunity. The ship's owner should also receive a copy. A further copy should be sent to the MCA at the earliest opportunity if serious shortcomings are found, and the Port Health Authority (PHA) at the next intended port of call, if in UK and, if

³⁹ The APHA Ship Sanitation / Food Safety Report Form is available on LACORS website

designated, the relevant HA. This should be prior to any possible visit to the vessel at the subsequent port of call.

4.4.5.4: Liaison with the Maritime and Coastguard Agency (MCA)

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

Should there be difficulties with serious shortcomings relating to the existence of a health risk condition (as defined by Regulation 7(2) / Regulation 8(4) i.e. there is a risk / imminent risk of injury to health) concerning food and water safety whilst a vessel is in port, consideration should be given to liaising with the MCA for the instigation of action to detain the vessel in accordance with procedures in the MoU. Such deficiencies should also be reported to the Competent Authority of the state of registration of the vessel (see Paragraph 4.4.3).

4.4.5.5: Frequency of Inspection

The frequency of inspection of vessels should be based on the following:

- Name and type of vessel, e.g. general cargo/passenger vessel, passenger ferries, cruise vessels;
- Port of registration;
- Age/condition/history of vessel;
- Crew and passenger numbers/profile/"turnover";
- Vessel's trading pattern/schedule/previous port(s) of call;
- Confidence in food and water safety management systems;
- Date and port of last food safety inspection see *Note below;
- Available documentation;
- Recent significant reports of food related problems on the vessel;
- Reports from previous inspections level of compliance. These could include inspection reports issued by competent authorities in the EU or Third Countries;
- Valid deratting certificate or exemption certificate, where appropriate.

*Note: Appropriate Intervention rating could be assessed by the use of Annex 5. In general, cruise ships and passenger ferries should be inspected at least

once every 12 months and, subject to the above, general cargo and merchant ships at least once every 18 months to 2 years, unless there are clear grounds to justify further investigations, e.g. the ship visiting a UK port for the first time or after an absence of 12 months or more. Visits to other vessels, such as training yachts, based at specific ports should be decided on a basis of number of vessels, local conditions and knowledge gained through previous inspections.

4.4.6: Aircraft Inspections

4.4.6.1: Preparation

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

The decision to board an aircraft should be based largely on any information provided by the airline; confirmation of the authenticity of the information, and the receipt of any food or food hygiene related complaints from passengers or crew. If such information (as outlined in Paragraph 4.4.6.2) is satisfactory, there might be no need to board an aircraft, particularly if the information shows that specific types of aircraft and food safety practices meet requirements.

It is, however, essential to verify on-board conditions and practices at regular intervals by inspection. At least annual checks should be made on the information provided by the airline concerning food hygiene issues, either by the HA, or in the absence of an HA, by an authorised officer of the relevant enforcing Food Authority. Such checks should confirm, for example, that no changes have taken place to in-flight caterers, source of water supply, etc.

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

4.4.6.2: Information to be Obtained to Assist Inspection Procedures

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

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

- Named contact and contact details for an airline to deal with enquiries (this
 might be a food safety advisor employed by the airline);
- Number of aircraft, their type and registration numbers, where appropriate;

- Routes flown long haul, short haul and countries of destination;
- Airline food safety policy/procedure documents or manual;
- Type of catering menus and the service of high risk foods;
- Food handler (cabin staff) knowledge up-to-date guidance notes/explanatory sheets and/or training commensurate with the food handling activity covering personal hygiene; handling of food; cross contamination issues arising from other duties; pest awareness; food temperature control (as required by Annex II of Regulation 852/2004), if appropriate, and monitoring; own health status and exclusion from work policy;
- Training records, standard of training, including retraining, when appropriate;
- Flight caterers, and/or nominated companies assembling and/or transporting meals to the aircraft, used by each airline. In-flight menus should assist in the assessment of whether high-risk foods are handled and/or prepared on board. The onus is on the airline to provide evidence that the food originates from a reputable source;
- Specifications in place with the caterer for the supply of food to aircraft and the accepted temperature for delivery, including for high-risk foods;
- Details of food and water safety arrangements when supplied to an aircraft in a foreign location;
- Potable water supply source, use of bowsers, cleaning/disinfection of storage tanks – frequency/effectiveness. To be checked prior to or after the inspection;
- Flights or routes with return catering including multiple sector catering, and from which airports;
- Pest control contract and monitoring;
- Cleaning contractor, with details of contracts, e.g. cleaning schedules, and monitoring of the effectiveness of the cleaning regime;
- Reports of analysis/examination of food and potable water on aircraft by the airline, which should relate to the Food Authority's own sampling regime;
- Whether the airline undertakes self-audits and whether any reports are available.

The above information should assist an officer to assess the need to actually board a particular aircraft to carry out an inspection. In practice, taking account of Annex 5, and with the appropriate information obtained from the

airline company and/or the relevant HA, this might result in a visit to particular types of aircraft, providing high risk meals once every eighteen months to two years, unless there are compelling reasons to undertake such visits in an intervening period.

4.4.6.3: Inspection of the Aircraft

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

4.4.6.4: Items for Consideration in Relation to Food Safety on Aircraft

Following a documentary check, the following matters should be considered/confirmed, as listed in Paragraph 4.4.6.2, when appropriate:

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

4.4.6.5: Action on Conclusion of the Inspection/Contact with Home Authority

A report should be sent to the airline following an inspection, with copies to the relevant HA where such an arrangement exists, in respect of UK registered aircraft. Where aircraft from a particular airline are checked and found to be in contravention of the applicable law, full details should be provided to allow adequate follow up, e.g. the type of aircraft; flight number; insufficient knowledge of food hygiene issues amongst the cabin crew, etc. See also Paragraph 4.4.3 concerning reporting deficiencies to the country of registration of the aircraft, when appropriate.

CHAPTER 4.5: ACTION FOLLOWING AN INTERVENTION

4.5.1: Introduction

This Chapter sets out minimum standards of report writing and record keeping

4.5.2: Reports following an Official Control

The outcome of an Official Control must always be reported in writing to the food business operator either at the conclusion of the Official Control or as soon as practicable thereafter, even if the outcome was satisfactory.

Please see Annex 6, the Food Business Establishment Report for information requirements that the report should contain.

Reports may include other legislation covered during interventions at food establishments, e.g. health and safety at work, weights and measures etc, although matters relating to food law should be clearly differentiated from other law.

4.5.3: Establishment Record Files

The Food Authority's establishment record files⁴⁰, which may be computer based, should be updated after each intervention and include:

- Information on the size and scale of the business and its customer base;
- Information on the type of food activities undertaken by the business, including any special equipment, processes or features;
- Copies of any correspondence with the business, including documentation associated with approvals or authorisations.
- Copies of food sample analysis/examination results;

and in respect of establishments inspected for food hygiene purposes:

- An assessment of the business compliance with procedures based on HACCP principles where appropriate;
- Information on hygiene training undertaken by employees; including any training on the implementation and operation of the food safety management system;

and in respect of premises inspected for food standards purposes:

• The existence and assessment of any documented quality system;

⁴⁰ See Chapter 2, Paragraphs 16.1 and 16.2 of the Framework Agreement

• Details of other businesses that produce or import for the business.

4.5.4: Retention of Records Relating to Interventions.

Records relating to interventions should be retained in the establishment file for at least 6 years, unless required for longer retention because of litigation, Local Government Ombudsman review the document management policy of the Food Authority, or instruction by the Agency.

SECTION 5: PRODUCT-SPECIFIC ESTABLISHMENTS

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

5.1.1: Introduction

This chapter relates to the establishments subject to approval under Regulation 853/2004 in respect of which Food Authorities are responsible for enforcement.

5.1.2: Division of Enforcement Responsibilities

Responsibility rests with Food Authorities for the approval of, and enforcement in relation to, establishments subject to approval under Regulation 853/2004 in respect of which control does <u>not</u> fall to an official veterinarian. These "product-specific" establishments will be producing any, or any combination, of the following: Minced Meat, Meat Preparations, Mechanically Separated Meat, Meat Products, Live Bivalve Molluscs, Fishery Products, Raw Milk (other than raw cows' milk), Dairy Products, Eggs (not primary production) and Egg Products, Frogs Legs and Snails, Rendered Animal Fats and Greaves, Treated Stomachs, Bladders and Intestines, Gelatine and Collagen, and will include certain cold stores and certain wholesale markets. Food Authorities are also responsible for enforcement in respect of collection centres and tanneries supplying raw material for the production of gelatine or collagen intended for human consumption.

The Agency, through the Meat Hygiene Service (MHS), is responsible for the approval of establishments subject to approval under Regulation 853/2004 where control falls to an official veterinarian in accordance with Article 4(7) of Regulation 854/2004⁴¹ and for enforcement in such establishments once approved. Such establishments are slaughterhouses, game handling establishments and cutting plants placing fresh meat on the market. The MHS is also responsible for establishments co-located with these establishments in which Minced Meat, Meat Preparations, Mechanically Separated Meat, Meat Products, Rendered Animal Fats and Greaves, Treated Stomachs, Bladders and Intestines, Gelatine and/or Collagen are also produced.

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

5.1.3: Collection Centres and Tanneries Supplying Raw Material for the Production of Gelatine or Collagen Intended for Human Consumption

Collection centres and tanneries may supply raw material for the production of

⁴¹ Regulation (EC) No. 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

gelatine and collagen intended for human consumption. They are not subject to the requirements of Regulation 852/2004 nor are they subject to approval under Regulation 853/2004. They will, however, need to be specifically authorised by the relevant Food Authority in accordance with Annex III, Section XIV, Chapter I(5) of Regulation 853/2004 (Gelatine) and Section XV, Chapter I(5) of Regulation 853/2004 (Collagen) and must also meet the other requirements of Annex III, Section XIV (Gelatine) and Annex III, Section XV (Collagen) of Regulation 853/2004.

5.1.4: Exemption of Establishments from the Requirements of Regulation 853/2004

5.1.4.1: Introduction

Article 1 of Regulation 853/2004 sets out the scope of that Regulation. The following paragraphs deal specifically with exemptions from the Regulation under Article 1(2) and under Article 1(5)(b)(ii). Additional guidance material is contained within Annex 3 of the Practice Guidance.

5.1.4.2: Article 1(2) of Regulation 853/2004: Food Containing Both Products of Plant Origin and Processed Products of Animal Origin

Article 1(2) of Regulation 853/2004 stipulates that "Unless expressly indicated to the contrary, this Regulation does not apply to food containing both products of plant origin and processed products of animal origin".

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

Food Authorities should be aware that establishments benefiting from this exemption would, in addition to compliance with Regulation 852/2004, need to comply with Article 1(2) of Regulation 853/2004 which requires such establishments to obtain the processed products of animal origin they use in compliance with Regulation 853/2004 (i.e. from approved establishments or non-approved establishments permitted to supply the establishment under the exemption described in Paragraph 5.1.4.3 below)) and that those products are handled in accordance with that regulation.

5.1.4.3: Article 1(5)(b)(ii) of Regulation 853/2004: Retail Exemption

Article 1(5)(a) of Regulation 853/2004 stipulates that "Unless expressly indicated to the contrary, this Regulation shall not apply to retail". Article 1(5)(b) stipulates that "this Regulation shall apply to retail when operations are carried out with a view to the supply of food of animal origin to another establishment", but goes on, in sub-paragraphs (i) and (ii) to exclude certain activities from this requirement.

Retailers otherwise exempt from the requirements of Regulation 853/2004 may, by virtue of Article 5(b)(ii) of Regulation 853/2004, supply food of animal origin from the retail establishment to other retail establishments, but only if

this is a marginal <u>and</u> localised <u>and</u> restricted activity. Guidance on such activity can be found in Annex 3 of the Practice Guidance.

5.1.5: Applications for Approval: Procedures / Forms

Article 31(2)(a) of Regulation 882/2004 obliges competent authorities to establish procedures for food business operators to follow when applying for the approval of their establishments in accordance with Regulation 853/2004. Procedures for handling applications for approval are set out in Paragraphs 5.1.6 *et seq.* below. Food Authorities should ensure that they, and food business operators, follow these procedures as appropriate. Any deviations from these procedures should be recorded and retained by the Food Authority and should, where possible, be agreed with the Food Authority beforehand.

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

5.1.6: Applications for Approval: Handling

Any application for approval from a food business operator should be dealt with promptly. In order to ensure consistency, Food Authorities should ask food business operators to submit applications for approval in the appropriate format as set out in Annex 11 of the Practice Guidance.

Applications for approval of establishments should only be accepted from food business operators that intend to engage in activities for which approval would be required in accordance with Regulation 853/2004. Under no circumstances should approval be granted to an establishment which is not subject to approval under Regulation 853/2004.

Food Authorities should ensure that the food business operator supplies all relevant information before an application for approval is determined. This information may be obtained from the food business operator in documentation supplied with the application or during the subsequent on-site visit to the establishment as required by Article 31(2)(b) of Regulation 882/2004 (see Paragraph 5.1.7). It is a matter for the Food Authority to decide at which stage of the application this information should be provided.

In considering applications for approval Food Authorities should ensure that they fully consider any exemption that may be available to the applicant afforded by Article 1 of Regulation 853/2004.

5.1.7: Determination of Applications for Approval

Before reaching a decision on an application for approval the Food Authority should ensure that an on-site visit is made in accordance with Article 31(2)(b) of Regulation 882/2004. This should take the form of a inspection of the establishment (see 4.1.2), to verify that, where necessary, all systems, procedures and documentation meet the relevant requirements of Regulation 852/2004 and Regulation 853/2004. The inspection should be conducted in accordance with, and cover, all aspects of the relevant inspection form for the business concerned, and consider all issues identified by Regulation 853/2004 as requiring Food Authority consent. As per Article 31(2) of Regulation 882/2004 all the requirements of food law relevant to that business must be met.

5.1.8: Conditional Approval

Article 31(2)(d) of Regulation 882/2004 permits the granting of conditional approval to an establishment, following an on site visit, which does not fully comply with the requirements of food law, but only if the establishment meets all the infrastructure and equipment requirements (see also Annex 3, Paragraph A.3.4 of the Practice Guidance).

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

If conditional approval is granted, a further visit must be carried out within three months of the conditional approval being granted in accordance with Article 31(2)(d) of Regulation 882/2004. This visit should be a inspection (see 4.1.3). In appropriate circumstances as set out in Article 31(2)(d) of Regulation 882/2004, conditional approval may be extended, but this is restricted to a maximum of six months from the date of the initial granting of conditional approval. Professional judgement should used in deciding whether it would be appropriate to extend conditional approval, on a case by case basis.

5.1.9: Product-Specific Establishments Producing More Than One Type of Product

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

There will be establishments where two or more products of animal origin subject to requirements of Regulation 853/2004 are applicable, e.g. an establishment producing both meat products and fishery products. In such cases the relevant provisions will apply to areas of the establishment where each type of product is produced. All relevant provisions of the Regulation will apply to those areas of the establishment where facilities are shared.

5.1.10: Live Bivalve Mollusc Purification Centres

Where an application for a proposed purification centre, or modification to an existing centre, is received, a copy of the application must be sent to the Agency for consultation with the Centre for Environment, Fisheries and Aquaculture Science (CEFAS).

Food Authorities must not determine such an application until they have received a response from CEFAS and must include any operating conditions set by CEFAS in the approval document.

5.1.11: Approval of Bivalve Mollusc Relaying Areas

It is the responsibility of the Agency to classify bivalve mollusc beds. A food business can apply to the Food Authority to have any suitable area classified as a relaying area. This area must fulfil the criteria necessary of the classification of bivalve mollusc beds. The procedure and criteria for the approval and classification of bivalve mollusc beds and relaying areas is set down in Annex II, Chapter II of Regulation 854/2004. Food Authorities should only designate relaying areas after consultation with the Agency. It should be noted that the live bivalve molluscs should, after relaying, be treated in accordance with the (A, B, or C) classification of the area in respect of placing on the market.

5.1.12: Approval Number / Identification Mark

(See also Chapter 5.1 of the Practice Guidance)

A Food Authority must give an approval number to each food business establishment it approves or conditionally approves in accordance with Article 3(3) of Regulation 854/2004. This approval number should be a three digit number unique to that authority. The approval number should form part of an approval code consisting of the Food Authority's two-letter code followed by the approval number.

The approval code should be incorporated into an identification mark which approved establishments are required to apply to their products, as appropriate (see also paragraph 5.1.13). The requirements for the form of the identification mark are set out in Annex II, Section I B of Regulation 853/2004. A Food Authority should agree an identification mark with each establishment it approves which (a) incorporates the approval code it has allocated and (b) meets the requirements of Annex II, Section I B of Regulation 853/2004.

Food Authorities should be aware that the UK has opted to use the transitional derogation provided by Article 8 of Regulation 2073/2005⁴² concerning compliance with the value set in Annex I to that Regulation for *Salmonella* in minced meat, meat preparations and meat products intended to be eaten cooked placed on the national market of a Member State. The Regulation permits this transitional derogation to be used up to 31 December 2009 and the UK has opted to use it until this date. In accordance with Article 8 of Regulation 2073/2005 a 'special mark', which cannot be confused with the

⁴² Commission Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs

identification mark provided for in Annex II, Section I B of Regulation 853/2004 must be applied to products which the transitional derogation applies.

The 'special mark' to be used is an oval within an oblong. Within the oval there should be the letters UK, the license/approval number, and the letter N, to indicate that the product is for the national market. This combines the oval shape of the identification mark and much of the information required by that mark whilst remaining distinct in itself – thereby meeting the requirement of the Regulation that the special mark 'cannot be confused with the identification mark'.

5.1.13: Identification Marking of Food to which Regulation 853/2004 Does Not Apply

Food Authorities should bear in mind that Annex II, Section 1, B 7 of Regulation 853/2004 stipulates that if an establishment manufactures both food to which Regulation 853/2004 applies and food to which it does not, the food business operator may apply the same identification mark to both types of food.

5.1.14: Refusal of Approval and Appeals – General

If an establishment does not fully meet the requirements of Regulation 853/2004, the Food Authority should consider whether conditional approval is appropriate in the circumstances (see Paragraph 5.1.8).

When a Food Authority has decided to refuse an application for approval it should notify the applicant in writing of the decision at the earliest opportunity. The Food Authority should also give the reasons for refusal in writing, the matters necessary to satisfy the requirements of the Regulation, and make it clear that activities requiring approval may not be undertaken unless approval or conditional approval is granted. Such notification should also make the food business operator aware of their right of appeal against the decision and provide the address of the Magistrates' Court where such an appeal may be made⁴³. Rights of appeal are subject to Regulation 12 of the Official Feed and Food Controls (England) Regulations 2006.

Food Authorities should bear in mind that Regulation 12(5) of the Official Feed and Food Controls (England) Regulations 2006 stipulates that following a timely appeal against a decision of a Food Authority to refuse or withdraw an approval, the food business operator who, immediately before such refusal or withdrawal, had been using the establishment concerned may continue to use it, pending the results of the appeal, subject to any conditions imposed by the Competent Authority for the protection of public health.

If the Food Authority considers that any activities undertaken in an establishment pending the result of an appeal may present a risk to public health, it should consider the use of other relevant enforcement powers, appropriate to the circumstances involved.

⁴³ A template form is provided at Annex 11, A.11.3 of the Practice Guidance

5.1.15: Notification of Approval - General

Once approval, or conditional approval, has been granted, the Food Authority should notify the applicant, in writing, of the nature and scope of the approval and any conditions or limitations that apply and the approval code⁴⁴ (see Paragraph 5.1.12).

When full approval is granted following conditional approval, the Food Authority should notify the food business operator in writing⁴⁵. Such a notification should also include details of the nature and scope of the approval any conditions or limitations that apply and confirmation that the approval code allocated to the establishment may continue to be used.

The Food Authority should retain a copy of the above notifications on the relevant establishment file and ensure that the Agency is notified of the approval in accordance with Paragraph 2.4.3.

5.1.16: Change of Details or Activities

Article 6(2) of Regulation 852/2004 requires food business operators to ensure that the relevant Competent Authority always has up-to-date information on establishments including significant changes in activities and closures of establishments. However, where this does not happen and a Food Authority becomes aware of any significant changes in, for example, the ownership, management or activities of approved establishment, they should carry out an inspection and take any necessary action.

5.1.17: Non-approved Establishments Thought to be Engaged in Activities Requiring Approval

Where Food Authorities become aware of businesses engaged in activities that require approval, but that are not approved, they should inform the food business operator, in writing, of the need for approval and consider appropriate enforcement action.

Officers are directed to Section 3 for general guidance on enforcement.

 ⁴⁴ A template form is provided at Annex 11, A.11.2 of the Practice Guidance
 ⁴⁵ A template form is provided at Annex 11, A.11.2 of the Practice Guidance

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

5.2.1: Introduction

In addition to the enforcement powers detailed in Section 3, authorised officers have other powers available to them under the Official Feed and Food Controls (England) Regulations 2006 in respect of product-specific establishments subject to approval under Regulation 853/2004.

Powers to withdraw, or suspend, the approval or conditional approval of an establishment subject to approval under Regulation 853/2004 are provided by Article 31(2)(e) of Regulation 882/2004. Regulation 3(3) / Schedule 5 of the Official Feed and Food Controls (England) Regulations 2006 designates Food Authorities as competent authorities for the purposes of Article 31 of Regulation 882/2004.

5.2.2: Suspension / Withdrawal of Approval or Conditional Approval - General

Food Authorities should bear in mind that the immediate effect of the suspension or withdrawal of an establishment's approval is such that the establishment may not be used for any activities which would render the it subject to approval under Regulation 853/2004 or to place products of animal origin, manufactured in the European community on the market

On the discovery of non-compliance in establishments subject to approval under Regulation 853/2004, the Food Authority should, before considering suspension or withdrawal, explore other enforcement options to control the food hazards presented by the establishment.

Non-compliance should not necessarily be considered sufficient to justify the *immediate* suspension or withdrawal of an establishment's approval or conditional approval, and a reasonable opportunity to achieve compliance should be allowed where this is appropriate.

5.2.3: Suspension of Approval or Conditional Approval

Food Authorities should only initiate procedures to suspend an establishment's approval or conditional approval if other enforcement options have been considered and circumstances exist in accordance with Article 31(2)(e) of Regulation 882/2004. Food Authorities should request that any guarantee regarding future production made by a food business operator in accordance with this Article is made in writing, although Food Authorities should be aware that they cannot insist on this as no requirement exists in law to provide such guarantees in writing.

5.2.4: Withdrawal of Approval or Conditional Approval

Food Authorities should only initiate procedures to withdraw an establishment's approval or conditional approval if other enforcement options have been considered, including suspension of the approval (see Paragraph 5.2.3), and if circumstances exist in accordance with Article 31(2)(e) of Regulation 882/2004.

An establishment's approval or conditional approval should only be withdrawn in circumstances where the food business operator is unable to satisfy the Food Authority to the extent that the food authority has a reasonable expectation that the identified deficiencies will be rectified an acceptable standard will be maintained in the future.

5.2.5: Notifications of Suspension or Withdrawal of Approval or Conditional Approval

Under Article 54(3)(a) of Regulation 882/2004, the Food Authority must notify the food business operator in writing of its decision to suspend or withdraw an establishment's approval or conditional approval. The Food Authority should also give the reasons for the suspension or withdrawal in writing, the matters necessary to satisfy the requirements of the Regulation, and make it clear that activities requiring approval may not be undertaken. Such notification should also make the food business operator aware of their right of appeal against the decision and provide the address of the Magistrates' Court where such an appeal may be made⁴⁶. Rights of appeal are subject to Regulation 12 of the Official Feed and Food Controls (England) Regulations 2006.

Copies of notifications should be retained on the Food Authority's files. The Food Authority should also notify the Agency when an establishment's approval or conditional approval has been suspended or withdrawn.

5.2.6: Appeals Against Suspension or Withdrawal of Approval or Conditional Approval

Food Authorities should bear in mind that Regulation 12(5) of the Official Feed and Food Controls (England) Regulations 2006 stipulates that following an appeal against a decision of a Food Authority to refuse or withdraw an approval, the food business operator who, immediately before such refusal or withdrawal, had been using the establishment concerned may continue to use it, pending the results of the appeal, subject to any conditions imposed by the Competent Authority for the protection of public health. This provision does not extend to appeals against the suspension of an approval.

If the Food Authority considers that any activities undertaken in an establishment pending the result of an appeal may present a risk to public health, it should consider the use of other relevant enforcement powers, appropriate to the circumstances involved.

⁴⁶ A template form is provided at Annex 11, A.11.3 of the Practice Guidance

CHAPTER 5.3: MATTERS RELATING TO LIVE BIVALVE MOLLUSCS

5.3.1: Introduction

This Chapter requires relevant Food Authorities to establish and maintain a local shellfish liaison group. It also deals with the need for registration documents or permanent transport authorisations, monthly checks on relaying areas, and the publication of information about prohibited areas.

5.3.2: Liaison Arrangements

(See also Paragraph A.6.6 of the Practice Guidance).

All Food Authorities where there are commercial shellfish activities should establish and maintain a shellfish liaison group comprising those people who will enable the group to be fully effective. The functions of the group are likely to vary depending on the local shellfish industry.

5.3.3: Registration Documents: Live Bivalve Molluscs

Under Regulation 853/2004, a gatherer of live bivalve molluscs (including pectinidae) to be placed on the market requires a registration document (unless issued with a permanent transport authorisation) to identify each batch that they gather for its movement from the harvesting site. The movement could be either from the harvesting site (a classified bed or area in the case of wild pectinidae) to the dispatch centre or relaying area, purification centre or processing centre.

Food Authorities should issue such registration documents to gatherers, including fishing vessels, that harvest live bivalve molluscs. (A model registration form can be found at Annex 6, Appendix 2 of the Practice Guidance). This should contain a unique code number and be given to the harvester or gatherer before they carry out harvesting. Food Authorities should provide registration documents on demand. Food Authorities may not make any charge for the issue of registration documents, nor may they unreasonably refuse to issue the documents to a gatherer. The Food Authorities should check registration documents when live bivalve molluscs come ashore.

Any Food Authority which issues registration documents should keep a record indicating the names and details of the persons to whom they were issued and the respective unique number(s), for at least 1 year.

Registration documents should be issued to gatherers who are harvesting within the area of another Food Authority only with the agreement of that other Food Authority.

To enable the system of documentation to be monitored the number of registration documents issued to a gatherer should be recorded.

Details of the requirements for Food Authorities to take microbiological samples can be found in Paragraphs 4.3.3.1 and 4.3.3.2.

Food business operators must keep copies of registration documents for each batch sent and received for at least twelve months after its dispatch or receipt dispatch, or such longer period as the Food Authority may specify.

5.3.4: Permanent Transport Authorisations

A Food Authority may issue to gatherers a Permanent Transport Authorisation as an alternative to separate movement documents when the gatherer also operates the purification centre, relaying area or processing establishment to which their harvested live bivalve molluscs are being delivered. However, all establishments operated by the gatherer must fall within the jurisdiction of the single Food Authority.

In deciding whether to issue a PTA a Food Authority should consider the requirements of Regulation 853/2004, Annex III, Section VII, Chapter 1, paragraph 7. In addition to these the history of an operators compliance with relevant food safety legislation and the application of management control procedures should be an influencing factor in any decision.

Where a Food Authority is not satisfied with the operators' compliance with hygiene legislation, after authorisation is given, the authority is at liberty to withdraw the PTA. A PTA should be issued for each individual shellfish harvesting bed.

5.3.5: Checks on Relaying Areas

Authorised officers should carry out checks at least every month in relaying areas to ensure that the relaying conditions specified by the Agency are being complied with. The conditions that must be observed when live bivalve molluscs are relayed in approved relaying areas are specified in Chapter II of Annex II to Regulation 854/2004.

Authorised Officers should ensure that there is a thorough examination of records retained by operators in respect of relaying areas whenever an inspection is carried out.

5.3.6: Closure Notices (temporarily closing harvesting areas)

Annex II, Chapter II, Section C.1 of Regulation 854/2004 requires that, where sampling results show that health standards for molluscs are exceeded, or that there may otherwise be a risk to human health, the Food Authority must close the production area concerned to prevent the harvesting of live bivalve molluscs or, if appropriate, to reclassify the area in accordance with the Regulation.

Annex II, Chapter II, Section E(b) and (c) of Regulation 854/2004 respectively, require the Food Authority to inform interested parties, such as producers, gatherers and operators of purification centres or dispatch centres,

immediately of the closure of any area, and to act promptly to close, reclassify, or re-open production areas. When the closure of a production area is required, the FSA recommends that a Closure Notice should be used as the means to inform interested parties; a model Closure Notice can be found at Annex 9.

The Food Authority should liaise with the Agency over the issue of a Closure Notice. Liaison with the Agency may include consideration of whether any action should be taken to withdraw any live bivalve molluscs from sale that may already have been distributed locally or nationally.

The Food Authority should ensure that Closure Notices, when used, are made quickly, and that all known food business operators in their district, who either have registration documents already issued, or have a permanent transport authorisation (issued by the Food Authority in accordance with Section VII Chapter 1.7 of Regulation 853/2004), are notified of the Closure Notice and its effect. This may best be achieved by sending a copy of the Notice to all known interests. Additionally, the Food Authority should prominently display Closure Notices where food businesses harvesting shellfish might reasonably be expected to see them.

Other Food Authorities with an interest should also be advised, who should, in turn, fulfil their responsibility by informing, as appropriate, operators within their own area affected by the closure.

A Closure Notice may not be time limited. The Food Authority should liaise with the Agency as soon as possible in relation to the undertaking of additional sampling of harvesting waters or live bivalve molluscs as may be necessary to determine when the closed area may reopen. The Food Authority should remove a Closure Notice immediately it is satisfied that harvesting in accordance with the Regulation may resume.

In the event a Food Authority decides not to use a Closure Notice to inform interested parties of a closure, it will need to satisfy itself that the means of communication chosen satisfies the legal requirements.

Under the terms of Regulation 17(1) of the Food Hygiene (England) Regulations 2006, it is an offence to contravene a specified Community provision.

CHAPTER 5.4: MATTERS RELATING TO FRESH MEAT

5.4.1: Introduction

This chapter relates to the division of enforcement responsibilities in relation to fresh meat.

5.4.2: Division of Enforcement Responsibilities

As stated in Paragraph 5.1.2, the Agency, through the Meat Hygiene Service (MHS), is responsible for enforcement in relation to establishments approved under Regulation 853/2004 where control falls to an official veterinarian, in accordance with Article 4(7) of Regulation 854/2004. Such establishments are slaughterhouses, game handling establishments and cutting plants placing fresh meat on the market. The MHS is also responsible for establishments co-located with these establishments.

Food Authorities are responsible for enforcement in relation to:

- Establishments newly subject to approval under Regulation 853/2004 until conditional or full approval is granted, or if approval is refused, by the MHS.
- establishments in which Minced Meat, Meat Preparations, Mechanically Separated Meat, Meat Products, Rendered Animal Fats and Greaves, Treated Stomachs, Bladders and Intestines, Gelatine and/or Collagen are produced and that are <u>not</u> co-located with slaughterhouses, game handling establishments and cutting plants;
- the direct supply, by the producer, of small quantities of primary products to the final consumer (Article 1(3)(c) of Regulation 853/2004);
- on farm slaughter and cutting of small quantities of poultry and lagomorphs (Regulation 853/2004);
- hunters supplying small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer (Article 1(3)(e) of Regulation 853/2004).

Further relevant material on matters relating to meat is contained in Annex 5 of the Practice Guidance.

SECTION 6: SAMPLING AND ANALYSIS

CHAPTER 6.1: SAMPLING AND ANALYSIS

6.1.1: Introduction

Effective routine sampling is an essential part of a well-balanced enforcement service and should therefore feature in the Sampling Policy of all Food Authorities. Guidance to help ensure sampling by Food Authorities is undertaken effectively and consistently is set out in the Practice Guidance and on microbiological sampling in LACORS advice⁴⁷.

Whilst the Food Safety Act 1990, the Food Safety (Sampling and Qualifications) Regulations 1990 and the Food Hygiene (England) Regulations 2006 provide a framework for Food Authority sampling which is carried out specifically with a view to pursuing legal action if the results show an offence has been committed, it is important to recognise that samples may also be taken for the purposes of surveillance, monitoring and providing advice to food business operators. A Food Authority's Sampling Policy and Programme should cover all types of sampling work undertaken.

6.1.2: Sampling Policy and Sampling Programme⁴⁸

Food Authorities should prepare and publish a food sampling policy and make it available to businesses and consumers. The policy should set out the Food Authority's general approach to food sampling and its approach in specific situations such as process monitoring, Home Authority Principle, inspections, complaints, special investigations and national, regional and local coordinated programmes. This sampling policy should cover all samples taken including those not taken in accordance with this Code.

The sampling policy should detail the factors that will be taken into account in formulating the sampling programme, including any national or local consumer issues that will influence the level of sampling to be undertaken.

Food Authorities should also prepare a sampling programme that details their intended food sampling priorities. The programme should take account of the number, type and intervention ratings of the food businesses and the type of food produced in the area, the Food Authority's originating or home authority responsibilities and the need to ensure that the provisions of food law are enforced. The sampling programme should not normally be published.

The sampling policy should commit the Food Authority to providing the resources necessary to carry out its food sampling programme.

The sampling policy and the sampling programme should be prepared in consultation with the Food Examiner and the Public Analyst, which may take place on a local or regional basis.

 ⁴⁷ Further advice for Food Authorities on microbiological sampling can be found in LACORS
 "Guidance on Food Sampling for Microbiological Examination" published in January 2006
 ⁴⁸ See Chapter 2, Paragraph 12.4 of the Framework Agreement

6.1.3: Requests for Information from Manufacturers or Importers

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

6.1.4: Sampling – General

The sampling provisions of the remainder of this Section do not apply to:

- Samples of food that are the subject of complaint and are brought to the Food Authority by consumers or other agencies;
- Samples of food that are submitted to the Public Analyst for monitoring or surveillance purposes alone, i.e. there is no intention at the time of sampling that any formal enforcement action will ensue from the result;
- Samples of food procured in accordance with food law which are not taken for analysis or examination, e.g. samples submitted for the opinion of other experts e.g. pest identification etc;
- Samples of food that are taken as evidence in their own right e.g. use-by dates;
- Samples that are taken under the provisions of regulations still in force that have their own detailed sampling provisions and are listed in Schedule 1 to the Food Safety (Sampling and Qualifications) Regulations 1990. Food Authorities should be aware that SI 1983 No. 1508, SI 1983 No. 1509, SI 1988 No. 2206 and SI 1989 No. 2383 have been revoked.

6.1.5: Samples for Analysis (Food Safety Act 1990, Section 29)

All samples for analysis, taken under Section 29 of the Food Safety Act 1990 in accordance with the Food Safety (Sampling and Qualifications) Regulations 1990 and with the requirements of this Code should be submitted to the appointed Public Analyst at a laboratory accredited for the purposes of analysis and which appears on the list of official food control laboratories⁴⁹.

6.1.6: Division of Samples for Analysis

Unless the sample meets the criteria for submission for analysis without division into three parts (see Paragraph 6.1.6.4. of the Practice Guidance), the formal sample should, as soon as possible, be divided into 3 representative parts. Subject to regulation 6.4, regulation 6(1) of the Food Safety (Sampling and Qualifications) Regulations 1990 requires that the sample should be divided into 3 representative parts. The resultant parts of the sample are referred to in this Code as final parts. Where practicable, the division should

⁴⁹ A list of UK official food control laboratories has been submitted to the European Commission and is published on the Agency's website www.food.gov.uk

be carried out in the establishment of the food business operator, who, if present, should be given the opportunity to observe the sampling and division before being invited to choose one of the parts for retention.

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

6.1.7: Notification of Formal Sampling Activity (Analysis)

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

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

6.1.8: Certificates of Analysis

In accordance with Regulation 9 of the Food Safety (Sampling and Qualifications) Regulations 1990, certificates of analysis must be in the format set out in Schedule 3 to those regulations.

6.1.9: Notification of Results (Analysis)

Where a certificate of analysis indicating that the foodstuff does not comply with legal requirements has been received, the Food Authority should refer to and implement any relevant provisions of Chapters 1.7 and 2.4 and the Home Authority Principle (see Paragraph 1.1.7)

In accordance with Regulation 9 of the Food Safety (Sampling and Qualifications) Regulations 1990, a copy of the certificate of analysis must be supplied, on request, to the owner of the food which has been analysed. If the alleged offence is thought to be related to the manufacturer, they should be informed at the earliest opportunity by the fastest possible means (e.g. fax or telephone, subsequently confirmed in writing) along with the relevant Food Authority. The packer or, in the case of imported food, the importer, or their agent, may also be notified.

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

6.1.10: Samples for Examination (Food Hygiene (England) Regulations 2006, Regulation 12)

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

In accordance with Regulation 13(10) of the Food Hygiene (England) Regulations 2006, the Food Safety (Sampling and Qualifications) Regulations 1990 apply in relation to a sample procured by an authorised officer of a Food Authority under Regulation 12 of the Food Hygiene (England) Regulations 2006 as if it were a sample procured by an authorised officer under Section 29 of the Food Safety Act 1990.

6.1.11: Notification of Formal Sampling Activity (Examination)

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

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

6.1.12: Certificates of Examination

In accordance with Regulation 13(11) of the Food Hygiene (England) Regulations 2006 certificates of examination must be in the format set out in Schedule 3 to the Food Safety (Sampling and Qualifications) Regulations 1990.

6.1.13: Notification of Results (Examination)

Where a certificate of examination indicating that the foodstuff does not comply with legal requirements has been received, the Food Authority should refer to and implement any relevant provisions of Chapters 1.7 and 2.4 and the Home Authority Principle (see Paragraph 1.1.7)

In accordance with Regulation 9 of the Food Safety (Sampling and Qualifications) Regulations 1990, a copy of the certificate of examination must be supplied, on request, to the owner of the food which has been examined. If the alleged offence is thought to be related to the manufacturer, they should be informed at the earliest opportunity by the fastest possible means (e.g. fax or telephone, subsequently confirmed in writing) along with the relevant Food Authority. The packer or, in the case of imported food, the importer, or their agent, may also be notified.

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

SECTION 7: MONITORING OF INTERVENTIONS

CHAPTER 7.1: MONITORING OF INTERVENTIONS

7.1.1: Introduction

This Section outlines the matters that need to be monitored by Food Authorities to ensure that interventions are carried out to a consistently high standard and that the planned intervention programme is being maintained.

7.1.2: What Needs to be Monitored

Food Authorities should maintain documented procedures for monitoring progress of the planned intervention programme and the quality and consistency of interventions undertaken by their officers, or staff supplied under contract, to ensure, so far as practicable, that interventions are carried out competently. The procedures to be followed should include arrangements for recording in-year changes to the planned intervention programme; newly opened establishments; establishments found to be closed; and establishments for which the Intervention rating is changed.

The monitoring system should include measures to review:

- Adherence to the Food Authority's planned intervention programme;
- The priority given to interventions with businesses according to Intervention ratings;
- Compliance with this Code of Practice, the Practice Guidance and other Agency guidance;
- The consistent assessment of Intervention ratings;
- Appropriate use of relevant inspection forms⁵⁰;
- Compliance with internal procedures, policies and the Food Authority's Enforcement Policy;
- That the interpretation and action taken by officers following an intervention is consistent within that Food Authority and is consistent with Agency and/or LACORS guidance;
- That officers are aware of and have access to other published industry codes of practice relevant to the businesses within the area of the Food Authority;

and in relation to food hygiene: interventions:

⁵⁰ The relevant inspection form is the inspection form that relates to the type of business being inspected and the type of inspection being carried out. Inspection forms and aide memoires can be found on the LACORS Website

• That officers have due regard to published UK or EU Guides to Good Practice.

SECTION 8: ANNEXES

ANNEX 1: Glossary of Terms

APHA	Association of Port Health Authorities
CCDC	Consultant in Communicable Disease
	Control
ССР	Critical Control Point
CEFAS	Centre for Environment, Fisheries and
	Aquaculture Science
CEN	The European Committee for
	Standardization
CIEH	Chartered Institute of Environmental Health
CPHM (CD/EH)	Consultant in Public Health Medicine
	(Communicable Disease/Environmental
	Health)
DCA	Diploma in Consumer Affairs
DEFRA	Department for Environment, Food and
DEITON	Rural Affairs
DH	Department of Health
DHSSPS	Department of Health, Social Services and
	Public Safety (Northern Ireland)
DTS	Diploma in Trading Standards
E. coli O157	Escherichia coli O157
EEA	European Economic Area
EHO	Environmental Health Officer
EHP	Environmental Health Practitioner
EHRB	Environmental Health Registration Board
EU	European Union
FAO	Food and Agricultural Organisation of the
	United Nations
Framework Agreement	Framework Agreement on Local Authority
	Food Law Enforcement
FVO	Food and Veterinary Office (of the
	European Commission)
НА	Home Authority
HACCP	Hazard Analysis and Critical Control Point
HPA	Health Protection Agency
HPS	Health Protection Scotland (formerly
	SCIEH)
IFST	Institute of Food Science and Technology
LACORS	Local Authorities Co-ordinators of
	Regulatory Services
MCA	Maritime and Coastguard Agency
MOD	Ministry of Defence
MoU	Memorandum of Understanding
PARNUTS	Foodstuffs intended for particular nutritional
	uses
PHA	Port Health Authority
RPA	Rural Payments Agency

REHIS	Royal Environmental Health Institute of Scotland
SFSORB	Scottish Food Safety Officers' Registration Board
The Agency TSI TSO UKAS VTEC	The Food Standards Agency Trading Standards Institute Trading Standards Officer United Kingdom Accreditation Service Vero cytotoxin-producing <i>Escherichia coli</i>

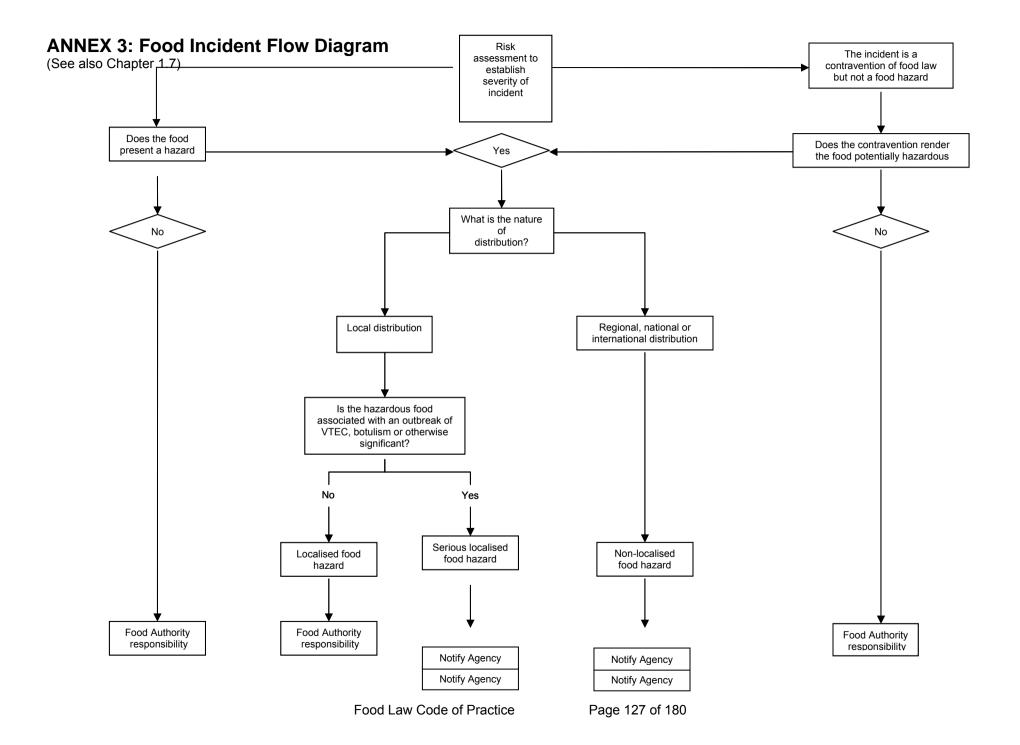
ANNEX 2: HACCP Evaluation Competencies

Standards of Competence for Food Authority Officers in Relation to procedures based on HACCP principles

Food Authorities must satisfy themselves that staff engaged in the food hygiene inspection of food business establishments except primary production, involving the audit of procedures based on HACCP principles, in addition to holding the relevant qualification prescribed in Chapter 1.2 for the category of business to be inspected, are able to demonstrate the following competencies.

- 1. To identify, through the conduct of an audit, the need for improved food safety control in establishments having regard to the nature and size of the business.
 - 1.1 Assess the quality of food safety hazard identification in a food business.
 - 1.2 Assess the quality of critical control point (CCP) identification in a food business.
 - 1.3 Assess the suitability of controls in place and their monitoring at CCPs.
 - 1.4 Assess the verification and review by business operators of procedures based on HACCP principles.
- 2. To promote and support the implementation of procedures based on HACCP principles appropriate to the nature and size of the business.
 - 2.1 Explain the principles of hazard analysis to food business operators or managers in terms appropriate to the nature and size of the business.
 - 2.2 Specify targets for improved control of food safety hazards.
 - 2.3 Provide advice on carrying out hazard analysis and implementing controls in terms appropriate to the nature and size of the business.
 - 2.4 Explain where appropriate, the relationship between HACCP systems (based on Codex) and other procedures based on HACCP principles.
- 3. To secure compliance with procedures based upon HACCP principles as required in legislation, appropriate to the nature and size of the business.
 - 3.1 Explain the legal requirements in relation to procedures based on HACCP principles.
 - 3.2 Secure progress towards compliance by discussion and persuasion.

3.3 Secure compliance by the issue of notices. Secure compliance through the courts (and gather and preserve evidence in a form usable in court).



ANNEX 4: Food Incident Report Form (Food Authorities)



FOOD INCIDENT REPORT FORM

TO BE COMPLETED BY THE INVESTIGATING OFFICER/REPRESENTATIVE AND FAXED TO THE AGENCY ON: 020 7276 8446 (Tel: 020 7276 8448/8453)

- 1. Reporting Food Authority's name and address:
- 2. Name of reporting Officer including telephone, fax and e-mail details:
- 3. Date and time initial information received by Food Authority:
- 4. Initial information received by:
- 5. Received from (include Food Authority, HPA etc, address, telephone number and contact name where possible):
- 6. Method (telephone/fax/letter/other):
- 7. Brief description of incident:
- 8. Type of contamination:
- 9. Description of product

Type of Product:

Product Name:

Brand Name:

Batch Code/s:

Description of Packaging:

Pack Size:

Durability Date/s or Code/s:

Country of Origin:

UK Importer/Distributor (including contact details):

Manufacturer (including contact details):

10. Has clinical illness occurred?

Details (type of illness, symptoms, numbers of consumers affected etc):

- 11. Full details of distribution (including EU and Third Countries) e.g. quantities/areas, and when the particular product/batch in question was first placed on the market:
- 12. Is the manufacturer/retailer/supplier aware of the incident, if so what are their proposals for dealing with it?

13. Assessment of hazard (please circle):

Local Retail Regional Catering Manufacture National International Import/Export

14. Other relevant contact details (e.g. home and/or originating authority/CCDC/HPA/other)

Name:

Address, telephone and fax numbers, e-mail address:

- 15. Has any enforcement action already been taken? For example, have samples been taken for examination or analysis, or detention notices served, or food seized? Please fax any laboratory reports or detention notices etc to the FSA with this form, or as soon as possible thereafter.
- 16. Has there been media interest? Yes/No

If there has been a press release please fax to the FSA with this form.

17. Any additional information: Please attach additional pages if necessary.

Signed:

Date:

Job Title:

ANNEX 5: Food Establishment Intervention Rating Schemes (Does not apply to primary production)

A.5.1: Introduction

This Annex deals with the food hygiene and food standards intervention ratings and frequencies for interventions at food establishments.

A.5.2: Food Hygiene Intervention Rating Scheme

Basic Principles

- i. Food Authorities that are responsible for enforcing food hygiene law should determine the food hygiene intervention frequencies of food establishments within their area using the risk assessment criteria in this Annex, in order to determine their planned food hygiene intervention programmes.
- ii. Establishments subject to approval under Regulation 853/2004 are included in this determination(see ix. below) <u>except</u> stand-alone cold stores.
- iii. The scheme incorporates an option for alternative enforcement strategies other than primary inspections for "low risk" establishments in which the inherent hazards are not significant by virtue of their trading activities or the number of consumers they supply (see below).
- iv. The scheme is set out in the form of an assessment document that can be used by officers in the field. An assessment should be completed at the end of every inspection.
- v. Officers should use the full range of scores available within the system, as the purpose of the rating system will be frustrated by cautious marking or by a reluctance to recognise effective management/control systems.
- vi. The operation of this intervention rating scheme within the Food Authority should be subject to periodic management review to ensure that staff are using the scheme correctly and consistently.
- vii. The intervention in higher risk businesses must always take preference over lower risk ones. The practice of completing the intervention programme at lower risk businesses that have not been visited during an earlier programme before commencing the intervention at higher risk businesses cannot be supported.
- viii. Interventions should normally be completed by the due date as determined by the intervention rating, but in any case no more than 28 days after that date, apart from circumstances outside the control of the Food Authority such as seasonal business closures.

- ix. Such "low-risk" establishments must, be subject to an alternative enforcement strategy or intervention not less than once in any 3-year period.
- x. Food Authorities that decide not to subject "low-risk" establishments to interventions must set out their alternative enforcement strategies for maintaining surveillance of such businesses in their Food Service Plan or Enforcement Policy.

It is not intended to preclude inspections of such establishments where inspection is the Food Authority's preferred surveillance option, in which case the minimum frequency of inspection is determined by the inspection rating

A.5.3: The Food Hygiene Scoring System

Part 1: The Potential Hazard

Three factors determine the potential hazard:

A. Type of Food and Method of Handling

Score	Guidance on the Scoring System		
40	Manufacturers of high-risk food including those subject to approval under Regulation 853/2004. Wholesalers and packers who re-wrap or re-pack high-risk foods. In this context, high-risk foods may be regarded as foods that support the growth of micro-organisms, and/or are intended for consumption without further treatment that could destroy pathogenic micro-organisms or their toxins.		
30	Preparation, cooking or handling of <u>open</u> high-risk foods by caterers and retailers, except caterers that prepare less than 20 meals a day (see below).		
10	Handling of pre-packed high-risk foods; Caterers that prepare high-risk foods but serve less than 20 meals a day; Other wholesalers and distributors not included in the categories above; Manufacture or packing of foods other than high-risk; Establishments involved in the filleting, salting or cold smoking of fish for retail sale to final consumer.		
5	Retail handling of foods other than high-risk, such as fruit, vegetables, canned and other ambient shelf stable products. Any other businesses not included in the categories above.		

Score:

B. Method of Processing

An additional score should be included for processes listed in the table below. If an additional score under this section is appropriate it may only be allocated once; i.e. the maximum score under this section is 20.

Score	Guidance on the Scoring System	
20	Thermal processing or aseptic packing of low-acid foods; Vacuum and sous-vide packing (except raw/unprocessed meat and dried foods); Manufacture of cook/chill food i.e. cooked and prepared meals or foods which may be eaten cold or after reheating (NB: Catering premises should not be included in this category unless they are engaged in the specific operation referred to commercially as the preparation of cook-chill meals. The simple reheating of cook-chill meals is excluded from the scope of this paragraph); Small-scale production of cooked meat products in food business establishments which are not subject to approval under Regulation 853/2004 e.g. by certain retailers including butchers.	
0	Any other case not included above.	

Score:

C. Consumers at Risk

The number of consumers likely to be at risk if there is a failure of food hygiene and safety procedures.

Score	Guidance on the Scoring System		
15	Manufacturers of food that is distributed nationally or internationally.		
10	Businesses serving a substantial number of customers including a significant proportion from outside the local area, e.g. superstore, hypermarket, airport caterer, motorway service area caterer; Manufacturers not included in the category above.		
5	Businesses, most of whose customers are likely to be living, staying or working in the local area, e.g. high street or corner shop, high street supermarket, or high street restaurant.		
0	Businesses supplying less than 20 consumers each day.		

Score:

<u>PLUS</u>

An **<u>additional</u>** score of 22 (in addition to the score above) should be included for establishments such as hospitals, nursing homes, day-care centres and child nurseries, where production and/or service of high-risk foods takes place, and where more than 20 persons in a vulnerable group are at risk. In this context, vulnerable groups are those that include people who are under 5 or over 65 years of age, people who are sick, and people who are immunocompromised.

Score	Guidance on the Scoring System	
22	Production and/or service of high-risk foods in premises where there are more than 20 people in a vulnerable group at risk;	
0	Any other case not included above.	

Score:

Part 2: Level of (Current) Compliance

The food hygiene and safety procedures (including food handling practices and procedures, and temperature control) and the structure of the establishment (including cleanliness, layout, condition of structure, lighting, ventilation, facilities etc) should be assessed **<u>separately</u>** using the scoring system below.

The score should reflect compliance observed during the inspection according to the guidance set out below. Adherence to any relevant UK or EU Industry Guide to Good Hygiene Practice should be considered when assessing compliance.

Conformity with relevant national guidelines or industry codes of recommended practice will also be necessary to score 0 or 5.

Score	Guidance on the Scoring System	
25	Almost total non-compliance with statutory obligations.	
20	General failure to satisfy statutory obligations – standards generally low.	
15	Some major non-compliance with statutory obligations – more effort required to prevent fall in standards.	
10	Some non-compliance with statutory obligations and industry codes of recommended practice. Standards are being maintained or improved.	
5	High standard of compliance with statutory obligations and industry codes of recommended practice, minor contraventions of food hygiene regulations. Some minor non-compliance with statutory obligations and industry codes of recommended practice.	
0	High standard of compliance with statutory obligations and industry codes of recommended practice; conforms to accepted good practices in the trade.	

Score – Hygiene:

Score – Structural:

Part 3: Confidence in Management/Control Procedures

The actual performance of management is scored in Part 2 on the basis of the results achieved and observed. A management that achieves good food hygiene performance, well understood by the workforce, should have achieved a good standard in Part 2, and consequently a low score for that factor.

Confidence in Management is not meant to reconsider this aspect. It is to elicit a judgement on the likelihood of satisfactory compliance being maintained in the future.

Factors that will influence the inspector's judgement include:

- The "track record" of the company, its willingness to act on previous advice and enforcement, and the complaint history;
- The attitude of the present management towards hygiene and food safety;
- Hygiene and food safety technical knowledge available to the company (internal or external), including hazard analysis/HACCP and the control of critical points;

Satisfactory HACCP based procedures

Score	Guidance on the Scoring System	
30	Poor track record of compliance. Little or no technical knowledge. Little or no appreciation of hazards or quality control. No food safety management procedures.	
20	Varying record of compliance. Poor appreciation of hazards and control measures. No food safety management system.	
10	Satisfactory record of compliance. Access to and use of technical advice either in-house, from trade associations and/or from Guides to Good Practice. Understanding of significant hazards and control measures in place. Making satisfactory progress towards a documented <i>4</i> procedures commensurate with type of business.	
5	Reasonable record of compliance. Technical advice available in- house or access to and use of technical advice from trade associations and/or from Guides to Good Practice. Have satisfactory documented procedures. Able to demonstrate effective control of hazards. Will have satisfactory documented food safety management system. Audit by Food Authority confirms general compliance with procedures.	
0	Good record of compliance. Access to technical advice within organisation. Will have satisfactory documented HACCP based food safety management procedures which may be subject to external audit process. Audit by Food Authority confirms compliance with documented procedures with few/minor non- conformities not identified in the system as critical control points.	

Score:

<u>PLUS</u>

An **<u>additional</u>** score of 20 (in addition to the score above) should be included where there is a significant risk:

- Of food being contaminated with *Clostridium botulinum* and the microorganism surviving any processing and multiplying; or
- Of ready-to-eat food being or becoming contaminated with microorganisms or their toxins that are pathogenic to humans, e.g. *E. coli* O157 *or* other VTEC, *Salmonella* sp.; *Bacillus cereus*;.

In this context, significant risk means the probability that an incident is more likely to occur than not. The following matters should be considered when assessing this factor:

- The potential for contamination or cross contamination by the specified micro-organisms;
- The likelihood of survival and growth of the specified micro-organisms;
- The existence of procedures based on HACCP principles and confidence in their implementation including documentation and records of monitoring of controls;
- The extent and relevance of training undertaken by managers, supervisors and food handlers;
- Whether intervention by the Food Authority is necessary to reduce the probability of an incident occurring.

The additional score must only be applied on a case-by-case basis, must not be applied generically to whole categories of food business establishments, and must be removed at the next inspection if the significant risk no longer exists.

The additional score must also be consistent with the baseline assessment of Confidence in Management/Control Systems. If confidence in management is assessed as 0 or 5, and there is also assessed to be a significant risk of contamination of food with one of the specified micro-organisms, then one of the assessments cannot be correct and each should be reviewed. Establishments should not pose a significant risk if there is high or moderate Confidence in Management/Control Systems.

Score	Guidance on the Scoring System		
20	Significant risk of food being contaminated with <i>Cl. botulinum</i> , and the organism surviving any processing and multiplying; or Significant risk of ready-to-eat food being contaminated with micro-organisms or their toxins that are pathogenic to humans.		
0	Any other case not included above.		

Score:

Inspection Ratings:

A.5.4: Food Hygiene	intervention	Frequencies

Category	Score	Minimum Intervention Frequency	
Α	92 or higher	at least every 6 months	
В	72 to 91	at least every 12 months	
С	42 to 71	at least every 18 months	
D	31 to 41	at least every 24 months	
E	0 to 30	A programme of Alternative enforcement strategies or interventions every 3 years	

Establishments rated as low risk (30 or less) need not be included in the planned inspection programme but must be subject to an alternative enforcement strategy at least once in every 3 years.

Food Standards Intervention Rating Scheme Basic Principles

- i. Food Authorities that are responsible for enforcing food standards law should determine the food standards intervention frequencies of food businesses within their areas using the risk assessment criteria in this Annex, in order to determine their planned food standards intervention programmes.
- ii. Alternatively, where the Food Authority is responsible only for food standards enforcement, or where food hygiene and food standards enforcement is carried out by separate departments within the same Food Authority, e.g. Environmental Health and Trading Standards, the food standards risk assessment may be based on the LACORS guidance on risk assessment for trading standards. Where assessments are based on the LACORS scheme, the intervention frequency for food standards purposes should not be less than would have been the case under this scheme.
- iii. Food Authorities in single tier local authority areas may opt to base their planned intervention programme on the food hygiene risk assessment scheme under this Code of Practice. Food Authorities that exercise this option must ensure that their interventions consider both food hygiene and food standards matters, that interventions of those matters occur no less frequently than would have been the case had both schemes been used, and that the food standards risk assessment is completed and recorded.
- iv. The scheme incorporates an option for alternative enforcement strategies other than inspections for "low-risk" businesses in which the inherent hazards are not significant by virtue of their trading activities or the number of consumers they supply (see below).
- v. Officers should use the full range of scores available within the system, as the purpose of the rating system will be frustrated by cautious marking or by a reluctance to recognise effective management/control systems.
- vi. Businesses that fall into more than one scoring category for a scoring factor should be allocated the highest score of those that are applicable.
- vii. The operation of this intervention rating scheme within the Food Authority should be subject to periodic management review to ensure that staff are using the scheme correctly and consistently.
- viii. The interventions in higher risk businesses must always take preference over lower risk ones. The practice of completing the intervention programme at lower risk businesses that have not been visited during an earlier programme before commencing the intervention at higher risk businesses cannot be supported.
 - ix. The minimum intervention frequencies described should not be regarded as strict and absolute. However, inspections should be completed no more than 28 days after the due date, apart from circumstances outside the control of the Food Authority such as seasonal business closures

Low-Risk Activities

- x. Such "low-risk" businesses must, however, be subject to an alternative enforcement strategy not less than once in any 5-year period.
- xi. Food Authorities must set out their alternative enforcement strategies for the monitoring of such businesses in their Food Service Plan or Enforcement Policy.
- xii. It is not intended to preclude inspections of such businesses where inspection is the Food Authority's preferred intervention option, in which case the minimum frequency of inspection is determined by the intervention rating.

A.5.5: The Food Standards Scoring System

Part 1: The Potential Risk

A. Risk to Consumers and/or Other Businesses

This factor considers the potential adverse effect on consumers, and the consequences for other businesses, should the business not comply with food standards legislation. Adverse effects on consumers include safety and economic prejudice. Consequences for other businesses include the economic effects of unfair trading.

Score	Guidance on the Scoring System		
30	Manufacturers of PARNUTS foods;		
	Manufacturers or packers of high value foods, or high volume		
	foods where there is an incentive for fraudulent adulteration;		
	Manufacturers of foods that contain a wide range of additives;		
	Businesses that make nutrition, nutrient content, or health claims		
	on pre-packed food labels or in advertising.		
20	Manufacturers or packers of foods that are subject to statutory		
20	compositional standards.		
	Local businesses that use in-store produced labels, window		
10	displays, chalk boards, menus etc, e.g. butchers, bakers, health		
	food shops, restaurants, take aways, caterers supplying more than		

	10 meals per day, and businesses using claims for marketing advantage.
0	Caterers supplying not more than 10 meals per day, e.g. bed and breakfast; Any business not included in the categories above.

B. Extent to Which the Activities of the Business Affect any Hazard

This factor considers the type of activities that the food business undertakes, the need for those activities to be closely monitored and controlled, and their potential effectiveness in maintaining compliance with food standards legislation. Consider whether the business produces, labels, or advertises products to which food standards law applies. If the business produces its own products, consider the monitoring and control of recipes and ingredients.

The scores below provide examples of food businesses to which a particular score could apply.

Score	Guidance on the Scoring System	
30	Food manufacturers, processors, importers processing a wide range of goods.	
20	Local businesses that label loose goods on display, and/or undertake pre-packing for direct sale.	
10	Non-manufacturing retail/catering selling only from their own establishment.	
0	Any business not included in the categories above.	

Score:

C. Ease of Compliance

This factor considers the volume and complexity of food standards law that applies to the business and with which it has a responsibility to ensure compliance. Consider the range and complexity of products, processes and services including the consistency of raw materials. Consider the difficulty of the task for the food business operator including how easy it is to recognise a hazard.

Score	Guidance on the Scoring System	
30	Manufacturer, packer or importer of a wide range of products.	
20	Manufacturer, packer or importer of a limited range of products.	
10	Retailers who apply descriptions to food such as butchers, bakers and delicatessens;	

	Caterers with complex menus.
0	Any business not included in the categories above.

D. Consumers at Risk

This factor considers the number of consumers likely to be at risk if the business fails to comply with food standards legislation.

Score	Guidance on the Scoring System	
20	Manufacturers, producers and packers of food that is distributed nationally or internationally.	
10	Businesses whose trade extends beyond the local area, e.g. regional supermarket/hypermarket; small-scale local manufacturer.	
5	Businesses supplying the local area, e.g. high street or corner shop; local supermarket; local restaurant.	
0	Businesses supplying less than 30 consumers each day. Any other business not included in the categories above.	

Score:

Part 2: Level of (Current) Compliance

This factor considers the level of compliance observed during the inspection. Adherence to relevant UK or EU Industry Guides to Good Practice and other similar guidance e.g. Agency, Food Advisory Committee and LACORS should be considered.

Score	Guidance on the Scoring System
40	General failure to satisfy statutory obligations. Standards generally
	low.
10	A typical business with some minor non-compliance with statutory
10	obligations.
	High standard of compliance with statutory obligations and industry
0	codes of recommended practice, conforms to relevant trade good
	practice.

Part 3: Confidence in Management/Control Systems

The actual performance of management is scored in Part 2 on the basis of the results achieved and observed. A management that achieves good food standards performance, well understood by the workforce, should achieve a good standard in Part 2, and consequently a low score for that factor.

Confidence in Management is not meant to reconsider this aspect. It is to elicit a judgement on the likelihood of satisfactory compliance being maintained in the future.

Factors that will influence the inspector's judgement include:

- The "track record" of the company, its willingness to act on previous advice • and enforcement, and the complaint history;
- The attitude of the present management towards food standards • legislation, and the existence or otherwise of relevant home or originating authority arrangements;
- Internal or external technical knowledge on food standards matters available to the company;
- The presence of quality systems, including supplier assessments and • performance monitoring, appropriate to the size of the business and the risks involved, with clearly defined responsibilities for managing risk;
- For small businesses, consider the checks appropriate to that business.

Score	Guidance on the Scoring System	
30	Little or no technical knowledge. Little or no appreciation of hazards or quality control. No food standards management system. Disproportionate number of justifiable complaints since the last inspection.	
20	Staff have a basic understanding of relevant food law. May not have a food standards management system. At least one justifiable complaint since the last inspection.	
10	Score of 10 or better in Part 2. Staff demonstrate awareness of relevant food law and necessary controls. Appropriate food standards management system. Smaller businesses may have minimal documented system. At least one justifiable complaint since the last inspection.	
0	Technical advice available. Subject to internal audit/checks. Good food standards management system, documented records of critical checks and supplier checks, which may be subject to third party audit. Evidence of compliance with documented management system with few/minor non-conformities. No justifiable complaints	

Score:

Food Standards Inspection Frequencies

Category	Points Range	Minimum Inspection Frequency	
Α	101 to 180	at least every 12 months	
В	46 to 100	at least every 24 months	
С	0 to 45	Alternative enforcement strategy or intervention every 5 years	

Establishments rated as low risk (45 or less) need not be included in the planned inspection programme but must be subject to an alternative enforcement strategy at least once in every 5 years.

ANNEX 6: Food Business Establishment / Food Premises Inspection Report

A report containing the following information must be provided to the food business operator / food business proprietor following each inspection. The information may be provided as a separate report or may be included as part of a letter from the Food Authority.

TRADING NAME AND ADDRESS OF THE BUSINESS, AND REGISTERED ADDRESS IF DIFFERENT:

NAME OF THE FOOD BUSINESS OPERATOR / FOOD BUSINESS PROPRIETOR :

TYPE OF BUSINESS:

NAME(S) OF PERSON(S) SEEN AND/OR INTERVIEWED:

DATE AND TIME OF INSPECTION:

SPECIFIC FOOD LAW UNDER WHICH INSPECTION CONDUCTED:

AREAS INSPECTED (to be specified):

DOCUMENTS AND/OR OTHER RECORDS EXAMINED (to be specified):

SAMPLES TAKEN (to be specified):

KEY POINTS DISCUSSED DURING THE INSPECTION (to be specified):

ACTION TO BE TAKEN BY THE FOOD AUTHORITY (to be specified):

SIGNED BY:

NAME IN CAPITALS:

DESIGNATION OF INSPECTING OFFICER:

CONTACT DETAILS OF INSPECTING OFFICER:

CONTACT DETAILS OF SENIOR OFFICER IN CASE OF DISPUTE:

DATE:

FOOD AUTHORITY NAME AND ADDRESS:

ANNEX 7: Model Forms for Use in Connection with the Food Hygiene (England) Regulations 2006

Model forms which may be used by authorised officers in connection with the Food Hygiene (England) Regulations 2006 are provided from A7.1 to A7.16, as summarised in the following table.

Location	Model Form	For Use In Connection With
A7.1 / A7.2	Hygiene Improvement Notice	Regulation 6
A7.3 / A7.4	Hygiene Emergency Prohibition Notice	Regulation 8
A7.5 / A7.6	Notice Of Intention To Apply For A Hygiene Emergency Prohibition Order	Regulation 8
A7.7 / A7.8	Remedial Action Notice	Regulation 9
A7.9 / A7.10	Detention Notice	Regulation 9
A7.11 / A7.12	Notice of Withdrawal of Remedial Action Notice / Detention Notice	Regulation 9
A7.13 / A7.14	Certificate That Health Risk Condition No Longer Exists	Regulation 7 and Regulation 8
A7.15 / A7.16	Notice of Determination That Health Risk Condition Remains in Existence	Regulation 7 and Regulation 8
A7.17 / 7.18	Certificate That Food Has Not Been Produced, Processed or Distributed In Compliance With The Hygiene Regulations	Regulation 27

Authority:
The Food Hygiene (England) Regulations 2006 - Regulation 6
HYGIENE IMPROVEMENT NOTICE
Reference Number:
1. To:(Food Business Operator)
At:(Address of Food Business Operator)
2. I have reasonable grounds for believing that you are failing to comply with the Hygiene Regulations because:
[Officer to insert grounds for believing that the Hygiene Regulations are being breached] in connection with your food business
(Name of Food Business)
at(Address of Food Business)
The matters which constitute your failure to comply are:
3. In my opinion, the following measure(s) are needed for you to comply with the Hygiene Regulations:
4. The measure or measures that will achieve the same effect must be taken by:
5. It is an offence not to comply with this hygiene improvement notice by the date stated.
Signed:(Authorised Officer)
Name in capitals:
Date:
Address:
Tel: Fax:
E-mail:

A7.1: Model Form 1 - Hygiene Improvement Notice

A7.2: Model Form 1 - Hygiene Improvement Notice (Reverse)

NOTES

- 1. In the opinion of the authorised officer you are not complying with the Hygiene Regulations as described in paragraph 2 of the notice. The work needed in the officer's opinion to put matters right is described and it must be finished by the date set.
- 2. You are responsible for ensuring that the work is carried out within the period specified, which must be at least 14 days from the date of the notice.
- 3. You have a right to carry out work that will achieve the same effect as that described in the notice. If you think that there is another equally effective way of complying with the law, you should first discuss it with the officer.

YOUR RIGHT OF APPEAL

- 4. In accordance with Regulation 20 of the Food Hygiene (England) Regulations 2006, if you disagree with all or part of this notice, you can appeal to the Magistrates' Court. You must appeal within one calendar month of the date of the notice or the period ending with the date stated in paragraph 4 of the notice, whichever ends earlier.
- 5. If you decide to appeal, the time set out in the notice is suspended and you do not have to carry out the work described until the appeal is heard. However, if you are not complying with the Regulations mentioned in the notice, you may still be prosecuted for failure to comply with those Regulations.
- 6. When the appeal is heard, the Magistrates' Court may confirm, cancel or vary the notice.



FAILURE TO COMPLY WITH THIS NOTICE IS AN OFFENCE

Offenders are liable to be fined and/or imprisoned for up to 2 years.

Autho	ority:
	The Food Hygiene (England) Regulations 2006 - Regulation 8
	HYGIENE EMERGENCY PROHIBITION NOTICE
Refe	rence Number:
	To:(Food Business Operator)
	At:(Address of Food Business Operator)
2.*	I am satisfied that the health risk condition is fulfilled with respect to:
	(Name of Food Business)
	At:(Address of Food Business)
	Because:
	(* See Note 1 overleaf)
	YOU MUST NOT USE IT FOR THE PURPOSES OF [THIS] [ANY] [THIS OR ANY SIMILAR]† FOOD BUSINESS.
	[† Officer to delete as appropriate]
Signe	ed:(Authorised Officer)
Name	in capitals:
Date	:
Addre	ess:
Tel:	
E-ma:	il:

A7.3: Model Form 2 - Hygiene Emergency Prohibition Notice

Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek legal advice.

A7.4: Model Form 2 - Hygiene Emergency Prohibition Notice (Reverse)

NOTES

- 1. When you receive this notice you must IMMEDIATELY stop using the premises, process, treatment or equipment described by the officer in paragraph 2 of the notice and located at the address stated.
- 2. Within 3 days of service of this notice, the authority must apply to a Magistrates' Court for an order confirming the prohibition. You will be told the date of the hearing which you are entitled to attend and at which you may call witnesses if you wish.
- 3. If you believe that you have acted to remove the health risk condition, you may apply in writing to the authority for a certificate of satisfaction which, if granted, would allow you to use the premises, process, treatment or equipment again. You can do this even if the court hearing has not taken place.
- 4. You are not allowed to use the premises, process, treatment or equipment for the purpose specified in paragraph 2 of the notice (see Regulation 7(3) of the Food Hygiene (England) Regulations 2006) as applied by Regulation 8(4)) until
 - (a) a court decides you may do so; or
 - (b) the authority issues you with a certificate as in paragraph 3 above; or
 - (c) 3 days have passed since the service of the notice and the authority has not applied to the court as in paragraph 2 above; or
 - (d) the authority abandons the application.
- 5. A copy of this notice must, by law, be fixed on the premises. It is an offence (under Section 1 of the Criminal Damage Act 1971) to deface it.
- 6. COMPENSATION: If the authority does not apply to the Magistrates' Court, for an order confirming its action within 3 days of the date of service of this notice, you will be entitled to compensation for any losses you have suffered because you could not use the premises, process, treatment or equipment because you were complying with this notice. You will also be entitled to such compensation if the Magistrates' Court, decide at the hearing that the health risk condition was not fulfilled with respect to the food business at the time when the notice was served.

WARNING WARNING
WANNING

ANYONE WHO CONTRAVENES THIS NOTICE IS GUILTY OF AN OFFENCE

Offenders are liable to be fined and/or imprisoned for up to 2 years.

A7.5: Model Form 3 - Notice of Intention to Apply For a Hygiene Emergency Prohibition Order

Autl	nority:
	The Food Hygiene (England) Regulations 2006 - Regulation 8
	NOTICE OF INTENTION TO APPLY FOR HYGIENE EMERGENCY PROHIBITION ORDER
Ref	erence Number:
1.	To:(Food Business Operator)
	At:(Address of Food Business Operator)
2.	You are the food business operator of the food business at:
3.	I give notice that I shall be applying to the Magistrates' Court sitting at
	on:(Date)* at:(Time)* [*Officer to insert if known]
	for a Hygiene Emergency Prohibition Order because:
	[Officer to state reason why the order is being sought in respect of the premises, process, treatment or equipment]
4.	If an order is made by the court you will not be able to use the [premises] [process] [treatment] [equipment]† described:
	for the purpose of [this] [any] [this or any similar] tood business.
	[† Officer to delete as appropriate]
Sig	ned:(Authorised Officer)
Name	e in capitals:
Date	2:
Add:	ress:
Tel	: Fax:
	ail:
Ple	ease read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek legal advice.

A7.6: Model Form 3 - Notice of Intention to Apply For a Hygiene Emergency Prohibition Order (Reverse)

NOTES

- 1. This notice tells you that the authority intends to apply to the Magistrates' Court for a Hygiene Emergency Prohibition Order which, if granted, would mean that you could not use the premises, process, treatment or equipment described for the purposes specified in paragraph 3 of the notice (see Regulation 7(3) of the Food Hygiene (England) Regulations 2006 as applied by Regulation 8(4)).
- 2. The court will consider the evidence from the authority as to why they believe the health risk condition is fulfilled from the operation of your food business or part of it. You may bring your own evidence and witnesses to put before the court and you may choose to be represented by a lawyer.
- 3. If the court is satisfied by the authority's evidence that the health risk condition is fulfilled, then an order will be made stating what you may not do. The order will be served on you by the authority. A copy of it must be fixed by the authority in a conspicuous position on your premises and it is an offence to deface it (Section 1 of the Criminal Damage Act 1971).
- 4. In accordance with Regulation 21 of the Food Hygiene (England) Regulations 2006, you have the right to appeal to the Crown Court against the decision of the Magistrates' Court if you think that it is wrong.
- 5. The making of an order does not mean you are guilty of an offence but the authority may seek to prosecute you for offences under the Food Hygiene (England) Regulations 2006 or associated regulations.
- 6. If you have been issued with a Hygiene Emergency Prohibition Notice from the authority, you will know what steps should be taken to remove the health risk condition.
- 7. If the court is not satisfied by the authority's evidence and an order is not issued, then you will be entitled to continue your business. If the authority has already issued you with a Hygiene Emergency Prohibition Notice and you have suffered loss because you have complied with it, then you will also be entitled to compensation from the authority.

A7.7: Model Form 4 - Remedial Action Notice

Authority:	
	The Food Hygiene (England) Regulations 2006 - Regulation 9
(Est	REMEDIAL ACTION NOTICE cablishments subject to approval under Article 4(2) of Regulation (EC) No. 853/2004)
Refe	erence Number:
1.	То:
	(Food Business Operator or a Duly Authorised Representative)
	At:
	(Address of Food Business Operator or a Duly Authorised Representative)
	Name of food business:
	Address of food business:
2.	In my opinion:
	The Hygiene Regulations are being breached*
	Inspection under the Hygiene Regulations is being hampered*
	because:
	[Officer to insert which provision(s) of the Hygiene Regulations is/are being breached and why]
	[* Officer to delete as appropriate]
3.	This notice requires you to:
	Cease use of the following rooms/areas/items of equipment*
	Observe the conditions imposed on the following process*
	Cease the following process* Reduce the rate of operation to the rate stated*
	Stop the following operation(s) completely*
	[* Officer to delete as appropriate]
4.	The action required to remedy the situation is as follows:

Signed:		(Authorised Officer)
Name in	capitals:	
Date:		
•••••		
Tel:		Fax:
E-mail:		

It is an offence under Regulation 9(7) not to comply with this notice.

Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek legal advice.

A7.8: Model Form 4 - Remedial Action Notice (Reverse)

NOTES

- 1. The authorised officer is satisfied that the requirements of the Hygiene Regulations are not being met and/or that an inspection under the Hygiene Regulations is being hampered for the reasons given.
- 2. When an authorised officer is satisfied that relevant action has been taken or any inspection by an authorised officer will not be hampered this notice will be withdrawn by means of a further notice in writing.

YOUR RIGHT OF APPEAL

- 3. In accordance with Regulation 20 of the Food Hygiene (England) Regulations 2006, you are entitled to appeal against this notice. If you want to do so, you should apply to the Magistrates' Court, within one calendar month of the date on which this notice is served on you.
- 4. This notice remains in effect even if you are appealing against the terms of this notice.



FAILURE TO COMPLY WITH THIS NOTICE IS AN OFFENCE

Offenders are liable to be fined and/or imprisonment for up to 2 years.

A7.9: Model Form 5 - Detention Notice

Authority: The Food Hygiene (England) Regulations 2006 - Regulation 9 DETENTION NOTICE (Establishments subject to approval under Article 4(2) of Regulation (EC) No. 853/2004) 1. To:.... (Food Business Operator or Duly Authorised Representative) At : (Address of Food Business Operator or Duly Authorised Representative) Name of food business:..... Address of food business:..... The following food is being detained for the purposes of examination: 2. Description: Quantity:..... Identification Marks / Health Marks: 3. This food is not to be used. 4. The food is being detained for the purposes of examination. 5. The food must not be removed from:.....(Name / address of food business where food is to remain) destruction. You may choose to voluntary surrender the food at any time.

6. You will be informed in writing as soon as the Authorised Officer is satisfied as to the result of the examination. The notice will then either be withdrawn and the food released, or the food will be seized to be dealt with by a Justice of the Peace, who may condemn the food and order its

Signed:		(Authorised Officer)
Name in	capitals:	
Date:		
Address:		
Tel:		
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Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek legal advice.

A7.10: Model Form 5 - Detention Notice (Reverse)

NOTES

- 1. The authorised officer has, by means of this notice, required the detention of the food specified for the purposes of examination.
- 2. The food must remain where it is. If it is moved it may only be moved to the place stated in paragraph 5 of this notice.
- 3. If an authorised officer is satisfied that the food need no longer be detained this notice will be withdrawn by means of a further notice in writing.
- 4. If, for some reason, you need to move the food after receiving this notice, you should contact the officer at the address given.

WARNING

WARNING

FAILURE TO COMPLY WITH THIS NOTICE IS AN OFFENCE

Offenders are liable to be fined and/or imprisonment for up to 2 years.

A7.11: Model Form 6 – Notice of Withdrawal of Remedial Action Notice / Detention Notice

Authority:

The Food Hygiene (England) Regulations 2006 -Regulation 9

NOTICE OF WITHDRAWAL OF A

REMEDIAL ACTION NOTICE / DETENTION NOTICE*

(Establishments subject to approval under Article 4(2) of Regulation (EC) No. 853/2004)

1.	To:
	(Food Business Operator or Duly Authorised Representative)
	At:
	(Address of Food Business Operator or Duly Authorised Representative)
	Name of food business:
	Address of food business:

[* Officer to delete as appropriate]

Signed: .	(Authorised Officer)
Name in o	capitals:
Date:	
Address:	
••••••	
Tel:	
E-mail: .	

Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek legal advice.

A7.12: Model Form 6 - Notice of Withdrawal of a Remedial Action Notice / Detention Notice (Reverse)

<u>NOTES</u>

- 1. The authorised officer is now satisfied that the action specified in the Remedial Action Notice has been taken and/or that the food specified in the Detention Notice need no longer be detained.
- 2. The relevant notice/notices is/are now withdrawn.

A7.13: Model Form 7 - Certificate That Health Risk Condition No Longer Exists

Authority:	
	The Food Hygiene (England) Regulations 2006 - Regulations 7 and 8
CE	RTIFICATE THAT THE HEALTH RISK CONDITION NO LONGER EXISTS
1.	To:(Food Business Operator)
	At:
	(Address of Food Business Operator)
	Name of food business
	Address of food business
2.	The enforcement authority certifies that it is satisfied that you have taken sufficient measures to secure that the health risk condition described in the:
	Hygiene Prohibition Order*
	Hygiene Emergency Prohibition Notice*
	Hygiene Emergency Prohibition Order*
	[* Officer to delete as appropriate]
	served on you on (date) is no longer fulfilled with respect to the food business.
	-
Sig	ned:(Authorised Officer)
Name	e in capitals:
Date	e:
	ress:
•••••	
Tel	: Fax:
E-ma	ail:

THIS CERTIFICATE MEANS THAT YOU MAY NOW USE THE PREMISES, PROCESS, TREATMENT OR EQUIPMENT AGAIN.

Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this certificate, you may want to seek legal advice.

A7.14: Model Form 7 - Certificate That Health Risk Condition No Longer Exists (Reverse)

NOTES

- 1. The enforcement authority is now satisfied that the health risk condition no longer exists in respect of the circumstances that caused the enforcement authority to issue you with a Hygiene Emergency Prohibition Notice or the court to impose a Hygiene Prohibition Order or Hygiene Emergency Prohibition Order.
- 2. The relevant notice or order is now lifted and you may use the premises, process, treatment or equipment again.

A7.15: Model Form 8 – Notice of Determination that Health Risk Condition Remains in Existence

Authority:		
	The Food Hygiene (England) Regulations 2006 - Regulations 7 and 8	
	NOTICE OF DETERMINATION THAT THE HEALTH RISK CONDITION REMAINS IN EXISTENCE	
1.	To:(Food Business Operator)	
	At:(Address of Food Business Operator)	
	Name of food business	
2.	The enforcement authority has determined that it is \underline{NOT} satisfied that you have taken sufficient measures to remove the health risk condition described in the:	
	Hygiene Prohibition Order*	
	Hygiene Emergency Prohibition Notice*	
	Hygiene Emergency Prohibition Order*	
	[* Officer to delete as appropriate]	
	served on you on (date) and is satisfied that the health risk condition remains fulfilledwith respect to the food business.	
3.	The enforcement authority is not satisfied because:	
-	ned:(Authorised Officer)	
Name	e in capitals:	
Date	e:	
Addı	ress:	
Tel	: Fax:	
E-ma	ail:	
	THIS NOTICE MEANS THAT YOU MAY NOT USE THE PREMISES, PROCESS, TREATMENT OR EQUIPMENT UNTIL THE ENFORCEMENT AUTHORITY NOTIFIES THAT YOU MAY DO SO.	
Ple	ease read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek legal advice.	
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A7.16: Model Form 8 - Notice of Determination that Health Risk Condition Remains in Existence (Reverse)

NOTES

- 1. The enforcement authority is not satisfied that the health risk condition no longer exists in respect of the circumstances that caused the enforcement authority to issue you with a Hygiene Emergency Prohibition Notice or the court to impose a Hygiene Prohibition Order or Hygiene Emergency Prohibition Order.
- 2. You still cannot use the premises, process, treatment or equipment in question for the purposes described in the Hygiene Emergency Prohibition Notice, Hygiene Prohibition Order or Hygiene Emergency Prohibition Order even if you are appealing against the terms of this notice.
- 3. In accordance with Regulation 20 of the Food Hygiene (England) Regulations 2006, you are entitled to appeal against the decision of the authority to refuse to issue a certificate of satisfaction under Regulation 7(6) or Regulation 8(8). If you want to do so, you should apply to the Magistrates' Court, within one calendar month of the date on which this notice is served on you.
- 4. As soon as you think that the health risk condition has been removed because of actions you have taken, you may apply in writing to the authority for a certificate of satisfaction which, if granted, would allow you to use the premises, process, treatment or equipment again. If a Hygiene Emergency Prohibition Notice has been issued, you can do this even if the court hearing has not taken place.



FAILURE TO COMPLY WITH THE ORIGINAL NOTICE OR ORDER IS AN OFFENCE

Offenders are liable to be fined and/or imprisonment for up to 2 years.

A7.17: Model Form 9 - Certificate that Food Has Not Been Produced, Processed or Distributed in Compliance with the Hygiene Regulations

Authority:		
	The Food Hygiene (England) Regulations 2006 - Regulation 27	
C	ERTIFICATE THAT FOOD HAS NOT BEEN PRODUCED, PROCESSED OR DISTRIBUTED IN COMPLIANCE WITH THE HYGIENE REGULATIONS	
1.	To:(Food Business Operator)	
	At:(Address of Food Business Operator)	
	Name of food business:	
	Address of food business:	
2.	Following an inspection, authorised officer certifies that the following food:	
	has not been produced, processed or distributed in compliance with the Hygiene Regulations, as outlined below:	
	The above food shall therefore be treated for the purposes of Section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements.	
Sigr	ned:(Authorised Officer)	
Name	e in capitals:	
Date	≥:	
Addı	ress:	
•••••		
Tel:	: Fax:	
E-ma	ail:	

Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this certificate, you may want to seek legal advice.

A7.18: Model Form 9 – Certificate that Food Has Not Been Produced, Processed or Distributed in Compliance with the Hygiene Regulations (Reverse)

NOTES

- 1. The authorised officer has certified that the food detailed has not been produced, processed, or distributed in compliance with the Hygiene Regulationsfor the reasons given.
- 2. The food shall therefore be treated for the purposes of Section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements.

ANNEX 8: Model Application Form for the Registration of a Food Business Establishment

APPLICATION FOR THE REGISTRATION OF A FOOD BUSINESS ESTABLISHMENT

(Regulation (EC) No. 852/2004 on the Hygiene of Foodstuffs, Article 6(2))

This form should be completed by food business operators in respect of new food business establishments and submitted to the relevant Food Authority 28 days before commencing food operations. On the basis of the activities carried out, certain food business establishments are required to be <u>approved</u> rather than <u>registered</u>. If you are unsure whether any aspect of your food operations would require your establishment to be approved, please contact [the Food Authority] for guidance.

1. Address of establishment (or address at which moveable establishment is kept) _____ Post code _____ 2. Name of food business ____ _____ Telephone no. ____ (trading name) 3. Full Name of food business operator _____ 4. Address of food business operator Post code Telephone no. E-mail ____ 5. Type of food activity (Please tick ALL the boxes that apply): Farm Shop Staff restaurant/canteen/kitchen Hospital/ residential home/ school Packer Food manufacturing/processing Catering Hotel/pub/guest house Importer Wholesale/cash and carry Private house used for a food business Distribution/warehousing Moveable establishment e.g. ice cream van Retailer Market stall Restaurant/café/snack bar Food Broker Market Takeaway П Seasonal Slaughterer Other (please give details): 6. If this is a new business Date you intend to open

Signature of food business operator_____

Date _____

(BLOCK CAPITALS)

ANNEX 9: Model Notice of Temporary Closure of Production Area(s) (Live Bivalve Molluscs / Shellfish)

NOTICE OF TEMPORARY CLOSURE OF PRODUCTION AREA(S)

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

Food Hygiene (England) Regulations 2006 S.I. 2006/14

Pursuant to the power conferred on it by Article 6 of, and paragraph C of Chapter II of Annex II to the above EC Regulation, being satisfied that [the results of sampling show that the health standards for molluscs are exceeded] [there may be a risk to human health]¹ –

As Competent Authority for the purposes of the above EC provision by virtue of regulation 4 of the Food Hygiene (England) Regulations 2006 S.I. 2006/14 –

[Insert authority] has temporarily closed the production area identified in the Schedule to this notice for the production of [insert list of all affected species] by food business operators until further notice.²

Signed:

Dated this [] day of [] 200[]

[Insert official position of signatory] On behalf of the [insert authority]

<u>SCHEDULE</u>

Area[s] in which the production of [insert list of all species affected] by food business operators is prohibited by reason of this order:-

- (a) [Insert area]
- (b) [Insert area]

Food business operators must not collect the affected animals from this area by any method, it is unsuitable for their production for health reasons and has been temporarily closed. For a food business operator to collect affected animals from the area that is temporarily closed amounts to the commission of a criminal offence under Regulation 17 of the Food Hygiene (England) Regulations 2006 S.I. 2006/14. On conviction a fine or imprisonment for a term of up to two years or both may be imposed.

[PRIVATE INDIVIDUALS ARE STRONGLY ADVISED NOT TO GATHER [insert description of affected animals] FOR THEIR OWN CONSUMPTION FROM THE AFFECTED PRODUCTION AREA. THERE MAY BE A RISK TO HUMAN HEALTH IN DOING SO.]

¹ Recent analysis of samples taken by [insert authority] from the affected area has shown that [insert animals] are affected by [insert problem].

² [insert authority] will continue to take samples for analysis and keep its decision to close the area under review. To check the current status of the area you may contact [insert authority] by [insert preferred method of contact, e.g. telephone no.]

ANNEX 10: Fishing Vessel Hygiene Checklist

Vessel name:	Inspecting officer:
Registration number:	
Date of inspection:	
Person seen:	

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

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

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

*n/a: not applicable

Comments: Comments:

Supplementary information

Scope

All registered vessels are obliged to comply with the basic hygiene requirements listed here. Factory vessels and freezer vessels are approved establishments and must comply with these basic requirements and also additional requirements. The definitions of factory and freezer vessels are in Regulation 853/2004, Annex I (3) and are:

'Factory vessel' means any vessel on board which fishery products undergo one or more of the following operations followed by wrapping or packaging and, if necessary, chilling or freezing: filleting, slicing, skinning, shelling, shucking, mincing or processing.

'Freezer vessel' means any vessel on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, followed by wrapping or packaging.

A. Vessel and Fish Handling Equipment

1. Other objectionable substances include galley waste, sewage, exhaust, and cleaning and disinfecting chemicals.

2. Untreated wood, rust and flaking paint should not come into contact with the catch.

3. Physical separation is necessary if there is a risk of the catch becoming contaminated. Smaller boats often do not have any crew quarters.

4. –

5. Clean water is defined in Article 2 of Regulation 852/2004 as ... water that does not contain microorganisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food. Because of possible contamination, harbour water is not clean water.

B. Handling

1. Contamination to look out for may be physical (such as nails and cigarette ends); chemical (such as diesel and cleaning chemicals) or microbiological (such as fish guts and dirt).

2. –

3. Spikes may be used for large fish, but care must be taken not to damage the flesh.

4. Where fish are gutted and/or headed on board, the operations must be carried out as soon as possible, and the fish washed thoroughly. Any water used must be potable water or clean seawater. Harbour water may be contaminated and does not qualify as clean seawater. Any removed guts must be kept away from the washed fish. Livers and roes intended for human consumption must be chilled or frozen. The enforcement officer may not be in a position to view the operations in progress – in that case the officer may wish to draw conclusions from the equipment layout and from interviews with crew members.

5. Boats that are intended to preserve fish for more than 24 hours must be equipped to preserve the fish at a temperature of melting ice. When chilling of the catch is not possible (i.e. on board certain vessels not intended to preserve the catch for more than 24 hours), the fishery products must be landed and iced as soon as possible. Fishery products kept alive must be kept at a temperature *that does not adversely affect food safety or their viability* (Regulation 853/2004, Annex III, Section VIII, Chapter I, Part I, B(1)). 6. See 5 above – there is no requirement for boats not equipped to store fish for 24 hours or longer to maintain their fish at the temperature approaching that of melting ice. Vessels that use chilled seawater (CSW) tanks for chilling and storing fish have special requirements detailed in Regulation 853/2004, Annex III, Section VIII, Chapter I, Part I, B(3): ... *tanks must incorporate devices for achieving a uniform temperature throughout the tanks. Such devices must achieve a chilling rate that ensures that the mix of fish and clean seawater reaches not more than 3°C six hours after loading and not more than 0°C after 16 hours and allow the monitoring and, where necessary, recording of temperatures.*

7. This is applicable only to vessels where ice is used.

C. Procedures

1. The health risks would primarily be through contamination as described in B1 above. Crew awareness can be assessed by interviewing staff or by the presence of health and hygiene-related signage.

2. –

- 3. –
- 4. –
- 5. –

6. Records do not need to be kept on board the vessel. Examples of records would be:

- records of temperatures in chilled seawater (CSW) storage tanks (where fishery products are stored in CSW)

- records of sulphite usage where fishery products are dipped in sulphite solution

- results of any analysis carried out that may have implications for public health.

Legislation key

A. Vessel and Fish Handling Equipment

1. Regulation 853/2004, Annex III, Section VIII, Chapter I, Part I, A(1); Regulation 853/2004, Annex III, Section VIII, Chapter I, Part II, 1; and Regulation 852/2004, Annex I, Part A, 4g

2. Regulation 853/2004, Annex III, Section VIII, Chapter I, Part I, A(2&3)

3. Regulation 853/2004, Annex III, Section VIII, Chapter I, Part I, B(2) and Part II, 2

4. Regulation 853/2004, Annex III, Section VIII, Chapter I, Part I, A(4)

5. Regulation 853/2004, Annex III, Section VIII, Chapter I, Part II, 5

B. Handling

1. Regulation 852/2004, Annex I, Part A, 2,3a&4abfg and Regulation 853/2004, Annex III, Section VIII, Chapter I, Part I, B(2)

2. Regulation 853/2004, Annex III, Section VIII, Chapter I, Part II, 2

3. Regulation 853/2004, Annex III, Section VIII, Chapter I, Part II, 3

- 4. Regulation 853/2004, Annex III, Section VIII, Chapter I, Part II, 6
- 5. Regulation 853/2004, Annex III, Section VIII, Chapter I, Part II, 4

6. Regulation 853/2004, Annex III, Section VIII, Chapter I, Part I, B(1)

7. Regulation 853/2004, Annex III, Section VIII, Chapter I, Part I, B(2)

C. Procedures

- 1. Regulation 852/2004, Annex I, Part A, 4e
- 2. Regulation 852/2004, Annex I, Part A, 4ab
- 3. Regulation 853/2004, Annex III, Section VIII, Chapter I, Part I, B(2) and Part II, 1
- 4. Regulation 852/2004, Annex I, Part A, 4f
- 5. Regulation 852/2004, Annex I, Part A, 6
- 6. Regulation 852/2004, Annex I, Part A, 7

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INTERVENTIONS TYPE

FSA Monitoring Category	Examples of Interventions actions included in category	Qualification Level required to carry out the Intervention
Inspections and audits	Inspection is defined under Article 2 of Regulation (EC) No.882/2004 as the examination of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of feed and food law and animal health and welfare rules	•
	Audit is defined under Article 2 of Regulation (EC) No.882/2004 as <i>The systematic and independent</i> <i>examination to determine whether activities</i> <i>and related results comply with planned</i> <i>arrangements and whether these</i> <i>arrangements are implemented effectively</i> <i>and are suitable to achieve objectives.</i>	
	Examples:	
	Investigation of complaints about food or a food establishment which require inspection or verification of some aspect of the food business. Food Hygiene and Food Standards inspections carried out as part of a targeted survey of Food establishments within the Local Authority area.	
Verification and surveillance	Verification is defined under Article 2 of Regulation (EC) No.882/2004 as The checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled	A appropriately qualified officer with experience in Food Law enforcement, See section 1.2.9 of the Code of Practice
	Surveillance is defined under Article 2 of Regulation (EC) No.882/2004 as The careful observation of one or more food businesses, or food business operators or their activities	A appropriately qualified officer with experience in Food Law enforcement, See section 1.2.9 of

the Code of Practice

	Examples:	
	 One-to-one follow-up inspections to verify compliance after participation of food business in a training seminar or completion of a business survey Verification visits to confirm that SFBB procedures had been implemented at an establishment Food Standards checks made with Head Offices by the Home Authority, on questions of labelling or composition. Surveillance of an establishment, e.g. checking whether the business is still trading undeclared purchase of food items for verification of compliance to food law Undeclared visits to verify for poor hygienic practices outside normal daytime working hours. 	
Sampling visits	Visits to take a formal sample are an official control where food samples are taken and analysed/examined at an accredited laboratory.	An appropriately authorised officer under Section 1.2.10 of the Code of Practice
	Examples:	
	Visits to collect samples, as part of a regional or national survey, or local survey.	
Advice and education	Visit to establishments to give advice and/or training	An appropriately authorised officer under Section 1.2.10 of the Code of Practice
	Examples:	
	Visit to establishments to give advice e.g. as part of the planning or building control application process or SFBB advice	
Information/ intelligence gathering	Information gathering visits that do not include verification. Examples:	An appropriately authorised officer under Section 1.2.10 of the Code of Practice
	I. Retail Enforcement Pilot in England II. A Premises survey	

Annex H

DRAFT

Food Law

Practice Guidance (England)

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

PREFACE

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

Food Authorities should be aware that law relating to food is not necessarily made under the Food Safety Act 1990. Law that applies to food is also contained in and/or made under, the Animal Health Act 1981, the Consumer Protection Act 1987, the Trade Descriptions Act 1968, and directly under EC Regulations.

Food Authority officers authorised under Section 5(6) of the Food Safety Act 1990 to carry out duties under that Act and Regulations made under it are not automatically authorised to deal with food law under other legislation. Separate authorisation in respect of other legislation is also required e.g. legislation made under the European Communities Act 1972, including the Food Hygiene (England) Regulations 2006¹ and the Official Feed and Food Controls (England) Regulations 2006², under which officers may be generally or specially authorised.

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

Material in the previous guidance has been reviewed and updated to take account of the Food Hygiene (England) Regulations 2006, the Official Feed and Food Controls (England) Regulations 2006 and relevant EU Regulations.

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

Food Authorities should be aware that Article 8(5) of Regulation 852/2004³ stipulates that guides to good practice drawn up pursuant to Directive 93/43/EEC (known in the UK as "Industry Guides to Good Hygiene Practice"), provided that they are compatible with its objectives.

Attention is drawn to the guidance on the scope and conduct of official checks on establishments subject to approval under Regulation 853/2004⁴.

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

¹ SI 2006 No. 14

² SI 2006 No. 15

³ Regulation (EC) No. 852/2004 on the hygiene of foodstuffs

⁴ Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin

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

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

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

SECTION 1: ADMINISTRATION

CHAPTER 1.1: INTER-AUTHORITY MATTERS

1.1.1: Introduction

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

1.1.2: Service to Consumers

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

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

CHAPTER 1.2: QUALIFICATIONS AND EXPERIENCE

1.2.1: Introduction

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

1.2.2: Pooling Expertise

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

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

CHAPTER 1.3: CONFLICTS OF INTEREST

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

CHAPTER 1.4: FOOD BUSINESS ESTABLISHMENT RECORDS

1.4.1: Introduction

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

1.4.2: Data Protection / Freedom of Information

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

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

CHAPTER 1.5: REGISTRATION OF FOOD BUSINESS ESTABLISHMENTS

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

CHAPTER 1.6: CROWN AND POLICE PREMISES

1.6.1: Introduction

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

1.6.2: Scope of Application - Food Hygiene (England) Regulations 2006

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

As there are no specific exemptions for certain members of the Royal Family or certain Royal residences as afforded by the Food Safety Act 1990 (see Paragraph 1.6.3 below), Food Authorities should use discretion when exercising their powers in respect of Crown premises. In practice, Food Authorities should adopt the same approach to the enforcement of the Food Hygiene (England) Regulations 2006 in respect of Crown premises as they do in respect of the Food Safety Act 1990.

1.6.3: Scope of Application - Food Safety Act 1990

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

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

1.6.4: Conduct and Frequency of Inspections

Food businesses in Crown and police premises, other than temporary or field catering facilities at military training camps, should be included in the Food Authority's planned inspection programme in accordance with the Code of Practice. Permanent kitchens serving military training camps should be subjected to inspection at times they are in use, within the bounds of security restrictions that will be dependent on the organisation using the facility at the time.

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

1.6.5: Enforcement - Food Hygiene (England) Regulations 2006

Unlike the Food Safety Act 1990, the Food Hygiene (England) Regulations 2006 do not exempt the Crown if it contravenes the Regulations. This means that the Crown can be prosecuted if it contravenes the Regulations. However, as mentioned in Paragraph 1.6.2 above, Food Authorities should use discretion when exercising their powers in respect of Crown premises and, in practice, should adopt the same approach to the enforcement of the Food Hygiene (England) Regulations 2006 in respect of Crown premises as they do in respect of the Food Safety Act 1990.

1.6.6: Enforcement - Food Safety Act 1990

1.6.6.1: Liability

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

A Food Authority may, however, apply, in the Queen's Bench Division of the High Court, for a declaration that any act or omission of the Crown, which amounts to a contravention of the Food Safety Act 1990 or regulations made under the Act, is unlawful.

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

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

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

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

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

1.6.6.2: Position of Individual Civil or Government Servants

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

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

1.6.6.3: Statutory Notices

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

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

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

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

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

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

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

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

CHAPTER 1.7: FOOD INCIDENTS AND HAZARDS

1.7.1: Introduction

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

1.7.2: Information Received Locally Which May Indicate a Wider Problem

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

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

The illustrations above are not intended to be comprehensive.

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

1.7.3: Guidance on Food Complaints

1.7.3.1: Notification of Food Complaints

As a general rule anybody who may be prosecuted as a result of a consumer complaint should be notified that the complaint has been made as soon as reasonably practicable. The Food Authority should normally notify anybody who has an interest as soon as preliminary investigations indicate that a complaint may be well founded. Other potential defendants should be notified as they emerge.

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

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

1.7.3.2: Involvement of Other Food Authorities

If an investigation of a complaint brings to light a problem or potential problem outside the area of the enforcing Food Authority, the other Food Authorities affected should be informed as soon as possible and, if appropriate, in accordance with the Home Authority Principle.

1.7.3.3: Scientific Investigation of Food Complaint Samples

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

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

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

SECTION 2: COMMUNICATION

CHAPTER 2.1: DISCLOSURE OF INFORMATION

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

CHAPTER 2.2: FOOD ALERTS

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

CHAPTER 2.3: AGENCY COMMUNICATIONS AND GUIDANCE

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

CHAPTER 2.4: INFORMATION TO BE SUPPLIED TO THE AGENCY

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

CHAPTER 2.5: LIAISON WITH OTHER MEMBER STATES

2.5.1: Introduction

This Chapter deals with the administration of and the approach to the European liaison arrangements that are to be operated by the Agency from 1 April 2006. Detailed provisions on administrative assistance and co-operation with other Member States are set out in Articles 34 to 38 of Regulation 882/2004⁵.

2.5.2: The Role of the Agency

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

The Agency, from 1 April 2006, is the designated liaison body for the purposes of Article 35 of Regulation 882/2004 and, as such, is responsible for assisting and co-ordinating communication between competent authorities and the transmission and reception of requests for assistance. However, this does not preclude direct contacts, exchange of information or co-operation between the staff of Food Authorities in different Member States.

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

2.5.3: The Role of Food Authorities

The "European Principle of the Home Authority" adopted by the European Forum of Food Law Enforcement Practitioners (FLEP) forms the basis for the arrangements for information exchanges involving the UK. The role of the Food Authority in the provision of administrative assistance will depend on whether they are acting as a "Home Authority", "Enforcing Authority" 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;

⁵ Regulation (EC) No. 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

 "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.

2.5.4: Enquiries from Member States

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

2.5.5: Documentation

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

2.5.6: Disclosure of Information

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

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

2.5.7: Use of Information in Criminal Proceedings

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

EU Member States are parties to The European Convention on Mutual Assistance in Criminal Matters⁶. This Convention requires that requests for

⁶ Council Act of 29 May 2000 establishing, in accordance with Article 34 of the Treaty on European Union, the Convention on Mutual Assistance in Criminal Matters between the Member States of the European Union (Official Journal C197, 12.07.2000).

information to be used as evidence in criminal proceedings be transmitted through the relevant authority.

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

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

The UK Central Authority address is:

Stuart Blackley Judicial Co-operation Unit Home Office 5th Floor, Fry Building, 2 Marsham Street, London SW1P 4DF. Tel: 020 7035 1280 Fax: 020 7035 6987 Email: <u>stuart.blackley2@homeoffice.gsi.gov.uk</u>

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

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

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

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

2.5.8: Non-compliance with Legislation

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

2.5.9: Form – Notification of Incident to the Food Standards Agency



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

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

Directed to (Member State)	Info Only* FA Ref:				
	Action Requested* Agency Ref:				
* (please tick as appropriate)					
Name and Address of Food Authority:					
Contract Officer					
Contact Officer:	Tel:				
E-mail:	Fax:				
Full product description (to include product name or brand name, identification codes):					
Full product description (to include product name or brand name, identification codes):					
Nature of complaint/request:					

Date of Notification:

Photo:	Yes	No No
--------	-----	-------

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

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

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

Is the information intended to be used for prosecution?

Yes: 🗌

No: 🗌

Maybe: (Please tick as appropriate)

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

Signed	Date sent:

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

SECTION 3: GENERAL ENFORCEMENT

CHAPTER 3.1: APPROACH TO ENFORCEMENT

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

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

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

CHAPTER 3.2: HYGIENE IMPROVEMENT NOTICES / IMPROVEMENT NOTICES

3.2.1: Introduction

This Chapter deals with the use of hygiene improvement notices under Regulation 6 of the Food Hygiene (England) Regulations 2006, and the use of improvement notices under Section 10 of the Food Safety Act 1990 in connection with food standards issues.

3.2.2: The Enforcement Approach

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

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

3.2.3: Service of Notices

The Food Hygiene (England) Regulations 2006 require a hygiene improvement notice to be served on a food business operator. Although unlikely to be used (see Paragraph 3.2.3 of the Code of Practice), the Food Safety Act 1990 requires an improvement notice to be served on the proprietor of a food business.

Hygiene improvement notices or improvement notices should normally be served in accordance with the statutory requirements.

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

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

3.2.4: Drafting of Notices

It should be clear from the hygiene improvement notice or improvement notice exactly what the recipient is required to do, and why; it should therefore be clearly drafted and easily understood. As failure to comply with the requirements of a hygiene improvement notice or improvement notice within the specified period is an offence, an officer who has decided to serve a notice should consider whether a single notice with a single time limit is appropriate.

Serving multiple notices, each with a different time limit, may be more appropriate where multiple contraventions are concerned. Separate notices with separate time limits may also be easier to handle if there is an appeal. An appeal against a single notice concerning multiple contraventions would result in the suspension of the whole notice until the appeal had been dealt with.

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

3.2.5: Time Limits

A hygiene improvement notice or improvement notice should clearly state the time limit by which the measures required by the notice must be completed. Both the Food Hygiene (England) Regulations 2006 and the Food Safety Act 1990 specify a minimum period of 14 days.

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

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

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

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

3.2.6: Extension of Time Limits

Although hygiene improvement notices and improvement notices are to be complied with by the stipulated time limit, Food Authorities should give due regard to any genuine difficulties that may occur in achieving compliance by that deadline.

There is no specific provision in the regulations to extend the time limit for compliance with a notice, but it may be unreasonable not to allow an extension

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

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

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

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

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

3.2.7: Works of Equivalent Effect

Notices should make it clear that Regulation 6 of the Food Hygiene (England) Regulations 2006 and Section 10 of the Food Safety Act 1990, as appropriate, allow a food business operator / food business proprietor to carry out measures of at least equivalent effect to those specified in a hygiene improvement notice / improvement notice and recommend that alternative measures are discussed with the officer who served the notice before starting work to avoid unnecessary expenditure or inappropriate work.

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

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

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

3.2.8: Compliance

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

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

3.2.9: Appeals

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

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

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

3.2.10: Other Discussion with the Food Authority

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

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

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

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

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

3.2.11: Other Guidance

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

CHAPTER 3.3: PROHIBITION PROCEDURES

3.3.1: Introduction

This Chapter deals first with the use of hygiene prohibition procedures and remedial action notice / detention notice procedures under Regulations 7, 8 and 9 respectively of the Food Hygiene (England) Regulations 2006 and the associated voluntary closure procedures. It then deals with the prohibition procedures of Section 11 and Section 12 of the Food Safety Act 1990, the associated voluntary closure procedures and the prohibition of persons under Section 11 of the Act, in connection with food standards issues.

3.3.2: The Food Hygiene (England) Regulations 2006

3.3.2.1: Regulation 7 - Hygiene Prohibition Procedures

A Magistrates' Court may make a hygiene prohibition order under Regulation 7 of the Food Hygiene (England) Regulations 2006 to:

- Prohibit the use of a process or treatment for the purposes of the business if the health risk condition is fulfilled;
- Prohibit the use of the premises or equipment for the purposes of the food business or any similar food business if the construction of the premises or use of any equipment fulfils the health risk condition;
- Prohibit the use of the premises or equipment for the purposes of any food business if the state or condition thereof fulfils the health risk condition.

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

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

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

3.3.2.2: Regulation 8 - Hygiene Emergency Prohibition Procedures

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

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

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

3.3.2.3: Regulation 9 - Remedial Action Notices / Detention Notices

See Chapter 3.5 of the Code of Practice.

3.3.3: The Food Safety Act 1990

3.3.3.1: Section 11 - Prohibition Procedures

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

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

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

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

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

3.3.3.2: Section 12 - Emergency Prohibition Procedures

An authorised officer may serve an emergency prohibition notice under Section 12 of the Act if there is an imminent risk of injury to health in food premises. The effect of the notice is to immediately close the premises, or prevent the use of the equipment or process.

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

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

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

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

3.3.4: "Health Risk Condition" / "(Imminent) Risk of Injury to Health"

Regulations 7 and 8 of the Food Hygiene (England) Regulations 2006 can only be used if the "health risk condition" is fulfilled. In respect of Regulation 7, there must be a risk of injury to health and in respect of Regulation 8 there must be an imminent risk of injury to health. Section 11 of the Food Safety Act 1990 can only be used if the "health risk condition" is fulfilled and Section 12 can only be used if there is an "imminent risk" of injury to health.

In respect of Regulation 8 of the Food Hygiene (England) Regulations 2006 and Section 12 of the Food Safety Act 1990, the word "imminent" qualifies the word "risk". There must always be an imminent risk of injury to health before a hygiene emergency prohibition notice or emergency prohibition notice can be served. It is the risk of injury that must be imminent. The injury itself may occur sometime in the future, but it is essential to show that it could occur for the action to succeed. Not everyone exposed to the risk of injury will actually suffer the injury. It is the exposure to the risk of injury that enables action to be taken.

3.3.5: Food Hygiene (England) Regulations 2006

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

Foods containing potentially harmful levels of pathogenic micro-organisms represent an imminent risk and should be seized or detained under Regulation 27 of the Food Hygiene (England) Regulations 2006 by using Section 9 of the Food Safety Act 1990 (see also Regulation 23 of FHER 2003 in this regard). However, the process or treatment which exposed the food to this microbiological contamination should be dealt with under Regulation 8 of the Food Hygiene (England) Regulations 2006 where appropriate.

3.3.6: Food Safety Act 1990

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

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

Foods containing potentially damaging levels of such chemicals represent an imminent risk and should be seized or detained under Section 9 of the Food

Safety Act 1990. However, the process or treatment which exposed the food to this chemical contamination should be dealt with under Section 12 of the Food Safety Act 1990.

3.3.7: Criteria for Action

3.3.7.1: Hygiene Prohibition Procedures / Prohibition Procedures

The criteria for action depend on the conditions in Regulation 7(2) of the Food Hygiene (England) Regulations 2006 and Section 11(2) of the Food Safety Act 1990 being met, i.e. that either the construction or condition of the premises, or any equipment or the use of any process or treatment involves a risk of injury to health.

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

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

3.3.7.2: Hygiene Emergency Prohibition Procedures / Emergency Prohibition Procedures

In the case of Regulation 8(2) of the Food Hygiene (England) Regulations 2006 and Section 12(2) of the Food Safety Act 1990, the application is made by the Food Authority and hence it bears the burden of proof. The necessary evidential requirements are respectively set out in Regulation 7(2) and 7(4) and Regulation 8(1) and 8(4) of the Food Hygiene (England) Regulations 2006, and Section 11(2) and 11(4) and Section 12(1) and (4) of the Food Safety Act 1990.

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

Further guidance can be found in Paragraph 3.3.9.

3.3.8: Seeking Additional Advice

Authorised officers should seek expert medical or other advice if a process or treatment is producing food that appears to contain chemicals or other substances that may pose an imminent risk of injury to health, or where the process or treatment in question itself requires other specialist knowledge or expertise⁷.

An authorised officer exercising a right of entry under Regulation 14 of the Food Hygiene (England) Regulations 2006 or Section 32 of the Food Safety

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

Act 1990 may be accompanied by anybody else who is necessary, including an expert or experts.

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

3.3.9: Deferring Immediate Action

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

The condition of retail food premises, for example, that would normally pose an imminent risk, would not necessarily warrant immediate closure if the condition was only discovered at the end of trading hours.

In such a case, the authorised officer might decide not to impose an emergency prohibition if, for example, the food business operator / food business proprietor undertook to get a team of contract cleaners to improve the position during the night.

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

3.3.10: Serving the Notice or Order

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

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

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

3.3.11: Methods of Serving the Notice or Order

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

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

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

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

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

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

Immediately the document has been legally served by one of the methods mentioned in Regulation 28 of the Food Hygiene (England) Regulations 2006 or Section 50 of the Food Safety Act 1990, the prohibition on the use of the premises, or equipment for the purposes of any food business, or a particular type of food business, or prohibition on a process or treatment, becomes effective under the order and the hygiene emergency prohibition notice or emergency prohibition notice ceases to have effect.

3.3.12: Evidence Required

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

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

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

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

3.3.13: Hygiene Prohibition Orders / Prohibition Orders

During an inspection of premises prior to a Court hearing for an offence under the Food Hygiene (England) Regulations 2006 or the Food Safety Act 1990, the authorised officer may discover that the matter(s) giving rise to the prosecution has either not been removed or has been removed but has recurred.

If the food business operator / food business proprietor is convicted, the Court's attention may be brought to the provisions of Regulation 7(1) of the Food Hygiene (England) Regulations 2006 or Section 11(1) of the Food Safety Act 1990 in order that the Court may consider making a hygiene prohibition order or prohibition order on the premises, process or equipment, thus ensuring that the risk of injury to health is removed.

3.3.14: Prohibition of a Person

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

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

3.3.15: Application to the Court

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

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

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

3.3.16: Action to be Taken Prior to the Hearing

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

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

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

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

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

If the authorised officer is considering bringing the attention of the Court to Regulation 7 of the Food Hygiene (England) Regulations 2006 or Section 11 of the Food Safety Act so that a hygiene prohibition order or prohibition order against a food business operator / food business proprietor is to be considered, it is important that suitable evidence is gathered to produce to the Court.

It is important that the authorised officers brief their legal advisers fully on the public health aspect of the case in hand, including the public health basis for the legal requirements which have been breached, so that they can, in turn, impress upon the Court the seriousness of the charges.

3.3.17: Information to be Given to the Court

Information that the Court may require includes:

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

It is usual practice for those prosecuting to ascertain whether there have been any previous convictions or cautions and to obtain details for presentation to the Court in the event of the prosecution being successful. They may also be used in evidence if the requirements of Section 101 of the Criminal Justice Act 2003 are met. Information on a trader's previous record may be held in the Office of Fair Trading's (OFT) Central Register of Convictions⁸, particularly if the trader operates from multiple sites in different Food Authority areas. Food Authorities are encouraged to use the register to discover relevant history when considering a prosecution or formal caution, and to notify the OFT of successful prosecutions and formal cautions so that they may be included in the Register.

3.3.18: Affixing the Notice or Order on the Premises

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

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

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

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

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

3.3.19: Unauthorised Removal or Defacement of Notices or Orders

Neither the Food Hygiene (England) Regulations 2006 nor the Food Safety Act 1990 make any reference to defacing or removing a hygiene prohibition order, a hygiene emergency prohibition notice or order, a prohibition order, or an emergency prohibition notice or order. This is, however, covered by other legislation.

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

An emergency prohibition notice is the property of the Food Authority. If the authorised officer discovers that a notice has been removed or defaced, he

⁸ The Office of Fair Trading, Central Register of Convictions, Craven House, 40 Uxbridge Road, Ealing, London, W5 2BS.

should replace the notice as soon as possible and consider starting proceedings for criminal damage.

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

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

3.3.20: Lifting the Notice or Order

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

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

If the Food Authority is of the opinion that the health risk condition has been removed, arrangements should be made for the certificate under Regulation 7(7) or 8(8) of the Food Hygiene (England) Regulations 2006, or Section 11(6) or 12(8) of the Food Safety Act 1990 as appropriate to be issued as quickly as possible, and in any case within 3 days. The certificate may be sent by fax, although the proprietor may also be informed of the decision verbally, thus allowing the premises to re-open immediately.

If the authorised officer is of the opinion that the health risk condition has not been removed, arrangements should be made under Regulation 7(7)(b) or 8(9)(b) of the Food Hygiene (England) Regulations 2006, or Section 11(7)(b) or Section 12(9)(b) of the Food Safety Act 1990 as appropriate for the Food Authority to issue a notification of continuing risk to health as quickly as possible. The Food Authority must give reasons why it is not satisfied that the health risk condition has been removed.

Although a certificate lifting an hygiene emergency prohibition notice or emergency prohibition notice may be issued before the application for an hygiene emergency prohibition order or emergency prohibition order can be heard, the operator / proprietor may still be prosecuted for the offence(s) against the Food Hygiene (England) Regulations 2006 or the Food Safety Act 1990 as appropriate.

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

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

3.3.21: Breach of a Notice or Order

A person who knowingly contravenes a hygiene prohibition order or a prohibition order is guilty of an offence under Regulation 7(5) of the Food Hygiene (England) Regulations 2006 or Section 11(5) of the Food Safety Act 1990, respectively. A person who knowingly contravenes a hygiene emergency prohibition notice or order or an emergency prohibition notice or order is guilty of an offence under Regulation 8(5) or (6) of the Food Hygiene (England) Regulations 2006 or Section 12(5) or (6) of the Food Safety Act 1990, respectively.

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

If the authorised officer believes that there is sufficient evidence to show that the proprietor is unlikely to respond to a summons, application should be made for a warrant rather than a summons. The Court will decide if the circumstances justify this action and may ask the authorised officer for their view as to whether to endorse the warrant with bail. The authorised officer should use their professional judgement and take into account all relevant circumstances in their decision.

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

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

Regulation 20(1)(b) of the Food Hygiene (England) Regulations 2006 and Section 37 of the Food Safety Act 1990 allow anybody who is aggrieved by a decision of a Food Authority to refuse to issue a certificate that there is no longer a risk to health to appeal by way of a complaint to the Magistrates' Court. The time limit for such an appeal is one month from the date when the Food Authority served the notice of their refusal to lift the prohibition.

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

3.3.23: Compensation

Regulation 8(10) of the Food Hygiene (England) Regulations 2006 and Section 12(10) of the Food Safety Act 1990 provide for the Food Authority to compensate the food business operator / food business proprietor for losses arising from the service of a hygiene emergency prohibition notice or emergency prohibition notice if a hygiene emergency prohibition order or emergency prohibition order as appropriate is not applied for or is not made by from the Court 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 spoilt food;
- Loss of goodwill;
- Loss of wages;
- How much of the damage to trade is repairable;
- Obligation of the operator / proprietor to mitigate their own loss;

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

CHAPTER 3.4: SEIZURE AND DETENTION

3.4.1: Introduction

This Chapter concerns the use of the detention and seizure powers under Regulation 27 of the Food Hygiene (England) Regulations 2006 and / or Section 9 of the Food Safety Act 1990, as amended.

3.4.2: General

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

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

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

3.4.3: When to Use Detention and Seizure Powers

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

Under Regulation 27 of the Food Hygiene (England) Regulations 2006, an authorised officer of a Food Authority may, on an inspection of any food, certify that it has not been produced, processed or distributed in compliance with the Hygiene Regulations as defined in Regulation 2. A model certificate for this purpose can be found in Annex 7 of the Code of Practice. The food must then be treated for the purposes of Section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements. Food Authorities must continue to use the forms set out in the Detention of Food (Prescribed Forms) Regulations 1990⁹ when using powers under Section 9 of the Food Safety Act 1990 following the issue of a certificate as mentioned above.

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

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

⁹ SI 1990 No. 2614

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

The following legislation, as at February 2006, gives powers of seizure and detention to County Council Food Authorities:

- The Tryptophan in Food Regulations 1990¹⁰
- The Food (Control of Irradiation) Regulations 1990¹¹
- The Miscellaneous Food Additives Regulations 1995¹²
- The Colours in Food Regulations 1995¹³
- The Sweeteners in Food Regulations 1995¹⁴
- The Kava-kava in Food (England) Regulations 2002¹⁵
- The Food (Jelly Confectionery) (Emergency Control) (England) Regulations 2002¹⁶
- The Contaminants in Food (England) Regulations 2007¹⁷
- The Genetically Modified Food (England) Regulations 2004¹⁸
- The Food (Chilli, Chilli Products, Curcuma and Palm Oil) (Emergency Control) (England) Regulations 2005¹⁹

3.4.5: Detention of Food

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

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

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

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

The decision to detain a whole batch, lot, or consignment needs careful consideration before a notice is served (see paragraph 3.4.9).

3.4.6: Seizure of Food

The officer may be required to prove that the food produced before the Justice of the Peace is the food that was seized. The food should only be left if the

¹⁰ SI 1990 No. 1728

¹¹ as amended, SI 1990 No. 2490

¹² as amended, SI 1995 No. 3187

¹³ as amended, SI 1995 No.3124

¹⁴ as amended SI 1995 No. 3123

¹⁵ as amended SI 2002 No. 3169

¹⁶ as amended SI 2002 No. 931

¹⁷ as amended, SI 2004 No.3062

¹⁸ SI 2004 No. 2335

¹⁹ SI 2005 No. 1442

officer is confident that it will not be moved, used for human consumption, or the evidence destroyed.

3.4.7: Food Condemnation Warning

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

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

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

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

3.4.8: Taking Action Without Inspecting

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

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

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

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

3.4.9: Dealing With Batches, Lots or Consignments of Food

Article 14(2) of Regulation 178/2002²⁰ defines unsafe food and is relevant to both the Food Hygiene (England) Regulations 2006 and the Food Safety Act 1990. General Roof Regulation 2004, deals with food that fails to comply with food safety requirements, if it is unsafe within the meaning of Article 14(2) of Regulation 178/2002.

²⁰ Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

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

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

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

3.4.10: Voluntary Procedures

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

The fact that food had been condemned by a 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: REMEDIAL ACTION NOTICES / DETENTION NOTICES

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

CHAPTER 3.6: TEMPERATURE CONTROL PROVISIONS

3.6.1: Introduction

This Chapter provides guidance on the enforcement of Regulation 30 / Schedule 4 of the Food Hygiene (England) Regulations 2006. In respect of circumstances to which this regulation is not applicable and where food is required to be kept under temperature control for safety reasons, the general requirements of Annex II which include Chapter I, Paragraph 2 (d), Chapter III Paragraph 2(g), Chapter IV Paragraph 7, Chapter V Paragraph (2) and Chapter IX Paragraphs (2), (5), (6) and (7), of Regulation 852/2004 would apply, as appropriate or any specific temperature control requirements in Regulation 853/2004.

3.6.2: General Approach to Temperature Checks

Stage 1 - Air Temperature Monitoring

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

Stage 2 – Between-pack Testing

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

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

Not all packs or packaging materials are suitable for between-pack testing. Irregularly shaped packs where good thermal contact is not possible, packaging materials that act as an insulator and products in cartons or bubble packs where large air spaces exist are all examples where a between-pack temperature measurement may not be sufficiently accurate to give an indication of product temperature. In such instances it may be necessary to proceed directly to a destructive temperature measurement. Stage 3 - Product Testing (Destructive) If a "stage 2" temperature measurement has not been possible, or there is reasonable doubt after a "stage 2" test about compliance with temperature requirements, it will be necessary to progress to destructive testing.

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

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

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

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

3.6.3: Taking Temperature Measurements

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

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

3.6.4: Tolerances

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

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

3.6.5: Checking and Calibration of Enforcement Measuring Thermometers etc

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

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

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

3.6.6: Pre-cooling of Instruments

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

3.6.7: Preparation of Samples for Temperature Measurement

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

3.6.8: Measurement of Product Temperature

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

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

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

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

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

3.6.9: Equipment Used for Chilled Product Temperature Measurement

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

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

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

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

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

CHAPTER 3.7: QUICK FROZEN FOODSTUFFS

3.7.1: Introduction

This guidance gives informal, non-statutory advice to Food Authorities on checking temperatures and temperature monitoring systems when enforcing the Quick-frozen Foodstuffs Regulations 1990^{21} , as amended, (the Regulations) which implement Directives $89/108/\text{EEC}^{22}$, $92/1/\text{EEC}^{23}$ and $92/2/\text{EEC}^{24}$ in Great Britain.

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

3.7.2: Legislative Changes

Commission Directive 92/1/EEC has been repealed and replaced by the directly applicable Commission Regulation 37/2005²⁵. Necessary amendments to the Quick-Frozen Foodstuffs Regulations 1990 are still under consideration. Once these have been decided, consequent amendments to this chapter will be necessary.

There are three main points of difference between Directive 92/1/EEC and Regulation 37/2005. First, in the case of transport there is no longer a requirement for competent authorities to approve the temperature measuring instruments used. Also, from 1 January 2006 all measuring instruments, used in transport, warehousing, or storage of quick-frozen foodstuffs must comply with the relevant CEN standards²⁶. Finally, from 1 January 2006, the legislation will apply to rail transport for the first time.

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

3.7.3: Division of Enforcement Responsibility Between County and District Councils

²¹ As amended, SI 1990 No. 2615

²² Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption

²³ Commission Directive 92/1/EEC of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption

²⁴ Commission Directive 92/2/EEC of 13 January 1992 laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption

²⁵ Commission Regulation (EC) No 37/2005 of 12 January 2005 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption

²⁶ European Committee for Standardization, www.cenorm.be

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

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

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

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

The division of enforcement responsibilities between Food Authorities is set out in Paragraph 3.7.3 of the Code of Practice.

3.7.4: Temperature Requirements

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

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

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

3.7.5: Staged Approach to Enforcement

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

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

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

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

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

3.7.6: Air Temperature Checks

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

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

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

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

3.7.6.1: Air Temperature Checks: Cold Stores

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

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

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

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

3.7.6.2: Air Temperature Checks: Transport

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

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

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

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

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

3.7.6.3: Air Temperature Checks: Retail Display Cabinets

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

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

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

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

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

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

3.7.7: Non-destructive Temperature Checks

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

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

Not all packs or packaging materials are suitable for this type of measurement. Irregularly shaped packs where good thermal contact is not possible, packaging materials that act as an insulator and products in cartons or bubble packs where large air spaces exist are all examples where a non-destructive between-pack temperature measurement may not be sufficiently accurate to be indicative of product temperature. If the packaging of the food is not suitable for this type of measurement it may be necessary to proceed directly to a destructive temperature measurement. When performing non-destructive between-pack temperature checks it is important to ensure good thermal contact between the product packaging and the probe. A total tolerance of +2.8°C (0.8°C for instrument accuracy, and 2°C for the limitation of the methodology) should be allowed.

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

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

3.7.8: Destructive Temperature Measurement

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

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

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

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

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

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

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

3.7.9: Sampling

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

3.7.9.1: Sampling: Cold Stores

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

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

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

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

3.7.9.2: Sampling: Transport

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

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

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

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

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

"Choose four samples from amongst the following critical points:

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

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

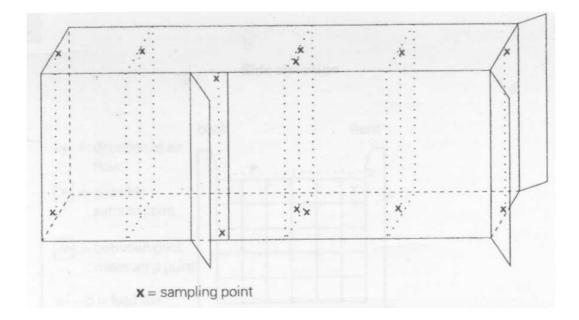


Figure 1. Sampling points for vehicles with more than one set of doors

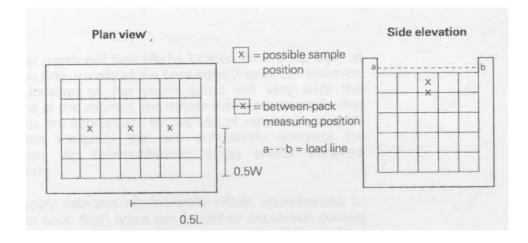
3.7.9.3: Sampling: Retail Display Cabinets

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

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

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

External parameters such as draughts and lighting can also affect the temperature distribution within a cabinet. In horizontal cabinets the warmest packs will generally be located at the surface where they are exposed to radiant heat from the surroundings. Of these, packs furthest away from the cold walls of a contact cooling cabinet, normally down the centre, will have the warmest temperature (Figure 2). This will also be the case in combination cabinets. In forced-air circulation cabinets the warmest packs will typically be located on the top layer at the air return side, usually at the front edge (Figure 3). However, since the location of the warm spots will vary with the performance of the cabinet, the officer may wish to verify that the positions are appropriate by the use of rapid temperature measurement methods that are sufficiently accurate for



this purpose, e.g. thermochromic strips and/or an infra-red thermometer.

Figure 2. Horizontal cabinet – contact cooling

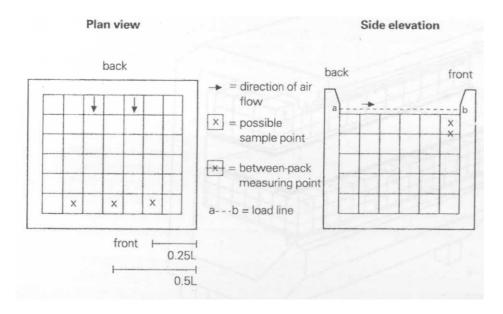


Figure 3. Horizontal cabinet – forced air circulation

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

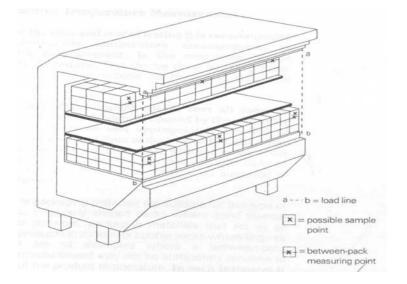


Figure 4. Open vertical cabinet

Side elevation		
AIRON'	x = possible sample point	
······	= between-pack measuring point	
		196 196 197

Figure 5. Vertical glass-fronted cabinet

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

3.7.10: Procedure for Product Temperature Measurement

(i) Pre-cooling of instruments

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

(ii) Preparation of samples for temperature measurement

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

(iii) Measurement of product temperature

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

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

(b) Where (a) is not possible the probe should be inserted to a minimum depth from the surface of at least 3 times the diameter of the probe. With some products, because of their small size, greater care has to be taken to avoid

excessive rises in product temperature from unnecessary handling of the sample.

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

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

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

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

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

3.7.12: General Specification for Temperature Measuring Instruments

Officers should check the accuracy of their temperature measuring instruments either prior to, or as soon as practicable after, any formal action. Officers should refer to Paragraph 3.6.5 of this guidance, and adapt the methodology to the range -20° C to $+30^{\circ}$ C.

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

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

(a) The response time should achieve 90% of the difference between the initial and final reading within three minutes;

(b) The instrument (readout and probe) must have an accuracy of $+0.5^{\circ}$ C within the measurement range -20° C to $+30^{\circ}$ C;

(c) The measuring accuracy must not be changed by more than 0.3°C during operation in the ambient temperature range -20°C to +30°C;

(d) The display resolution of the instrument should be 0.1°C;

(e) The accuracy of the instrument (readout and probe) should be checked at regular intervals;

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(f) The instrument (readout and probe) should have a current certificate of calibration;

(g) The temperature probe can be easily cleaned / disinfected;

(h) The temperature-sensitive part of the measuring device must be so designed as to ensure good thermal contact with the product;

(i) The electrical equipment must be protected against undesirable effects due to the condensation of moisture.

CHAPTER 3.8: FOOD WASTE

3.8.1: Introduction

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

The legislative framework that controls the identification, categorisation, segregation, collection and disposal of food waste includes regulations and orders that are made under both the Food Safety Act 1990 and the Animal Health Act 1981and (EC) regulation 852/2004

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

3.8.2: Inspection of Food Businesses

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

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

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

3.8.3: Major Investigations

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

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

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

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

CHAPTER 3.8: DISTANCE SELLING/MAIL ORDER

3.8.1: Introduction

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

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

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

3.8.2: Location of the Seller

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

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

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

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

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

3.8.3: Location of the Buyer

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

3.8.4: Distance Selling of Food from the UK

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

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

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

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

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

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

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

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

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

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

Food Authorities should generally use the liaison role of the Agency (See Chapter 2.5 of both the Code of Practice and of this Guidance) to resolve problems relating to the distance selling of food from the EU.

3.8.6: Distance Selling of Food from Third Countries

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

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

3.8.7: Generic Distance Selling Legislation

Generic law regulating distance selling in the UK is set out in the Consumer Protection (Distance Selling) Regulations 2000²⁷, 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 Business Enterprise and Regulatory Reform (BERR). Enforcement is the responsibility of the Office of Fair Trading (OFT) and Trading Standards Departments.

BERR, 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 <u>www.lacors.gov.uk</u> or via links from the LACORS website to the relevant DTI or OFT web addresses. If any further advice is required, officers should contact the Contract Regulation Unit at OFT.

3.8.8: Other References

A Guide to Good Practice for the mail order food industry, developed in accordance with Article 8 of Regulation 852/2004, is scheduled for publication in 2006.

²⁷ SI 2000 No. 2334

CHAPTER 3.9: BOTTLED WATERS

3.9.1: Introduction

This Chapter provides guidance to Food Authorities on enforcement of the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999²⁸, as amended (the Regulations).

3.9.2: Legislation

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

The Regulations were amended by The Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) (England) Regulations 2003²⁹ which implement, in relation to spring water and bottled drinking water, Council Directive 98/83/EC relating to the quality of water intended for human consumption.

A further amendment, The Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) (England) Regulations 2004³⁰ came into force on 5th April 2004 and implement Commission Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters.

3.9.3: Natural Mineral Waters

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

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

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

A list of recognised UK sources is available on the Agency's website at

http://www.food.gov.uk/foodindustry/mineralwaters

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

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

²⁸ SI 1999 No. 1540

²⁹ SI 2003 No. 666

³⁰ SI 2004 No. 656

3.9.4: Recognition of Natural Mineral Waters

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

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

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

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

3.9.5: Labelling of Natural Mineral Waters

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

3.9.6: Spring and Other Bottled Drinking Water

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

Spring water is normally extracted from a private water supply and is, therefore, also subject to the requirements of the Private Water Supplies Regulations 1991³¹, which specify the frequency of local authority monitoring of a range of compositional and microbiological parameters.

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

3.9.7: Labelling of Spring and Other Bottled Water

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

³¹ SI 1991 No. 2790

Bottled drinking waters are subject to the general labelling requirements of the Food Labelling Regulations 1996³².

³² as amended, SI 1996 No. 1499

CHAPTER 3.10: MICROBIOLOGICAL CRITERIA REGULATION

3.10.1: Agency Guidance for Food Business Operators

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

http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygienel eg/microbiolreg

Contact:

Joanna Higgins, Campylobacter Strategy, Microcriteria, Research & Zoonoses Branch, Microbiological Safety Division, Food Standards Agency, Room 816c, Aviation House, 125 Kingsway, London, WC2B 6NH.

Phone: 020 7276 8960 Fax: 020 7276 8907 Email: <u>micro.criteria@foodstandards.gsi.gov.uk</u>

3.10.2: Further Development of the Agency Guidance

The primary aim of the above guidance is to help UK food business operators understand the requirements of new European legislation. The consultation held between November and December 2005 resulted in a number of requests for further detailed advice in areas, such as, enforcement, primary production, small businesses and training

3.10.3: Other Guidance

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

CHAPTER 3.11: IMPORT OF FOOD FROM THIRD COUNTRIES

See Annex 14 of this Guidance.

SECTION 4: Interventions and Alternative Enforcement Strategies

CHAPTER 4.1: Interventions

4.1.1: Intervention Types

Interventions are activities which are designed to monitor, support and increase Food Law compliance with a food establishment. Details of all official controls are collected by the Agency to satisfy the reporting requirements of EU regulation 882/2004. The figures will also be reported to the Food Standards Agency Board.

During the undertaking of an intervention at a food establishment the qualified officer is also expected to deliver the required advice and education that will help the business operator maintain or improve their compliance with Food Law.

Inspections and Audit

Inspections are the examination of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of feed and food law and animal health and animal welfare rules.(Article 2, EU regulation 882/2004)

Audits are the systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives. .(Article 2, EU regulation 882/2004)

There are a number of circumstances that require inspection of the food establishments. These would include:

- When a new food business begins trading.
- A programmed inspection is due.
- Where a establishment has not previously been risk rated
- When new information becomes available indicating an inspection is required

When carrying out inspections local authorities have discretion to cover only certain parts of the inspection form. Circumstances that may warrant a partial inspection of the food establishments may include, (see 4.2 of the code of practice)

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

• Partial inspection as part of a published food rating system or food award scheme.

Verification and Surveillance

Verification is the checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled. (Article 2, EU regulation 882/2004)

Surveillance is the careful observation of one or more food businesses, or food business operators or their activities. (Article 2, EU regulation 882/2004)

There are a number of circumstances that require verification or surveillance of the food establishments. These would include:

- Investigation at a food establishment in response to a food poisoning incident where it is necessary to verify key aspects of the food business operation.
- Verification visit as part of a food incident/alert.
- Surveillance to check compliance with the law.
- Revisit to food establishments to verify compliance
- Information gathering visits if they include verification of information collected on site by an appropriately qualified officer with experience in Food Law enforcement. (See section 1.2.9 of the Code of Practice)

Sampling

Visits to take a sample are an official control where food samples are taken and analysed/examined at an official laboratory.

Samples may also be taken as part of:

- A national or regional sampling programme, whether organised through LACORS, Health Protection Agency the Agency or by a group of LAs.
- The investigation of a complaint or a food incident.

Education and advisory work at the premises

Providing education, advice and training to businesses can be a key part of a local authority's strategy to change behaviour and increase compliance in food businesses and should be undertaken wherever possible.

Information and Intelligence Gathering visits

These are visits to confirm key information relating to the food establishment. They may be carried out under a scheme of information sharing between different regulatory agencies e.g. Retail Enforcement Pilot. The information or intelligence gathered must be reviewed by an appropriately qualified officer (see section 1.2.9), who will assess whether further action is appropriate. A sample which is not sent for analysis/examination to an official laboratory, but which does provide information on some aspect of the food business may be recorded as an intervention under this category.

CHAPTER 4.1.2 Alternative Enforcement Strategies

Alternative Enforcement Strategies are methods by which low risk (hygiene category E and standards category C) establishments are monitored to ensure their continued compliance with Food Law. Alternative Enforcement Strategies typically use questionnaires, with a sample of businesses receiving a follow up visit to verify the information provided. They are often used as part of an educational campaign which might also include provision of information and training seminars as part of the Alternative Enforcement Strategy.

Currently the Agency has commissioned research into the effectiveness of Alternative Enforcement Strategies and the production of guidance on how to evaluate their effectiveness.

Alternative Enforcement Strategies are suitable for low risk food establishments. Visits to check the information supplied, by an appropriately qualified officer, can be recorded as a verification visit.

Chapter 4.1.3 Other activities

Education and advisory work away from the premises

Educational and advisory work can also be delivered away from the food establishments, e.g. through a business forum or seminar, targeted at specific types of food businesses or around specific food safety topics. Local authorities should have a strategy for delivering education and advice which should be risk based. All training or education initiatives should be properly evaluated by the local authority to assess if the resources invested in training and education increase compliance in food businesses. Local authorities may target a specific group of food businesses with information and training prior to implementing an inspection regime. Details of such education and advisory work should be recorded in the free text box of the monitoring form.

Best Practice and Research

The Agency wants to encourage contributions from local authorities in the design and delivery of interventions. Where an intervention is thought, by the Food Authority or by the Agency, to have the potential to drive up compliance within food businesses, the Agency will work with the local authority in commissioning research, assisting in evaluating different intervention policies to see whether they have potential to be applied nationally. It is anticipated that the interventions policy will evolve over time, as new ideas emerge and

are tested in the field. The Agency will continue to carry out research which will aid local authorities in identifying and developing intervention strategies. Research projects currently include food awards, scores on the doors, and interventions in low risk food establishments (currently alternative enforcement strategies). We will also work with local authorities to provide further guidance on evaluating small scale projects.

CHAPTER 4.2: MATTERS RELATING TO INSPECTION

4.2.1: Introduction

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

4.2.2: Notice of Inspection

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

There will, however, be circumstances when it is advantageous to give advance notice, particularly when the purpose of inspection is to see a particular process in operation. Authorised officers should exercise discretion in this area guided by the overriding aim of ensuring compliance with food legislation (see also Paragraph 1.6.4 of the Code of Practice on obtaining entry to Crown Premises).

4.2.3: Co-ordination of Inspections

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

Wherever it is practicable and appropriate to do so, Food Authorities should co-ordinate inspections of food premises. The inspection team should include all the expertise necessary to inspect the premises in question and where appropriate further experts in particular fields of food technology³³.

4.2.4: Shellfish Identification Marks

As part of the monitoring of the use of shellfish identification marks, Food Authorities should, from time to time, select a batch or consignment from a retail outlet or restaurant and seek to trace the batch or consignment back through a dispatch centre, and any purification centre, to the original gatherers

³³ The Institute of Food Science and Technology maintains a list of experts in particular fields.

to establish that records relating to the batch and the identification mark are in order. Food Authorities should co-operate with other Food Authorities in any random check through the production and distribution chain.

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

CHAPTER 4.3: Matters Relating to Primary Production Assurance Schemes

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

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

Copies of the evaluations are on the FSA website at

http://www.food.gov.uk/foodindustry/hygiene/primprodganda/

CHAPTER 4.4: INSPECTION OF SHIPS AND AIRCRAFT

4.4.1: Introduction

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

4.4.2: General

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

Examples include:

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

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

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

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

During any inspection of a ship or an aircraft, authorised officers must be aware of their own health and safety and have regard to any requirements of the port authority and the shipping operator or airline. In many cases it would not be necessary to inspect aircraft on a regular basis, if sufficient information has been obtained from the airline and/or relevant Home Authority (HA) and has been verified.

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

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

4.4.3: Catering Waste

The disposal of international catering waste to landfill is regulated by the Products of Animal Origin (Third Country Imports) (No. 4) Regulations 2004³⁴. DEFRA has identified significant risks to animal health if this waste is not dealt with effectively at landfill. Specific measures are needed to ensure that disease is not introduced into the UK from landfill sites, which receive this waste. A mechanism for suspending or amending the conditions of a landfill site approved to deal with such waste is in place, in the event that the conditions of approval are not observed.

4.4.4: Other Issues: Aircraft

Airlines should be encouraged to adopt, where necessary, approved codes of practice, for example, the IFCA³⁵/IFSA World Food Safety Guidelines, and to develop in-house supplier audits and aircraft audits and to make any reports available to the authorised officer.

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

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

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

Inspections of aircraft may be undertaken at the maintenance base, taking account of any documentation on, for example, food supply specifications,

³⁴ SI 2004 No. 3388

³⁵ The International Flight Caterers' Association (IFCA) became The International Travel Catering Association (ITCA) in 2005

cabin crew training and food temperature control, that is supplied by the airline or HA.

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

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

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

4.4.5: Other Issues - Ships

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

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

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

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

Examples of relevant documentation:

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

4.4.6: Other References

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

Inspection Template: Aircraft - Food Safety Inspection Report Form

Food Authority:		Airpor	t:		
Name of Authorised Officer:		Desigi	nation:	Tel. No:	
Date of Inspection:		Time o	of Inspection	Flight No:	
Airline Company or Airline opera	ating th	e aircra	aft:		
Address:		Airline	Tel. No:		
Airline Person interviewed/Desig	gnation	:			
Aircraft Reg. No:	Aircra	ft type:	ł	Home Authority:	
 Date of previous inspection: (if known) 			2.Return cater	ed: Yes/No	
3. High risk foods served:	Yes/N	0	4. HACCP-bat $(\sqrt{\text{tick box if s}})$	ised procedures atisfactory)	
5. Training/Exclusion procedur	re 🗌		6. Pest contro	bl	
7. Time/Temp control (outbour	nd)		8. Temp cont	rol (return catering)	
9. Cooking/Reheating			10. Galley hy	giene/storage areas	
11. Cleaning/Waste control			12. Toilets		
13. Potable Water supply			14. Airline san	npling (food/water)	
Note: details of items 1 to 6 and Authority) prior to attending an a		14 shou	uld be obtained	from the airline (or F	lome
Comments (including any samples procured)					

Summary of Action taken to be taken by Food Authority ($\sqrt{1}$ tick box(es))						
Satisfactory Outcome		Follow-up With Airline HQ/HA				
Prosecution		Emergency Prohibition Notice		Formal		

Detention/Seizure Improvement Notice		Letter to follow	Verbal advice (not to cabin crew)	
Signature of Officer				
Signature of Person int	erviewed			

SECTION 5: PRODUCT-SPECIFIC ESTABLISHMENTS

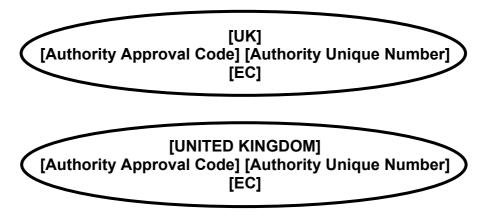
CHAPTER 5.1: APPROVAL OF PRODUCT-SPECIFIC ESTABLISHMENTS SUBJECT TO APPROVAL UNDER REGULATION 853/2004

5.1.1: Identification Marks

(See also Code of Practice, Paragraph 5.1.12)

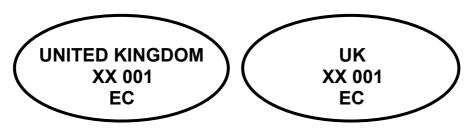
The requirements for the form of the identification mark which establishments subject to approval under Regulation 853/2004 must apply to their products as appropriate are set out in Annex II, Section I B of that Regulation. In accordance with Paragraph 5.1.12 of the Code of Practice the Food Authority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

5.1.1.1: Example Identification Mark Formats



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

5.1.1.2: Example Identification Marks



5.1.2: 'Special Mark' for Minced Meat/Meat Preparations/Meat Products: (Article 8 of Regulation 2073/2005)

(See also Code of Practice, Paragraph 5.1.12)

The UK has opted to use the transitional derogation provided by Article 8 of Regulation 2073/2005 concerning compliance with the value set in Annex I to that Regulation for *Salmonella* in minced meat, meat preparations and meat

Food Law Practice Guidance

products intended to be eaten cooked placed on the national market of a Member State. Relevant products must be marked with a 'special mark'.

5.1.2.1: Format of 'Special Mark'



Specific Requirements:

- 1. The oval should touch the four sides of the surrounding oblong, as shown.
- 2. Within the oval there should be the letters UK, the approval number of the premises of manufacture/production, and the letter N, to denote that the product is for the national market only.
- 3. There is no size requirement for the special mark.
- 4. The general requirements given in Annex II, Section I, Paragraph B5 of Regulation 853/2004 for the Identification Mark must be met i.e. the special mark must be:
 - clearly displayed;
 - legible;
 - in indelible ink; and
 - the characters must be easily decipherable.

5.1.2.2: Example 'Special Mark'



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

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

CHAPTER 5.3: MATTERS RELATING TO LIVE BIVALVE MOLLUSCS

All relevant material on enforcement options in establishments is contained in the Code of Practice and in Annex 6 of this Guidance.

CHAPTER 5.4: MATTERS RELATING TO FRESH MEAT

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

SECTION 6: SAMPLING AND ANALYSIS

CHAPTER 6.1: SAMPLING³⁶

6.1.1: Introduction

This Section concerns the procedures that should be followed when food samples are procured under Regulation 12 of the Food Hygiene (England) Regulations 2006 or Section 29 of the Food Safety Act 1990, and the associated requirements of the Food Safety (Sampling and Qualifications) Regulations 1990³⁷.

6.1.2: Procurement of Samples

The Food Hygiene (England) Regulations 2006 and the Food Safety Act 1990 allow samples to be procured either by "purchasing" or "taking". The choice is at the discretion of the authorised officer, having regard to the policy of the Food Authority. Where the quantity or frequency of sampling gives rise to significant financial consequences for the owner of the food, the Food Authority should offer an ex-gratia payment if samples are not purchased. The officer should give the owner a receipt for, or a record of, all samples the officer has taken. If enforcement action is anticipated following microbiological examination or chemical analysis the sampling officer should purchase the sample.

6.1.3: Certificate Issued by Public Analyst or Food Examiner

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

6.1.4: Avoiding Contamination

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

6.1.5: Continuity of Evidence

Food samples are normally dealt with in a food laboratory and faecal specimens in a clinical laboratory, operating independently of the Food

³⁶ See also "Food Standards and Feeding Stuffs Sampling, Practical Guidance for Enforcement Officers" by the Food Standards Agency – published May 2004; http://www.food.gov.uk/enforcement/foodsampling/guidance/ ³⁷ SI 1990 No. 2463

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

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

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

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

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

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

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

6.1.6: Samples for Analysis

6.1.6.1: Quantity of Samples for Analysis

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

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

6.1.6.2: Containers for Samples for Analysis

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

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

6.1.6.3: Transport and Storage of Samples for Analysis³⁸

Final parts of food which are perishable should be kept refrigerated or in a frozen state, as necessary. The method of storage used will differ, depending on whether the final part is to be submitted to the Public Analyst, or retained for possible submission to the Laboratory of the Government Chemist.

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

³⁸ The Campden and Chorleywood Food Research Association publication "Guidelines for the preservation of official samples for analysis" (CCFRA Guideline No. 36) includes further guidance.

6.1.6.4: Samples which Present Difficulties in Dividing into Parts

An exception to division into three parts applies where the authorised officer is of the opinion that division of the sample is either not reasonably practicable, or is likely to impede proper analysis. Regulation 6(4) of the Food (Sampling and Qualifications) Regulations 1990 allows for the sample to be submitted for analysis complete without division into three parts. There is no final part for the seller/owner, neither is there a final part to be retained. This procedure must therefore be used with caution. Situations where this procedure may be used will depend on the tests to be carried out but may include the following:

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

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

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

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

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

6.1.7: Samples for Examination

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

6.1.7.1: Quantity of Samples for Examination

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

6.1.7.2: Handling of Samples for Examination

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

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

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

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

For general sampling information see the LACORS "Guidance on Food Sampling for Microbiological Examination", January 2006. Annex 3 of that Guidance contains details of information to be given to the Food Examiner, when samples are submitted.

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

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

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

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

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

6.1.7.4: Request for Examination

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

SECTION 7: MONITORING OF INTERVENTIONS

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

SECTION 8: ANNEXES

ANNEX 1: GLOSSARY OF TERMS

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

Seafish SFPA SFSORB	Sea Fish Industry Authority Scottish Fish Protection Agency Scottish Food Safety Officers'
	Registration Board
The Agency	The Food Standards Agency
TSE	Transmissible Spongiform
	Encephalopathy
UKAS VMHA	United Kingdom Accreditation Service Veterinary Meat Hygiene Adviser

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

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

http://www.food.gov.uk/enforcement/foodlaw/foodlawcop/copengland

Regulations Relating to England

The Food Hygiene (England) Regulations 2006 (SI 2006 No. 14): <u>http://www.opsi.gov.uk/si/si2006/20060014.htm</u>

Official Feed and Food Controls (England) Regulations 2006 (SI 2006 No. 15): <u>http://www.opsi.gov.uk/si/si2006/20060015.htm</u>

EU Regulations

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

<u>http://europa.eu.int/eurlex/pri/en/oj/dat/2002/I_031/I_03120020201en00010024.pdf</u>

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

<u>http://europa.eu.int/eur-</u> lex/pri/en/oj/dat/2004/I_191/I_19120040528en00010052.pdf

Regulation (EC) No. 852/2004 on the hygiene of foodstuffs: <u>http://europa.eu.int/eur-</u> <u>lex/lex/LexUriServ/site/en/oj/2004/I_226/I_22620040625en00030021.pdf</u>

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

<u>http://europa.eu.int/eur-</u> lex/lex/LexUriServ/site/en/oj/2004/I_226/I_22620040625en00220082.pdf

Regulation (EC) No. 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption: <u>http://europa.eu.int/eur-</u> lex/lex/LexUriServ/site/en/oj/2004/l 226/l 22620040625en00830127.pdf

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

<u>http://europa.eu.int/eurlex/lex/LexUriServ/site/en/oj/2005/I_271/I_27120051015en00170028.pdf</u> Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs:

<u>http://europa.eu.int/eurlex/lex/LexUriServ/site/en/oj/2005/I_338/I_33820051222en00010026.pdf</u>

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

<u>http://europa.eu.int/eur-</u> lex/lex/LexUriServ/site/en/oi/2005/I_338/I_33820051222en00270059.pdf

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

lex/lex/LexUriServ/site/en/oj/2005/l_338/l_33820051222en00830088.pdf

European Commission Guidance Documents

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

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

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

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

http://europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance_doc haccp_en.pdf

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

Draft FSA guidance on the requirements of food hygiene legislation: <u>http://www.food.gov.uk/multimedia/pdfs/fsaguidefoodleg.pdf</u>

Draft Summary guidance on the new food hygiene regulations for businesses making or handling foods of animal origin: <u>http://www.food.gov.uk/multimedia/pdfs/summguidpoao011205.pdf</u>

Draft Summary guidance on the new food hygiene regulations for businesses manufacturing food not of animal origin: <u>http://www.food.gov.uk/multimedia/pdfs/summguidnonpoao011205.pdf</u>

Draft Summary guidance on the new food hygiene regulations for restaurants, caterers and businesses selling food to the final consumer: <u>http://www.food.gov.uk/multimedia/pdfs/summguidcater011205.pdf</u>

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

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

Model Forms / Template Forms in Microsoft Word Format

Model Forms for use in connection with the Food Hygiene (England) Regulations 2006 <u>http://www.food.gov.uk/multimedia/worddocs/hygieneregsformsfeb06.doc</u>

Template Forms for use in connection with the Approval of Product-Specific Establishments http://www.food.gov.uk/multimedia/worddocs/approvalformfeb06.doc

Model Application Form for the Registration of a Food Business Establishment: http://www.food.gov.uk/multimedia/worddocs/registrationformfeb06.doc

Model Notice of Temporary Closure of Production Area(s) (Live Bivalve Molluscs / Shellfish): http://www.food.gov.uk/multimedia/worddocs/shellfishformfeb06.doc

Template Live Bivalve Molluscs / Live Shellfish Registration Document: <u>http://www.food.gov.uk/multimedia/worddocs/shellfishregfeb06.doc</u>

<u>Central Register of Letters Sent by the Food Standards Agency to Local</u> <u>Authorities</u>

England:

http://www.food.gov.uk/multimedia/webpage/centralref_england

<u>UK:</u>

http://www.food.gov.uk/multimedia/webpage/centralref_uk

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

A.3.1: Introduction

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

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

A.3.2: Division of Enforcement Responsibilities

(From Code of Practice, Paragraph 5.1.2)

Responsibility rests with Food Authorities for the approval of, and enforcement in relation to, establishments subject to approval under Regulation 853/2004 in respect of which control does <u>not</u> fall to an official veterinarian. These "productspecific" establishments will be producing any, or any combination, of the following: Minced Meat, Meat Preparations, Mechanically Separated Meat, Meat Products, Live Bivalve Molluscs, Fishery Products, Raw Milk (other than raw cows' milk), Dairy Products, Eggs (not primary production) and Egg Products, Frogs Legs and Snails, Rendered Animal Fats and Greaves, Treated Stomachs, Bladders and Intestines, Gelatine and Collagen, and will include certain cold stores and certain wholesale markets. Food Authorities are also responsible for enforcement in respect of collection centres and tanneries supplying raw material for the production of gelatine or collagen intended for human consumption.

The Agency, through the Meat Hygiene Service (MHS), is responsible for the approval of establishments subject to approval under Regulation 853/2004 where control falls to an official veterinarian in accordance with Article 4(7) of Regulation 854/2004³⁹ and for enforcement in such establishments once approved. Such establishments are slaughterhouses, game handling establishments and cutting plants placing fresh meat on the market. The MHS is also responsible for establishments co-located with these establishments in which Minced Meat, Meat Preparations, Mechanically Separated Meat, Meat Products, Rendered Animal Fats and Greaves, Treated Stomachs, Bladders and Intestines, Gelatine and/or Collagen are <u>also</u> produced.

The Agency is also responsible for enforcement in relation to the matters regulated by Schedule 6 of the Food Hygiene (England) Regulations 2006 in

³⁹ Regulation (EC) No. 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

so far as it applies in relation to raw cows' milk intended for direct human consumption.

A.3.3: Exemptions from the Requirement for Approval

A.3.3.1: Introduction

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

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

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

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

Article 1(2) of Regulation 853/2004 stipulates that. Food Authorities should be aware that the regulation does not set any minimum amounts of product of plant origin, or processed product animal origin, that such food must contain.

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

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

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

3. This Regulation shall not apply in relation to:

(a) primary production for private domestic use;

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

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

A.3.3.2.3: Definition of Retail

Paragraphs A.3.3.2.4 *et seq* contain details of provisions in Regulation 853/2004 which either mention 'retail' or exclude retail activities from the scope of that regulation, unless expressly indicated to the contrary. It is therefore important, when considering such provisions, to be clear on the definitions of 'retail' and 'final consumer', which is given in Article 3(7) of Regulation 178/2002 is as follows:

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

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

It should be noted that "wholesale <u>outlets</u>" are included in the definition of 'retail'; the terms "wholesale", "wholesale activities" or similar are <u>not</u> used. Food Authorities should bear this distinction in mind. Although a wholesale outlet may be considered to be 'retail' as defined, if it is handling products of animal origin for which Annex III of Regulation 853/2004 lays down requirements and is not supplying final consumers exclusively, approval may be required. Establishments claiming exemption will therefore need to be considered on a case by case basis.

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

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

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

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

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

Article 1(3)(c)

Direct supply to a final consumer can be via mail order or internet sales as well as by delivery or collection. The final consumer does not have to be local to the primary producer. In respect of the supply of small quantities of primary products to 'local retail establishments', 'Local' should be interpreted in the same way as 'Localised' (see Paragraph 3.3.2.7).

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Article 1(3)(d)

Requirements in respect of those producers benefiting from the exemption afforded by Article 1(3)(d) of Regulation 853/2004 are set out in Regulation 31/ Schedule 5 to the Food Hygiene (England) Regulations 2006. Guidance on this exemption is given in Annex 5, Paragraph A.5.4.5 of this Practice Guidance.

Article 1(3)(e)

Guidance on the exemption afforded by Article 1(3)(e) of Regulation 853/2004 is given in Annex 5, Paragraph A.5.4.4 of this Practice Guidance.

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

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

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

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

The effect of the Article 1(5) is that, in general, Regulation 853/2004 does not apply to retail. The Regulation does, however, apply to retail if food of animal origin is supplied to another establishment unless the activities in Article 1(5)(b)(i) or (ii) are undertaken (see Paragraph A.3.3.2.6). The Regulation also applies to retail where this is expressly indicated. Such indications can be found in Annex III, Section VII, Paragraph 3 (Live Bivalve Molluscs) and Annex III, Section VIII, Paragraph 2 (Fishery Products) which stipulate that certain requirements of those respective Sections apply to retail.

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

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

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

or

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

Article 1(5)(b)(i)

Article 1(5)(b)(i) affords an exemption in respect of the supply of food of animal origin from a retail establishment to another establishment where the operations consist of only storage or transport. However, retailers benefiting from this exemption must, nonetheless, ensure that there is compliance with relevant temperature requirements in Annex III of Regulation 853/2004.

Article 1(5)(b)(ii)

Article 1(5)(b)(ii) affords an exemption for retailers which allows them to supply food of animal origin, which would ordinarily trigger the need for approval, from their retail establishment to other <u>retail</u> establishments, but only if this is a marginal <u>and</u> localised <u>and</u> restricted activity (see Paragraph A.3.3.2.7, below).

Approval would, however, be required if an establishment considered to be 'retail' as defined handles products of animal origin for which Annex III of Regulation 853/2004 lays down requirements <u>and</u> these products are supplied to other establishments <u>and</u> the supply is:

- To non-retail establishments e.g. manufacturers, and/or;
- To retail establishments, but the supply involves activities <u>beyond</u> those which can be considered marginal, localised and restricted.

A.3.3.2.7: "Marginal, Localised and Restricted"

The concept of marginal, localised and restricted activity is described in Recital 13 of Regulation 853/2004 as follows:

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

<u>'Marginal'</u>

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

The European Commission Guidance Document on Regulation 853/2004 provides that 'marginal' may also be interpreted as a 'small amount of food of animal origin' in absolute terms, but an interpretation of this phrase in England has been limited only to fresh or processed meat, including meat products, but excluding wild game and wild game meat (see Annex 5). In respect of products of animal origin other than these, Food Authorities should interpret 'a small part of the establishment's business' as meaning

up to a quarter of the business in terms of food

<u>'Localised' / 'Local'</u>

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

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

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

In this regard, Food Authorities should interpret 'county' as meaning:

Metropolitan or non-metropolitan counties in England and Wales as defined in the Local Government Act 1972 and London Government Act 1963⁴⁰ (e.g. Greater London, North Yorkshire, Leicestershire, Powys), a local authority in Scotland, or an administrative county in Northern Ireland (e.g. Co. Fermanagh).

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

'Restricted'

'Restricted' is described in Recital 13 of Regulation 853/2004 as 'concerning only certain types of products or establishments'. Having to list establishments and products is seen as bureaucratic and a potential barrier to trade and there are, in any case, other legal requirements for the traceability of food products. In relation to the meat sector, Food Authorities should interpret 'restricted' as set out in Annex 5, Paragraph A.5.4.2. In respect of other products of animal origin, Food Authorities should consider whether the supply is in some way restricted in relation to either:

- The products being supplied i.e. by product category as referenced in Regulation 853/2004 (e.g. dairy products, fishery products etc.), or;
- The type of retail establishment supplying the products, and/or;
- The type of retail establishment(s) being supplied with the products.

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

A.3.3.3.1: Regulation 853/2004, Article 4(2)

...establishments handling those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the Competent Authority has approved them...with the exception of establishments carrying out only:

(a) primary production;

⁴⁰ Except that the Isles of Scilly and the combined counties of Mid Glamorgan, South Glamorgan and West Glamorgan shall be regarded as one county each. For some larger authorities in Scotland a finite limit might be considered more appropriate.

(b) transport operations;

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

or

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

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

A.3.4: Conditional Approval

(Includes the text of Code of Practice, Paragraph 5.1.8)

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

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

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

If conditional approval is granted, a further visit must be carried out within three months of the conditional approval being granted in accordance with Article 31(2)(d) of Regulation 882/2004. This visit should be a secondary inspection (see Paragraph 4.1.3 of the Code of Practice). In appropriate circumstances as set out in Article 31(2)(d) of Regulation 882/2004, conditional approval may be extended, but this is restricted to a maximum of six months from the date of the initial granting of conditional approval. Professional judgement should used in deciding whether it would be appropriate to extend conditional approval, on a case by case basis.

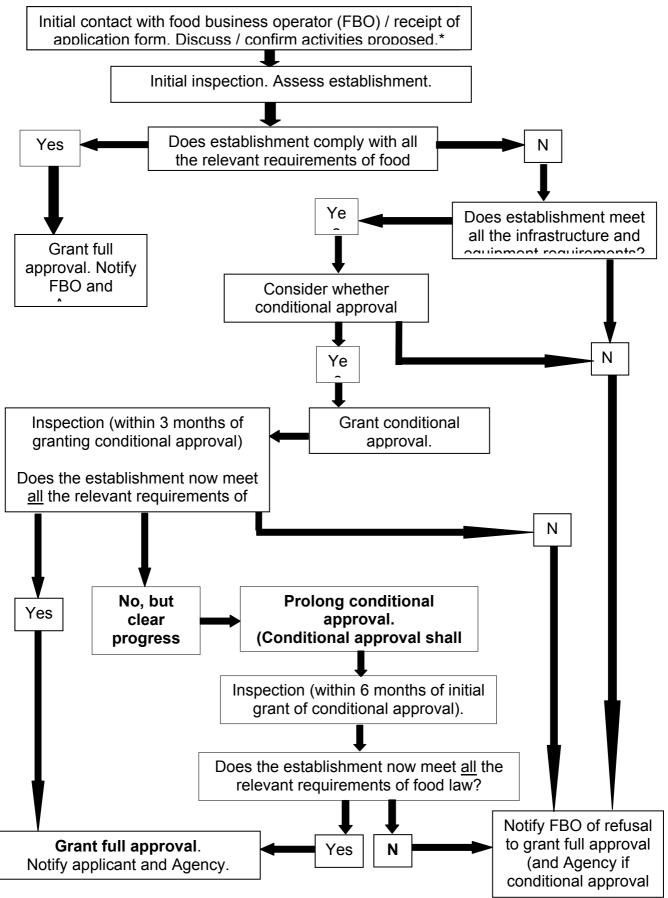
A.3.5: Approval Procedures

(From Code of Practice, Paragraph 5.1.5)

Article 31(2)(a) of Regulation 882/2004 obliges competent authorities to establish procedures for food business operators to follow when applying for the approval of their establishments in accordance with Regulation 853/2004. Procedures for handling applications for approval are set out in Paragraphs 5.1.6 *et seq* of the Code of Practice. Food Authorities should ensure that they, and food business operators, follow these procedures as appropriate. Any deviations from these procedures should be recorded and retained by the Food Authority and should, where possible, be agreed with the Food Authority beforehand.

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

ANNEX 4: APPROVAL PROCESS FLOWCHART



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

ANNEX 5: MEAT

A.5.1: Guidance

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

A working draft of this Guide can be found on the Agency's website at:

http://www.food.gov.uk/foodindustry/meat/.

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

http://www.food.gov.uk/multimedia/pdfs/foodmandiary2006.pdf

A.5.2: Approval of Establishments

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

Food authorities are responsible for approving establishments that are not subject to veterinary control (except for co-located premises described above) and for registering establishments that are exempt from approval.

A.5.3: Enforcement in Meat Establishments

The Meat Hygiene Service (MHS) is responsible for enforcement in meat establishments that require veterinary control (see A.5.2 above).

A.5.3.1: Co-located Establishments

The MHS is responsible for enforcement in meat products, minced meat, meat preparations, mechanically separated meat plants, cold stores or edible coproducts plants that are <u>co-located</u> with an approved slaughterhouse, cutting plant or game handling establishment. (This is a change to the previous arrangement whereby meat products plants co-located with cutting plants were subject to dual Food Authority/MHS enforcement). When a co-located meat establishment does not require approval e.g. a retail butcher, dual Food Authority/MHS enforcement continues to apply.

A.5.3.2: Stand-Alone Establishments

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

A.5.3.3: Cold Stores

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

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

A.5.3.4: Wild Game

There are limited exemptions for individual hunters and retail establishments (see A.5.4 below) but otherwise, establishments that process wild game require approval as game handling establishments under veterinary control. This includes processors that have been supplying only the national market under Food Authority control and certain small-scale processors that do not qualify for the hunter and retailer exemptions and for which EU agreement may be sought to vary the level of official veterinary control. Until the approval process is completed, they remain subject to Food Authority enforcement and may continue to supply game meat within the UK while complying with Regulation 852/2004 Annex II. Primary production of game stops when it enters the handling establishment and therefore all food business operators who process game into game meat must have food safety management plans based on HACCP principles.

The supply of game through game handling establishments (GHEs) is also now subject to the specific rules of Regulation 853/2004. One such rule is that a "trained person" must examine game immediately after killing. GHEs should therefore only accept game that has undergone such an examination. However, in particular circumstances, when a trained person is not available, deer may be delivered with the head and pluck for post-mortem inspection. See the wild game guidance (see Paragraph A.5.3.4 below) on the "trained person", requirement, but the most robust way of demonstrating the necessary knowledge is by possessing a VRQ qualification.

Regulation 854/2004 contains rules for the Competent Authority, and includes a requirement for official post-mortem inspection. This requirement will not be implemented in unlicensed premises until after they are approved. In the meantime the operator should, through his HACCP based procedures, ensure that any game meat placed on the domestic market is fit for human consumption. Operators of premises licensed prior to 31 December 2005 should continue to present carcases of wild game animals intended for export to the official veterinarian.

A.5.3.5: Edible Co-products

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

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

http://www.food.gov.uk/foodindustry/guidancenotes/meatregsguid/coproductby productguide

A.5.4: Exemptions from Approval

(See also Annex 3)

A.5.4.1: Retail Establishments (Regulation 853/2004, Article 1(5)(b)(ii))

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

A major change as far as butchers are concerned is that, whereas the previous definition of "*final consumer*" in the Meat Hygiene Regulations included caterers, the definition in the new Regulations does not. "*Final consumer*" is now defined as "*the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity*", i.e. the public. This means that establishments supplying caterers will be considered to be supplying other establishments as opposed to supplying the final consumer.

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

A.5.4.2: Retail Establishments - "marginal, localised and restricted" supply to other establishments

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

• 'Marginal:

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

- (i) "a small part of the establishment's business" means "up to a quarter of the business in terms of food"; and
- (ii) "a small amount of food of animal origin" means, in relation to meat (fresh or processed, excluding wild game and wild game meat) up to two tonnes per week, subject to the establishment having a genuine retail element to its operation supplying the final consumer with part of its production of meat.
- (iii) If either (i) or (ii) applies, except in relation to wild game and wild game meat, when only (i) applies, the establishment is exempt from the requirements of Regulation 853/2004.

and

• "Local" / "localised" (see Paragraph A.3.3.2.7)

and

• "Restricted"

For wild game and wild game meat, supply is subject to the game having been examined by a trained person. Large wild game carcases must be accompanied by a trained person's declaration stating that no abnormalities were observed either before or after shooting. For other meat, restrictions relate to the amounts of meat supplied.

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

The "marginal, localised and restricted" exemption will allow a butcher to cut meat on a farmer's behalf and return it to that farmer for onward sale, provided this is a marginal part of that butcher's business and the farmer being supplied is local.

A.5.4.4: Wild Game (Primary Producers / Hunters)

The Regulation 853/2004 Article 1(3)(e) exemption repeats the one at Regulation 852/2004 Article 1(2)(c) allowing primary producers to supply small quantities of wild game carcases (i.e. in-fur/in-feather) either direct to the final consumer or to local retail establishments directly supplying the final consumer (see Paragraph A.5.4.2). Primary producers, whether individual hunters or shooting estates, are exempt from both Regulation 852/2004 and Regulation 853/2004.

The Regulation 853/2004 Article 1(3)(e) exemption applies only to individual hunters who prepare wild game meat from carcases they have shot themselves. Only small quantities of this meat may be sold either direct to the final consumer or to local retailers directly supplying the final consumer (see Paragraph A.5.4.2). However, because the meat is not a primary product, the hunter is exempt only from Regulation 853/2004, not from Regulation 852/2004.

For these exemptions, the UK is interpreting supply of "small quantities" as being under 10,000 small wild game carcases or under 300 large wild game carcases per year. In the case of the hunter claiming a Regulation 853/2004 Article 1(3)(e) exemption, the meat he supplies would have to be part of this amount, rather than in addition to it. Supply direct to a final consumer can be via mail order or internet sales as well as by delivery/collection. The interpretation of "local" is the same as for "localised" (see Paragraph A.5.4.2).

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

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

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

Regulation 853/2004 does not apply to the direct supply, by the producer, of small quantities of meat from poultry or lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer (Article 1(3)(d))⁴¹. Article 1(4) goes on to say that the rules governing the persons and activities benefiting from this exemption (in addition to those in Regulation 852/2004) will be set out in national law. These national rules are set out in Schedule 5 to the Food Hygiene (England) Regulations 2006.

A.5.4.5.1: Which producers benefit from this exemption?

The exemption applies to producers of poultry (i.e. farmed birds except ratites) or lagomorphs (i.e. rabbits, hares and rodents) who slaughter their own animals on the farm of production, as long as only *small quantities* of meat are supplied.

The UK is interpreting 'small quantities' as:

• producers annually slaughtering under 10,000 birds or lagomorphs;

or

 producers annually slaughtering over 10,000 birds or lagomorphs who are members of an appropriate assurance scheme <u>and</u> who either (a) dry pluck by hand or (b) slaughter for 40 days per year or less.

The limit of 10,000 birds or lagomorphs in the first category should allow for some fluctuation in annual throughput around that level provided that it does not habitually exceed a combined limit of 10,000 a year.

⁴¹ As amended by Article 3 of Regulation (EC) 2076/2005 (Transitional and Implementing Measures)

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

A.5.4.5.2: Where can the meat be sold?

Meat produced under this exemption may be supplied:

• direct to the final consumer,

or

• direct to local retail establishments directly supplying such meat to the final consumer.

In the first category, direct supply to the final consumer would include mail order or internet sales, as long as the supply is *direct* to the consumer. Such supplies are not necessarily limited to meat in the form of fresh meat. They could be in the form of meat products or preparations.

In the second category, the supply must be direct to local retail establishments (in the form of fresh meat, meat preparations or meat products), and could include the supply by the producer to restaurants or other catering establishments. The retail establishments supplied must be *local.* 'Local' supply is interpreted as being the same as 'localised' (see Paragraph A.5.4.2 above) and, in addition, anywhere within the UK in the two weeks preceding Christmas and Easter and (for geese) Michaelmas (*late September*).

A.5.4.5.3: What rules apply?

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

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

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

A.5.5: Meat products, Minced Meat and Meat Preparations – Cutting of meat

Paragraph 2 of Section VI of Annex III to Regulation 853/2004 has the effect that premises that cut meat exclusively for the manufacture of meat products, minced meat, meat preparations or mechanically separated meat need to comply with the relevant requirements of Annex III of Regulation 853/2004 for red or white meat cutting plants, but will not need approval as cutting plants.

A.5.6: Meat Preparations and Meat Products Obtained by Mechanical Separation from Bones or Sinew

A new generation of separating machines can separate meat from bones or sinew, where the material obtained (e.g. Baader meat, desinewed meat) retains most of its muscle fibre structure. Hence such material does not meet the definition of Mechanically Separated Meat in Annex I of EC Regulation 853/2004, where the mechanical process results in the loss or modification of the muscle fibre structure. Neither can such material be considered as minced meat because it is produced under pressure and not by cutting. Such material would appear to fall within the definition of a meat preparation of Annex I of EC Regulation 853/2004, which includes meat that has been reduced to fragments, or undergone a process insufficient to modify the internal muscle fibre structure and thus to eliminate the characteristics of fresh meat.

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

- a) be approved as <u>meat preparations establishments</u> by local authorities when the premises are stand-alone premises;
- b) be approved <u>as meat preparations establishments</u> by the Agency when colocated with a slaughterhouse, cutting plant or game handling establishment;
- c) should comply with the hygiene and microbiological testing rules for meat preparations, not those for minced meat or mechanically separated meat.

A.5.7: Slaughter for private domestic consumption

Where slaughter is carried out for private domestic consumption and the meat is not placed on the market (whether free of charge or not) such activity falls out of the scope of both Regulation 852/2004 and Regulation 853/2004. However, it is unlawful to supply the meat of cattle, sheep and goats to any third party, including family members, unless the TSE (England)(No2) Regulations 2006(as amended), which come into effect on 1 March 2006, and the EU Animal By-Products Regulation 1774/2002 have been complied with. In

practice this is only possible if the meat has been slaughtered in an approved slaughterhouse. A more detailed guide is at Appendix 2 to this Annex.

ANNEX 5, APPENDIX 1: The Wild Game Sector - Which Regulations Apply to Which Activities?

THE WILD GAME SECTOR: WHICH REGULATIONS APPLY TO WHICH ACTIVITIES?

WHICH REGULATION IS APPLICABLE?	Regulation 852/2004	Regulation 853/2004	Regulation 854/2004
ACTIVITY			
Shooting for own consumption	No	No	No
	Art 1.2a exemption	Art 1.3a exemption	
Supply direct to final consumer or to local retailers (directly supplying final consumer) of small quantities of:			
a) whole carcasses by primary producer (hunter or estate)	No Art 1.2c exemption	No Art 1.3c exemption	No
b) meat from carcasses (produced by hunter from own shooting)	National rules apply ¹ Yes Premises to be registered as food business ⁴ and to operate under Annex II	No Art 1.3e exemption National rules apply ¹	No
 c) meat from carcasses (produced by estate, shot by others) This is a type of approved game handling establishment (AGHE) 	Yes	Yes² Premises to be approved by CA ³	Yes ²
1. <u>Supply of whole carcasses to</u> <u>approved game handling</u> <u>establishments (AGHEs)</u> either direct from shoot or from game larder operated by primary producer	Yes Premises to be registered as food business ⁴ and to operate under Annex I	Parts relating to primary producer ("trained person ⁵ " requirements and hygiene practices e.g. initial handling, temperature controls and transport)	Parts relating to primary producer's documentation and hygiene practices, including OV ⁶ examination of "trained person ⁵ " information
2. <u>Supply of whole carcasses to</u> <u>approved game handling</u> <u>establishments (AGHEs)</u> <u>not</u> by the primary produce	Yes Premises to be registered as food business ⁴ and to operate under Annex II (including any game larders and vehicles)	Parts relevant to documentation originally supplied by "trained person ⁵ ", plus temperature controls, hygienic handling and transport	Parts relevant to supplier's hygiene practices, plus OV ⁶ to check supply of documentation from "trained person ⁵ "
 <u>All other (non-retail)</u> <u>establishments preparing wild</u> <u>game meat for placing on the UK</u> <u>domestic or export market</u> These are approved game handling establishments (AGHEs) 	Yes	Yes Premises to be approved by CA ³	Yes

¹ Food Safety Act 1990 (as amended by General Food Regulations 2004). "Small quantities" limits currently set by Food Standards Agency (after consultation with stakeholders) as 10,000 small wild game carcasses per year or 300 large wild game carcasses per year (subject to review in due course)

² [Insert derogation details when/if appropriate]

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

⁴ By the Local Authority

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

⁶ Official Veterinarian

ANNEX 5, APPENDIX 2: Private Slaughter of Livestock - Guidance for Food Authorities in England

- 1. Private slaughter is the killing of an animal for the personal consumption of the owner. Such slaughter and consumption is often considered to be a human right of the animal's owner.
- 2. Article 4 of Regulation (EC) 853/2004 provides that no person shall carry on the business of a slaughterhouse or place on the market products of animal origin for human consumption unless the premises are approved under that Regulation (exception see paragraph 5 below). The legality of slaughter outside approved premises therefore depends on whether placing on the market is intended. "Placing on the market" is widely defined for the purposes of the Hygiene Regulations to mean "the holding of food for the purposes of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves". The transaction underlying a private slaughter (i.e. the supply of a carcase back to the owner) in general amounts to placing on the market under the above definition because:
 - a) in general there would be the supply of food in the course of a business;
 - b) such supply would in essence amount to a contract for the supply of goods, rather than of services, in that what is returned after slaughter (i.e. the carcase or dressed meat) is fundamentally different in kind from what was delivered to the slaughterhouse or slaughterman (i.e. the live animal); and
 - c) The Hygiene Regulations contain no derogation for private slaughter (other than that described in paragraph 6 below).
- 3. The Transmissible Spongiform Encephalopathy (No.2) Regulation 2006 (as amended), make provision for the enforcement of EC Regulation 999/2001 (as amended) on Transmissible Spongiform Encephalopathies (TSE). Like all EC Regulations it is directly applicable in all Member States (i.e. it is automatically the law in those States with effect from the date from which it applies).
- 4. As far as private slaughter is concerned, the EC TSE controls apply to the extent provided for by Regulation 999/2001 (as amended). It applies not only when a sale of meat for human consumption takes place, but also where there is supply to a third party in the community. This means that the controls apply in all situations where a third party is involved. It is, therefore, no longer lawful for the farmer to supply privately killed meat to the rest of his household without the TSE Regulations having been applied, as they are considered to be a third party. The only exception is a truly private kill where a farmer slaughters the animal himself, processes it himself, and consumes it himself.
- 5. The TSE Regulation **only** applies to those TSE susceptible species under SRM controls: bovine (cattle), ovine (sheep) and caprine (goat) species.

Porcine (pig) species, poultry, farmed game species and rabbits are not under SRM controls and may be supplied by a farmer to the rest of his household - though not to any other third party. Any slaughter of an animal for placing on the market for human consumption would need to take place in an approved slaughterhouse, as now, <u>except</u> as permitted for the direct supply, by the producer, of small quantities of meat from poultry or lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat (See A.5.4.5 above concerning on-farm slaughter of small quantities of poultry and lagomorphs).

- 6. There is also legislation to protect the welfare of farmed livestock (both red meat animals and poultry) during the slaughter or killing process. Whenever such livestock is slaughtered (death caused by bleeding after stunning) or killed (immediate death), it must be carried out in accordance with the Welfare of Animals (Slaughter or Killing) Regulations 1995 (as amended). This is enforced by the Meat Hygiene Service in approved slaughterhouses. Outside approved premises i.e. on-farm, the Regulations are enforced by the State Veterinary Service. These Regulations make it an offence to cause or permit any avoidable excitement, pain or suffering to any animal or bird during the slaughter or killing process. They also require everyone carrying out such operations to have the knowledge and skill necessary to perform the tasks humanely and efficiently in accordance with the Regulations. Only the permitted stunning and killing methods laid down in the Regulations may be used. The Regulations also require most people involved in the slaughter or killing process to be licensed, although there are a number of exemptions from this requirement. These exemptions include:
 - (i) the slaughtering or killing of an animal or bird by the owner for his/her private consumption;
 - (ii) the use of a free bullet to kill an animal in the field; and
 - (iii) the killing of a bird by dislocation of the neck on premises on which the bird was reared.
- 7. The Department for Environment, Food and Rural Affairs (Defra) is responsible for legislation on animal health and welfare. The Humane Slaughter Association has produced a leaflet entitled On-farm slaughter of Livestock for Consumption. This provides detailed information on legislation and best practice for farmers on humane slaughtering on-farm. Contact points are at Annex A below.

For further information, please see extended guidance at:

http://www.food.gov.uk/foodindustry/guidancenotes/meatregsguid/livestockguid ance/

ANNEX 5, APPENDIX 2, ANNEX A

Department for Environment, Food and Rural Affairs – Disposal of Animal By-products

Jon Rouse Control/ tel: 020 7904 6385 Dealing with Endemic Disease fax: 020 7904 6303 Area 707 e-mail: jonathon.rouse@defra.gsi.gov.uk 1A Page Street London SWIP 4PQ

Department for Environment, Food and Rural Affairs – Animal Health and Welfare Issues

Peter Walker tel: 020 7904 6454 Animal Welfare Core Team fax: 020 7904 6464 Area 501 e-mail: <u>kirk.thompson@defra.gsi.gov.uk</u> 1A Page Street London SWIP 4PQ

Humane Slaughter Association – 'On-Farm Slaughter of Livestock for Consumption'

Charlie Mason HSA The Old School Brewhouse Hill Wheathampstead Herts AL4 8AN

tel: 01582 831919 fax: 01582 831414 e-mail: <u>info@hsa.org.uk</u>

ANNEX 5A: GUIDANCE FOR FOOD LAW ENFORCEMENT OFFICERS ON HALAL FOOD ISSUES

A.5A.1: Background

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

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

A.5A.2: Examples of where the requirements of food law relate to *Halal* requirements

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

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

To be Halal:

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

(as amended)⁴². Animals/birds must be slaughtered by severance of neck arteries and jugular veins.

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

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

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

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

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

Where officers suspect misdescription of fresh meat they should liaise with the Official Veterinarian (OV) – through the relevant Regional Meat Hygiene Service office. See Annex 2 for a list of contacts.

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

⁴² Under Regulation 22 "Schedule 5 (which relates to the stunning and killing of animals) shall not apply to any animal which is slaughtered in accordance with Schedule 12 (which relates to slaughter by a religious method)".

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

ANNEX 5A, APPENDIX 1

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

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

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

NB: This is included for information

ANNEX 5A, APPENDIX 2

MHS REGIONAL CONTACT LIST

North Region (covers NE England, Lancashire, Yorkshire and Humberside)	Tel: Fax:	01904 455541 01904 455539
Central Region	Tel:	01902 693396
(covers Cheshire to East Anglia)	Fax:	01902 693337
South & West Region	Tel:	01823 330066
(covers Cornwall to Kent north to Oxfordshire)	Fax:	01823 332549
Wales Region	Tel:	02920 647810
(includes Shropshire and Hereford/Worcester)	Fax:	02920 647808
Scotland Region	Tel:	0131 244 8441
(includes North Cumbria)	Fax:	0131 244 8442

ANNEX 6: LIVE BIVALVE MOLLUSCS

A.6.1: Introduction

This Annex provides specific guidance to Food Authorities on the application and enforcement of the live bivalve mollusc aspects of Regulations 852/2004, 853/2004 and 854/2004. In line with Annex III, Section VII(1) of Regulation 853/2004, references to live bivalve molluscs in this Annex also include live echinoderms, tunicates and marine gastropods, with the exception of guidance on the provisions on the purification of live bivalve molluscs.

A.6.2: The Local Market Exemption

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

Species	Annual Maximum amount
Cockles	25.0 tonnes
Oysters	5.0 tonnes
King Scallops	5.0 tonnes
Queen Scallops	10.0 tonnes
Mussels	20.0 tonnes
Other Live Bivalve Molluscs	10.0 tonnes
Marine Gastropods	20.0 tonnes

A.6.3: Table

While Regulation 853/2004 does not apply to this allowance it is still the responsibility of the harvester to ensure that the live bivalve molluscs meet the end product standards set down for placing them on the market. Any amount of the catch which include live bivalve molluscs must have originated from an 'A' class area, which designates the product as suitable for placing on the market with no further treatment required.

A.6.4: Heat Treatment

Live Bivalve Molluscs which are to undergo an approved heat treatment process or other processing, e.g. freezing, are subject to the requirements of Regulation 853/2004 that relate to live bivalves up to the point where processing begins in an approved establishment. After that point they are considered to be fishery products.

The controls that must be exercised over any heat treatment process for bivalve molluscs from Class B or Class C areas are set out in Annex II, Section

VII, Chapter II(5) of Regulation 853/2004 and, if appropriate Annex II, Chapter XI of Regulation 852/2004.

A.6.5: Shellfish Liaison Arrangements

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

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

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

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

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

The liaison group's functions should include:

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

A.6.6: Notification of Designated Live Bivalve Mollusc (LBM) Production Areas and Relaying Areas

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

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

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

A.6.7: Monitoring of Registration Documents

Food Authorities should be aware of the commercial advantages of abusing the registration document procedure, e.g. by suggesting that live bivalve molluscs have been taken from waters producing molluscs with a better microbiological quality.

It is not possible for Food Authorities to monitor every landing in their areas, or to detect abuses in the use of registration documents by concentrating resources at this point.

An appropriate system of monitoring for batches described as being from class A, B and C areas is to take samples and consider the test results against the standards referred to in Section VIII of Chapter V of Regulation 853/2004. On a cautionary note, it should be recognised that shellfish *E. coli* monitoring from any one production area may show significantly variable results, both temporally and spatially, due to environmental and other factors e.g. class C areas may occasionally yield single results <230 *E.coli*/100g (for this reason classifications are based on a time series of data rather than single results). Therefore a batch sample returning a single result that meets the requirements of a particular classification category should not be considered conclusive proof that the batch originated from the same class of production area.

Food Authorities will find that liaison with other statutory inspectorates e.g. the Sea Fisheries Inspectorate and the local Sea Fisheries Committee is helpful in monitoring the harvesting of live bivalve molluscs and other shellfish.

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

A.6.8: Sampling by Operators

Operators of approved purification / dispatch centres should also have adequate laboratory arrangements to ensure that the live bivalve molluscs comply with the health standards referred to in Annex III, Section VII, Chapter V of Regulation 853/2004.

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

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

A.6.9: Laboratories Used in Connection with Dispatch or Purification Centres

Laboratories used by operators of dispatch or purification centres to examine samples to meet their obligations under Annex III, Section VII, Chapter V of Regulation 853/2004 must be recognised by the Food Authority. The laboratory may be directly associated with the approved centre, or may be a Health Protection Agency (HPA) Food Examiner, or any other appropriate laboratory.

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

A.6.10: Sampling of Live Bivalve Molluscs by Food Authorities

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

A.6.11: Information on Standards to be Applied

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

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

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

A.6.12: Molluscs and Other Shellfish Which Fail to Satisfy Requirements

In accordance with Regulation 27 of the Food Hygiene (England) Regulations 2006, any live bivalve molluscs or other shellfish that have not been produced, processed or distributed in accordance with the Regulations may be treated, for the purposes of Section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements and may be seized and taken before a Justice of the Peace to be condemned, implementing Directive 91/67/EEC on the animal health conditions governing the placing on the market of aquaculture animals and products.

A.6.13: Transfer of Seed Molluscs to Designated Production Areas

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

Transfers of "seed bivalve molluscan shellfish", i.e. immature bivalve molluscs taken from an unclassified area, to be used to seed a classified production area are permitted, provided that they remain in the designated production area for a period of not less than six months before they are harvested for human consumption. This does not permit the movement of adult or partially developed bivalve molluscan shellfish from an unclassified area for further short-term growth before marketing. It is restricted to the seeding of new areas or the re-seeding of existing classified production areas. If new areas are seeded they must be classified before harvesting can take place. Harvesters should inform the relevant Food Authority if any such movements are contemplated.

A.6.14: Closure Notices (temporarily closing harvesting areas)

(See also Chapter 5.3 of the Code of Practice)

It is recommended that the Food Authority should issue a Closure Notice as the appropriate means to notify interested parties where is satisfied that the consumption of species covered by the Regulation taken from the area is likely to cause a risk to public health. A Closure Notice might be considered appropriate where, for example, the designated mollusc production area was subject to sudden or accidental pollution which affected the quality of the production area. The use of a Closure Notice may also be appropriate where there is a local problem with environmental pollution caused by chemical contamination or toxin producing plankton

There may also be circumstances when it would be appropriate for the Food Authority to consider seeking the opinion of appropriate experts such as the consultant in communicable disease control and consultant microbiologist at the HPA.

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

ANNEX 6, APPENDIX 1: Guidance Note for Food Authorities in England – Live Bivalve Molluscs / Shellfish

GUIDANCE NOTE FOR FOOD AUTHORITIES IN ENGLAND

LIVE BIVALVE MOLLUSCS / SHELLFISH

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Registration documents

6. Can a Food Authority issue registration documents to gatherers of shellfish in another Food Authority's area?

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7. If a dispatch centre is selling live shellfish to individual consumers on a retail basis, does the identification mark need to be applied to each sale?

Seed Shellfish

8. What is the minimum period of on-growing of seed mussels before they can be harvested for human consumption?

Approval of Establishments

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

Annex 1(2) of Regulation 853/2004 defines a dispatch centre as 'any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption.' All dispatch centres must be approved. As fishing vessels are considered primary production, fishing vessels do not need approval for washing and grading live bivalve molluscs at sea. Though fishing vessels will need to be registered.

Annex III, Section VII, Chapter I of Regulation 853/2004 requires all live bivalve molluscs destined to be placed on the market to enter the market via a dispatch centre. At the dispatch centre they are wrapped, identification marked and sampled. The dispatch centre need not be on the shoreline but could be some distance away, even in another Member State.

2. May inland markets become dispatch centres?

Yes. The market would need to meet the approval conditions in the same way as other dispatch centres. Approval as a dispatch centre is not necessary to enable a market to unwrap parcels of live shellfish already sent from a dispatch centre and to split up the parcels for sale to retailers or consumers.

3. Are separate approval numbers needed for dispatch and purification centres operating from the same site?

No. Where both exist on the same premises then the same number should be used for the dispatch centre and for the purification centre. Different suffixes (D and PC) are no longer used to separately identify dispatch and depuration centres.

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

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

5. Does the dispatch centre working area need to be physically identifiable from the purification centre working area, when both activities are carried out on the same premises?

The need to separate clean from contaminated live shellfish would dictate this. It would also be in the interests of the business to have separate areas in the event of enforcement action on either the dispatch or purification centre. In small plants this is subject to a risk assessment by the Food Authority.

Registration documents

6. Can a Food Authority issue registration documents to gatherers of shellfish in another Food Authority's area?

Registration documents should generally be issued by the Food Authority with responsibility for the harvesting area. This ensures that up to date information about any public health issues relating to the harvesting area may be given to gatherers. However, a Food Authority may allow gatherers to apply to it for registration documents for gathering in another Food Authority's area. In these circumstances the two Food Authorities should liaise regarding the issue of the registration documents and ensure that arrangements operate effectively to assist industry and avoid abuse. Inter-authority arrangements of this kind should normally be restricted to adjoining Food Authorities.

Identification Marking

7. If a dispatch centre is selling live shellfish to individual consumers on a retail basis, does the identification mark need to be applied to each sale?

Regulation 853/2004 does not, generally, apply to retail. Under this regulation there is only a requirement for identification marks to accompany consignments of live shellfish prior to retail sale. After live shellfish are sold the retailer should retain a copy of the registration document for at least 12 months, or for as long as the Competent Authority requires. Therefore, where a dispatch centre is acting as a retailer, record keeping of the dispatch of batches of live shellfish through the retail outlet may suffice. The position is similar for live shellfish sold by mail order.

Seed Shellfish

8. What is the minimum period for on growing of seed mussels before they can be harvested for human consumption?

The minimum period for growing on genuine seed mussels should be six months.

ANNEX 6, APPENDIX 2: Model Registration Document

LIVE BIVALVE MOLLUSCS / LIVE SHELLFISH REGISTRATION DOCUMENT

(Regulation (EC) No. 853/2004 - Article 7 / Annex III, Section VII, Chapter I)

Registration Document No			
Issued by:			
Date of Issue:			
Name of gatherer	Signature of gatherer		
Food Authority where shellfish landed	Address of gatherer		
Date of gathering	Location of production area [described in as precise detail as practicable] and, if live bivalve molluscs, class of production area (A, B* or C*)		
Name of shellfish species being moved (common and scientific name) and quantity of shellfish being moved	Place of destination and (if applicable) approval number		
*When shellfish originate from a production area classified as B or C:			
Relaying area			
Duration of relaying			
OR			
Address of Purification Centre			
Date of Receipt			
Place of Receipt			
[Date of Signature]			

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

ANNEX 7: FISHERY PRODUCTS

A.7.1: Introduction

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

A.7.2: Competent Authority

The Agency is the UK central Competent Authority with lead responsibility for these Regulations.

Food Authorities are responsible for enforcement of the EU food hygiene Regulations at their local level, and therefore approve fishery products establishments, register certain markets and fishing vessels, and otherwise enforce the EU food hygiene Regulations.

A.7.3: Scope of Approval

The Regulations do not apply to retail unless expressly indicated. They would however apply when operations are carried out to supply fishery products to other establishments.

Auctions and wholesale markets are required to have approval and should be inspected at regular intervals to check for compliance with hygiene and temperature requirements and subject to Regulation 853/2004 Annex III Section VIII Chapter II.

A.7.4: Direct supply of small quantity of Fish.

The Regulations do not apply the direct supply of small quantities of fishery products (i.e. primary products) to the final consumer or to local retail establishments directly supplying the final consumer. For the purposes of fishery products (not including live bivalve molluscs) a small amount is a total amount of not more than 25 tonnes of fishery products in a calendar year. While the Regulations do not apply to this allowance it is still the responsibility of the harvester to ensure that these products meet the end product standards set down for placing these fishery products on the market. Any amount of the catch which include live bivalve molluscs must have originated from a class 'A' area, which designates the product as suitable for placing on the market with no further treatment required.

A.7.5: Conditions During and After Landing

One of the public health and quality measures in the Regulations is periodic inspection and checks on the fitness for human consumption of fish at the time of landing or before the first sale. Where fishery products are sold at a market associated with the landings, these inspections should take place in that auction hall or wholesale market. It should not normally be necessary for any inspections to be carried out at the time of landing. An organoleptic examination of the fishery products would normally satisfy this requirement.

Food Law Practice Guidance

A Food Authority may authorise the transfer of fishery products from the landing (ex-quay) into containers for immediate delivery to an approved establishment or auction or wholesale market for the checks to be carried out there. Deferring the checks to be carried out later in an auction or wholesale market should not normally require any special arrangements with the receiving Food Authority.

Deferring checks to an approved establishment must, however, be subject to liaison and agreement with the receiving Food Authority, and have regard to the compliance record of the receiving establishment and confidence in its management. Authorisation of such deferred checks should be withdrawn if there is any suspicion of non-compliance with the requirements of the Regulations.

If an organoleptic examination of any product raises doubt as to the freshness of the product, the Food Authority may consider submitting the product for chemical analysis or microbiological examination.

With respect to the landing of fresh fish, checks required under the Regulations are without prejudice to other checks that may be required under EC marketing standards regulations by other statutory agencies.

Authorised officers should, where necessary, liaise with other statutory inspectors, e.g. the DEFRA Sea Fisheries Inspectorate, or the Scottish Fish Protection Agency (SFPA) to ensure that any enforcement action taken is appropriate

A.7.6: Information on Standards to be applied

Guidance on the requirements of the Regulations may be obtained from the Sea Fish Industry Authority (Seafish).

Food Authorities may use the guidance as a reference in establishing a consistent approach to the requirements of the Regulations. Food Authorities should, however, exercise caution and avoid using, in support of formal enforcement action, those parts of the Seafish guidance that is directed towards the achievement of good industry practice and high quality standards.

ANNEX 7, APPENDIX 1: Guidance Note for Food Authorities in England – Fishery Products

GUIDANCE NOTE FOR FOOD AUTHORITIES IN ENGLAND

FISHERY PRODUCTS

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- 22. The Regulations require that operations such as filleting and slicing must be carried out in a place other than that used for heading and gutting operations. How should this be interpreted?
- 23. Is there a list of approved detergents and similar substances for maintaining general conditions of hygiene in establishments and on equipment?

<u>Fish Farms</u>

24. Are fish farms covered by the Regulations?

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

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

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

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

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

Certain establishments such as those carrying out 'primary production' and 'retail' (as defined in Article 3(7) of Regulation 178/2002) establishments carrying out certain activities are also exempt from the requirement to be approved, although some provisions of Regulation 853/2004 are nonetheless applicable. Primary production establishments exempt from approval, including vessels, are required to comply with Section VIII (Fishery Products) of Regulation 853/2004 as appropriate. Retailers exempt from approval are required to comply with Chapter III, Parts A, C and D, and Chapter IV and V of Section VIII (Fishery Products), of Regulation 853/2004. Section VIII Paragraphs 2 and 3 of Regulation 853/2004 refer respectively.

In order to decide whether a retail activity is or is not exempt from approval, Article 1(5) of Regulation 853/2004 must be considered. If a retail operation consists of transport and storage only then it will not require approval. Although the regulation generally applies to retail when food operations are conducted with the purpose of supplying another establishment, a retail establishment without approval may supply products of animal origin which would normally trigger the need for approval, but only to other <u>retail</u> establishments on a marginal, localised and restricted (see Paragraph A.3.3.2.7).

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

2. What is retail?

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

'retail' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets See also Paragraph A.3.3.2.3.

3. Who is the Final Consumer?

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

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

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

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

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

Auction halls and any units within wholesale markets considered to be 'retail' under the definition would not require approval and would be subject to Regulation 852/2004 only. They would be permitted to supply the final consumer and other <u>retail</u> establishments on a marginal, localised and restricted basis (see Paragraph A.3.3.2.7). Auction halls and units within wholesale markets that do not sell, or deliver, to the 'final consumer' cannot be considered to be 'retail' as defined and as such would need to be approved and would be subject to the relevant requirements of both Regulation 852/2004 and Regulation 853/2004.

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

Individual stalls / units within auction halls and wholesale markets are classed as establishments. If the stall / unit can be considered to be 'retail' as defined (see Q&A 2 and 4, above) and is supplying only the final consumer and other retail establishments on a marginal, localised and restricted basis (see Paragraph A.3.3.2.7) approval would not be required and Regulation 852/2004 only would be applicable. Otherwise, the stall / unit would require approval and would be subject to the relevant requirements of both Regulation 852/2004 and Regulation 853/2004.

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

Establishments falling under the definition of 'retail' as defined (see Q&A 2 and 4, above) which also sell wholesale other than to the final consumer and/or

other <u>retail</u> establishments on a marginal, localised and restricted basis (see Paragraph A.3.3.2.7) would require approval. Such establishments would be subject to the relevant requirements of both Regulation 852/2004 and Regulation 853/2004.

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

Unless they are only selling processed fish to the final consumer and to other <u>retail</u> establishments on a marginal, localised and restricted basis (see Paragraph A.3.3.2.7), retail establishments would require approval and would be subject to the relevant requirements of both Regulation 852/2004 and Regulation 853/2004.

8. Do cold stores need to be approved?

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

Stand-alone Cold stores supplying the final consumer exclusively or supplying retail establishments (including caterers) on a marginal, localised and restricted basis (see Paragraph A.3.3.2.7) are not subject to approval and must therefore be registered under Regulation 852/2004.

9. Do cash and carrys need to be approved?

The definition of 'retail' in Article 3(7) of Regulation 178/2002 (see Q&A 2, above) includes 'wholesale <u>outlets</u>'. Cash and carrys may therefore fall into this category and could, depending on their specific activities, be exempt from the requirements of Regulation 853/2004. Although a wholesale outlet may be considered to be 'retail' as defined, if it is <u>not</u> supplying final consumers exclusively and/or other <u>retail</u> establishments on a marginal, localised and restricted basis (see Paragraph A.3.3.2.7) approval would be required.

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

Owing to the exemption provided by Article 1(2) of Regulation 853/2004, sandwich makers will not be subject to approval under that Regulation if the fishery products they use to make the sandwiches enter their establishment as <u>processed</u> products. However, the processed fishery products used in the production of the sandwiches must be obtained and handled in accordance with the requirements of Regulation 853/2004. Such sandwich makers will still need to comply with the relevant requirements of Regulation 852/2004.

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

Retail fishmongers that sell their own processed products, but only to the final consumer would not be subject to approval under Regulation 853/2004. They would, however, need to comply with Regulation 852/2004. If a retail fishmonger sells their own processed products to other establishments (including those in the same ownership) it will be subject to approval under Regulation 853/2004, unless the other establishments are <u>retail</u> establishments and the supply is marginal, localised and restricted (see Paragraph A.3.3.2.7).

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

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

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

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

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

No.

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

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

16. If an establishment has been approved and the business changes hands, does the new owner need to apply for approval and the business reassessed?

Under Regulation 853/2004, an approval relates to an establishment and not the business occupying the establishment or the food business operator, so

the new operator of an establishment would not have to seek approval in order to continue the activities for which approval was granted as long as there is compliance with the relevant regulations. The new owner is, however, obliged to provide the Competent Authority with up-to-date information on the establishment in accordance with Article 6(2) of Regulation 852/2004 and is therefore obliged to inform the relevant Food Authority of the change in circumstances.

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

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

Conditions of Approval

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

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

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

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

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

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

21. Are communal filleting premises permissible?

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

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

The main requirement under Regulation 853/2004 is to avoid contamination of fillets. There may be a number of ways in which this can be achieved, one of which is to separate operations by time rather than place. As long as the Food Authority is content that contamination of the fillets is prevented then this separation by time may be allowed. We would assume that filleting and slicing is carried out where necessary at a different time or a place other than that where heading and/or gutting is carried out.

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

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

<u>Fish Farms</u>

24. Are fish farms covered by the Regulations?

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

Identification marks

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

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

Landings of fishery products

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

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

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

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

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

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

- Laboratory arrangements for the purpose of carrying out sampling in accordance with the Regulations;
- Documented cleaning schedules with details of any checks, including sampling, carried out by the occupier to establish the efficacy of proposed cleaning and disinfection methods;
- Documented maintenance schedules. These should specify the checks to be carried out and any reporting arrangements;
- Documented pest control arrangements, including copies of any contracts with external pest control companies;
- Details for calibrating and monitoring automatic temperature control equipment, where required by the Regulations;
- Staff hygiene training programme, including records of training undertaken to date;
- Written company policy on staff illness and exclusion from work;

- Medical certificates for all staff;
- Details of traceability system, including checks on incoming raw materials, arrangements for controlling application of the health mark and correct use of commercial documentation. Details should include arrangements for documenting these procedures. It may also be appropriate to request examples of identification marked labels;
- Emergency withdrawal procedure;
- Up to date list of suppliers;
- Up to date list of customers (National, EU, 3rd Country).

ANNEX 8: RAW MILK AND DAIRY PRODUCTS

A.8.1: Introduction

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

A.8.2: Enforcement

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

Requirements in Regulation 5(1)(a) of the Food Hygiene (England) Regulations 2006 relating to the approval of production holdings and the subsequent supervision and inspection of approved production holdings (apart from animal health checks - see below). These are dealt with on behalf of the agency by the Dairy Hygiene Inspectorate (DHI) of the Rural Development Service in DEFRA. Separate guidelines are issued for enforcement of these requirements;

Controls in Regulation 32 of the Food Hygiene (England) Regulations 2006 on the sale of raw cows' drinking milk, i.e. cows' milk that is supplied raw to the final consumer or to distributors, from farms direct to consumers, temporary guests or distributors and standards for such milk in Schedule 6. These are also dealt with by the DHI (the separate guidelines mentioned above also cover enforcement of these requirements); The Department of Environment, Food and Rural Affairs (Defra) is responsible for carrying out official tests for tuberculosis and brucellosis where appropriate.

Food business operators whose operations are both production holdings and processing establishments are approved by the agency as a production holding, and approved by the Food Authority as a dairy establishment.

A.8.3: Food Business Operators Selling Raw Milk and Cream

Article 10(8) of Regulation 853/2004 allows member states to retain national rules on the retail sale of raw milk and cream. Food businesses that are on-farm processors of raw cows' drinking milk (i.e. those wrapping/packing/bottling raw milk) who sell such products exclusively direct to the final consumer (including from their own milk van and at Farmers Markets) are exempt from approval. Article 1(2)(c) also allows for the supply of small quantities to local retail establishments directly supplying the final consumer.

However, such establishments still need to meet the relevant requirements for processing establishments in Regulation 853/2004 and the relevant requirements of Regulation 852/2004.

Processors selling to cash and carry's etc. or to other retail establishments or to distributors that are a separate business must be approved.

The restrictions on sales of raw cows' drinking milk are set out in Schedule 6 of the Food Hygiene (England) Regulations 2006 and are enforced by the DHI at farm level.

Food Authorities are responsible for enforcing the requirements of Schedule 6 of the Food Hygiene (England) Regulations 2006 in respect of sales of raw cows' drinking milk on milk delivery rounds and for enforcing the microbiological standards in respect of sales of raw drinking milk (including raw drinking milk from cows, sheep, goats, buffaloes and other species). Distributors have to be registered with the Food Authority as food businesses.

A.8.4: Reusable Containers

The requirements for equipment to be clean and to disinfect reusable containers mechanically may be difficult to comply with, particularly for some smaller establishments. Dairies that obtain clean bottles from central units will not normally require mechanical bottle washing facilities, providing the clean bottles are not exposed to any risk of contamination during storage and before being filled at the dairy. Bottle washing and storage can take place in the same room where products are handled, but at different times or in a separate area - providing hygiene is not compromised.

A.8.5: Health Requirements for Raw Milk Production

Food business operators are responsible for ensuring that the requirements of Regulation 853/2004, Annex III, Section IX, Chapter 1 are met through private veterinary inspections at regular intervals. The frequency of such inspections will be dependent on the individual circumstances. Such inspections can take place when a farmer's private veterinary surgeon is present for other purposes. Food business operators will need to keep evidence of such visits e.g. a receipt/invoice - and of any follow up action taken if problems occur - for checking by authorised officers. Purchasers (or processors) of raw milk are also required to ensure, e.g. through contracts, that checks have been carried out to assess compliance with relevant animal health standards. Immediate problems that may affect the safety of milk will normally be notified to Food Authorities by private veterinary surgeons or (more rarely) the State Veterinary Service. Longer-term issues arising from records could also be referred to Food Authorities. Where Food Authorities suspect that requirements are not being complied with, or that follow up action has not been taken, they should raise the matter with the purchaser/processor, or in the case of producer/retailers of raw milk with the producer direct, and advise them to take appropriate advice e.g. from their private veterinary surgeon.

A.8.6: Criteria and Standards for Raw Milk

In the case of the standards laid down in Regulation 853/2004, Annex III, Section IX, Chapter III, Paragraph 3 for plate counts and somatic cell counts, the Regulations specify a minimum frequency of sampling by the food business operator or the purchaser. Authorised officers need to ensure that food business operators are carrying out the specified sampling programme. Authorised officers should check Food Business Operators' records, and when

they have concerns about the test results, consider random official checks to satisfy themselves that the required standards are being met. Arrangements relating to milk for heat-treatment are set out in Annex III, Section IX, Chapter II of Regulation 853/2004, as amended by Article 8 / Annex VII(2)(d) of Regulation $2074/2005^{43}$

A.8.7: Temperature Requirements for Milk Used for the Manufacture of Dairy Products

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

A.8.8: Heat Treatment of Raw Milk or Dairy Products

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

A.8.9: Phosphotase Testing

The statutory test method, as detailed in Commission Decision 91/180/EEC⁴⁴ (and as specified in Schedule 11 of the now revoked Dairy Products (Hygiene) Regulation 1995⁴⁵) should continue to be used until further notification.

⁴³ Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 ⁴⁴ Commission Decision 91/180/EEC: Commission Decision of 14 February 1991 laying down

certain methods of analysis and testing of raw milk and heat-treated milk. $^{\rm 45}$ SI 1995 No. 1086, as amended

ANNEX 8, APPENDIX 1: Guidance to Food Authorities in England on Officially Tuberculosis Free Status and Dairy Hygiene Legislation

GUIDANCE TO FOOD AUTHORITIES IN ENGLAND ON OFFICIALLY TUBERCULOSIS FREE STATUS AND DAIRY HYGIENE LEGISLATION

(January 2006)

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Scope

- 1. This guidance has been produced by the Food Standards Agency in consultation with Food Authorities, Defra, The Specialist Cheesemakers' Association and the Institute of Animal Health and updates the version forwarded by the Department of Health to CEHOs with an accompanying letter of 13 March 2000.
- 2. It provides information and advice for Food Authorities in England who have dairy herds and/or dairy establishments in their area producing raw cows' drinking milk¹ (RCDM) and/or unpasteurised milk-based products. The guidance will be of assistance to those involved with investigations following notification from the Department for the Environment, Food and Rural Affairs (Defra) of the loss² of "Officially Tuberculosis Free" (OTF) status of dairy herds.
- 3. This guidance incorporates the changes resulting from the introduction of the Food Hygiene (England) Regulations 2005, which applied from 1 January 2006 and revoked the Dairy Products (Hygiene) Regulations 1995 and were then themselves revoked and replaced, on 11 January 2006, by the Food Hygiene (England) Regulations 2006.

Introduction

- 4. Tuberculosis (TB) is an infectious disease of humans and many animal species, caused by some bacteria of the genus *Mycobacterium*. Most cases of human tuberculosis are caused by *Mycobacterium tuberculosis* (*M. tuberculosis*). TB in cattle is primarily caused by *Mycobacterium bovis* (*M. bovis*), which unlike *M. tuberculosis* has a very broad host range.
- 5. Regular tuberculin testing of dairy herds ensures that most cases of TB in cattle are detected in the early stages of infection, before the development of clinical signs and the shedding of bacteria in milk. *M.bovis* is however responsible for some human infection and the introduction of pasteurisation in the 1930's helped minimise the transmission of TB to man via milk from infected cows. *M.bovis* in humans is now rare around 40 cases a year which is less than 1% of all TB cases in the UK. Most, if not all of these cases are thought to be due to reactivation of disease acquired in the past.
- 6. EC Regulation 853/2004 requires that RCDM must come from animals belonging to a herd which is OTF (Annex III, Section IX, chapter 1,1,2(b)). Milk, which does not satisfy this condition, may only be sold for human consumption after it has been heat-treated (Annex III, Section IX, chapter 1, 3). The State Veterinary Service (SVS) will notify Food Authorities of conditions in a herd that result in the loss of OTF status.

¹ In this context raw cows' milk also includes raw buffaloes milk.

² For the purpose of this guidance and for the purposes of Dairy Hygiene legislation, the herd will have lost OTF status if: a reactor is disclosed by tuberculin testing ("status suspended"); when a reactor is confirmed by post mortem examination and /or bacteriological culture ('status withdrawn'); disclosure of an inconclusive reactor within 3 years of a herd breakdown; or the tuberculin test has become overdue.

Food Authority Enforcement Issues

Action to take on loss of OTF status of a dairy herd

7. When a dairy herd is placed under TB movement restrictions for whatever reason the Divisional Veterinary Manager (DVM) will send a copy of the herd restriction notice (Form 'TB2') to the relevant Chief Environmental Health Officer (CEHO) with a covering letter. Service of the TB restriction notice effectively suspends the OTF status of that herd.

On receipt of the notification, the Food Authority should ensure that milk from the herd is no longer used for raw milk based products. Milk from the affected herd may be used for human consumption providing it has been pasteurised, or subjected to a stronger heat treatment. Processors making raw milk based products must not use milk from the affected herd and will only be able to continue their production of such products by obtaining an alternative source of supply from an OTF herd. From 1 January 2006, milk from individual reactor animals within a herd may not be used for human consumption in any circumstances.

To give effect to this Local Authority Enforcement Officers will need to:

- a) liaise with the first buyer(s) of the milk (primary wholesaler) to establish where the milk from the affected herd is being transported and delivered;
- b) confirm the use of the milk and the cleaning in place systems for the means of transport ;
- c) ensure that all the milk from the affected herd, and any milk with which it may be mixed, will receive adequate heat treatment before consumption or use for milk based products;
- d) establish whether milk from the herd is being sold as raw cows' drinking milk (RCDM);
- e) establish whether the milk is being offered as part of an on-farm B&B business, or in a farm shop, or at a market stall or to a distributor selling raw milk direct to the ultimate consumer; and
- f) establish whether the milk is being used to make unpasteurised milkbased products either on the particular farm or elsewhere.
- 8. These investigations may be facilitated by contacting the appropriate regional office of the Dairy Hygiene Inspectorate (DHI) and if necessary the producer and the milk buyer. This may involve liaison with other Food Authorities, including the Food Authority of the first buyer where appropriate.

9. Where the affected farm has heat treatment facilities installed, the Authority should confirm that all hazard analysis controls are in place and working effectively, including adequate heat treatment.

Action to be taken on stocks of raw milk based products following loss of OTF status

- 10. Food Authorities will wish to consider the public health implications, via a risk assessment undertaken locally with the Consultant in Communicable Disease Control (CCDC) and the DVM, for products made prior to the herd losing its OTF status. Advice should also be obtained where appropriate from the local Health Protection Agency (HPA). If, as a result of the risk assessment, it is concluded that it would be appropriate to withdraw or destroy such products, a voluntary withdrawal/destruction should be pursued. Enforcement Officers will have to decide on appropriate action based on the circumstances of individual cases. The factors to be taken into account in the risk assessment will include:
- 11.1 <u>The reasons for the loss of OTF status.</u> This can be due to the disclosure of test reactors, inconclusive reactors only, a slaughterhouse case, or an overdue TB test (see footnote 2).
- 11.2 <u>Number of reactors identified.</u> This would be the number of reactors in relation to the total herd size and numbers of cattle tested. A single or a low number of reactors in a large herd may represent a lower risk, since it may indicate that the infection has not had time to spread within the herd. A large number of reactors in any herd could indicate either a long term spread within the herd or multiple infections linked to a common source. Herds with larger number of reactors at the initial test are more likely to have additional reactors disclosed at the next test.
- 11.3 <u>Types of cattle reacting to the test.</u> For example, heifers or bullocks being non-milk-producing animals would be of less significance.
- 11.4 <u>The number and location of any lesions found at post mortem examination (PME) and tissue culture results.</u>
 a) If no TB lesions are found, or lesions are confined to one organ or one part of the body other than the mammary gland, the risk of TB bacilli being present in milk would be considered low. If TB lesions were found in the mammary gland or in more than one organ or part of the body in a lactating dairy cow, the risk of TB bacilli being present in milk would be considered significant. TB bacilli being present in milk even in the absence of obvious udder disease when the disease has been distributed systemically.</u>

b) Following PME tissue samples are collected from all reactors, including those where no visible lesions were found. Tissue culture takes a minimum of 6 weeks to positively identify *M. bovis*, with approximately 10% of reactors with no visible lesions at PME yielding a positive culture of *M. bovis*.

- 11.5 <u>Testing history of the individual herd</u>. Aspects to consider include:
 - a) time elapsed since the last clear TB test;
 - b) previous TB history of the herd; and
 - c) the reason for the test.
- 11.6 <u>The baseline testing frequency for the civil parish.</u> This provides an indication of whether the herd is in a high TB prevalence area. The SVS case veterinary officer will provide expert opinion and judgement of the TB incidence in the locality.
- 11.7 <u>General herd health and herd bio-security.</u> Consideration should also be given to:
 - a) milk somatic cell counts higher cell counts may indicate a higher likelihood of TB organisms being present in the milk; and
 - b) animal trading record for the farm, highlighting numbers brought in, from where and their last TB test date (this is important because it takes a minimum of 6 weeks from the time of infection for an animal to react to the tuberculin test).
- 11.8 <u>Type(s) of milk-based product and production process.</u> For example, the use of bought in milk may make it more difficult to establish the necessary herd information. Consideration should be given to any scientific evidence, including that provided by the milk processors, that the production process may eliminate the pathogens and that TB organisms are absent from the product.
- 11.9 <u>Fresh milk products.</u> The shelf life of the product may have been exceeded by the time the post-mortem report or tissue culture results are received.
- 11.10 <u>Size of the TB restricted herd</u>. The likelihood, severity and duration of TB incidents tends to increase as herd size increases. Although this trend has been identified the affect is difficult to quantify and therefore the other factors detailed above are of greater significance for the risk assessment.
- 12. Where there is evidence of active disease in an animal, then it is likely that withdrawal of batches of the product produced before the date of TB testing would be appropriate as a precaution. The case Veterinary Officer dealing with the TB incident is often the person best placed to provide information and assist the Food Authority with the risk assessment.
- 13. The Regulations do not prohibit the marketing of products made before the removal of OTF status. If a voluntary solution cannot be concluded with the producer any action taken will need to be under the Food Safety Act 1990 (as amended) and the General Food Regulations 2004. Enforcement Officers may consider further action under Section 9 of the Act if they suspect that the products concerned fail to comply with food

safety requirements as defined in Article 14 of EC Regulation 178/2002 on general food law. It would however be necessary, for any prosecution to succeed, to prove that an offence had occurred under regulation 4 of the General Food Regulations 2004. This makes it an offence to contravene Article 14 of EC Regulation 178/2002.

Action to take before OTF problems arise

- 14. Food Authorities and the DHI should liaise with DVMs to ensure that herds supplying RCDM and/or establishments or processors manufacturing unpasteurised dairy products are tuberculin tested annually. For example, Food Authorities and the DHI should notify DVMs when they become aware of the sale of RCDM for human consumption or the production of unpasteurised dairy products in their area. Food Authorities should advise manufacturers producing unpasteurised dairy products that the law requires that the milk they use may only come from herds classified as OTF. Therefore, enforcement officers should verify that those processors who buy in milk are able to produce evidence that the milk they purchase only comes from dairy herds that are tested annually for TB and are classified with OTF status. Food Authorities should contact the DVM who will be able to supply further information about these issues.
- 15. Food Authorities may find it helpful to liaise with Local Authority Animal Health and Welfare Inspectors as their responsibilities include checking farm records under animal health legislation.

Contacts

- 16. For detailed guidance on dealing with human cases or contacts please refer to the Department of Health's "Guidance on Management of the Public Health Consequences of TB in Cattle". For copies of the guidance telephone 020 7972 5672.
- 17. If further advice is needed on the action to be taken on stocks of raw milk based products following the loss of OTF status Food Authorities should contact the Food Standards Agency Food Incident Branch, telephone number 020 7276 8448, who will work with the local investigation team.
- 18. If more information is required on Defra procedures concerning TB controls in England and Wales, you should contact the duty Veterinary Officer at the local Animal Health Divisional Office of the SVS.
- 19. Additional details may be found on the following web sites:

http://www.defra.gov.uk/animalh/tb/index.htm

http://www.hse.gov.uk/hthdir/noframes/bovine.htm

http://www.hpa.org.uk/infections/topics_az/tb/infosheets/english.pdf

http://www.lacors.gov.uk

ANNEX 1

Legislative Background and Human Health

Raw cows' drinking milk and unpasteurised milk-based products

- 1.1 EC Regulation 853/2004, Annex III Section IX, Chapter 1,1,2(b) requires that RCDM must come from animals belonging to a herd which is officially tuberculosis free. Annex III Section IX, Chapter 1,1,3 requires that milk which does not satisfy this condition may only be sold for human consumption after it has been heat treated.
- 1.2 Where Food Authorities investigating a notification of the loss of OTF status become aware that milk is being sold raw for direct human consumption, they must consider taking action (Annex III Section IX, Chapter 1,1.3 of EC 853/2004) to ensure that milk from herds that have lost their OTF status is heat treated. Annex 3 provides a draft form, which may be used by Food Authorities to remind milk producers of this requirement.
- 1.3 Heat treatment notices previously made under the Milk and Dairies (General) Regulations 1959 no longer apply as the Food Hygiene (England) Regulations 2005 revoked the Milk and Dairies (General) Regulations 1959 (and were themselves revoked and replaced, on 11 January 2006, by the Food Hygiene (England) Regulations 2006).
- 1.4 While the law requires that raw milk based products may only be manufactured with milk from herds classified as OTF the Regulations do not prohibit the marketing of products made before the removal of OTF status. If a voluntary solution cannot be concluded with the producer any action taken will need to be under the Food Safety Act 1990 and the General Food Regulations 2004 (see paragraph 13).

Cases of human illness

1.5 In the event of a CCDC being notified that a person(s) has confirmed bovine TB, and the infection is thought to be recently acquired, the CCDC should ascertain any connection with cattle that might indicate the infection could have been caught from an animal source or could be passed to animals. If so they should inform the Food Authority. If there is a risk that a herd and/or other farm stock could be infected then the enforcement officer should notify the DVM so that checks can be made on the herds. It may also be appropriate to notify other relevant Food Authorities, local farmers, dairies and producers, milk buyers or distributors that might be affected (with due regard for patient confidentiality).

ANNEX 2

Animal Health Issues and the Role of the SVS (Defra)

M. bovis infection in cattle

- 2.1 Tuberculosis (TB) in cattle is caused by *Mycobacterium bovis (M.bovis*) and bovine TB can affect other species such as deer and badgers. Humans can also be affected, although this is now rare in the UK. In the past infection from raw milk occurred, but now with regular testing of herds, slaughter of reactors and milk pasteurisation, human cases are relatively rare and usually thought to be due to the reactivation of disease contracted earlier, for example before milk pasteurisation was widely in use, or, occasionally, infection contracted abroad. Regular testing of cattle on the farm detects most cases early, before the organism is shed in milk. The bacteria can be inhaled in aerosols from the lungs of infected cattle, or ingested through drinking contaminated raw milk or consuming contaminated unpasteurised milk-based products.
- 2.2 In recent years, TB in cattle has increased in the UK in both numbers and geographic spread. Since the early 1980s the number of herds reported each year where the OTF status has been withdrawn has steadily increased. This initially affected mainly the southwest of England, but in recent years has spread to parts of South Wales and the West Midlands.
- 2.3 The routine tuberculin skin testing of herds is a key part of TB control in cattle in the UK. Any animal showing a positive reaction (i.e. a "reactor") to this test is slaughtered and compensation paid. Slaughtered reactors undergo post-mortem and lymph node and other tissue samples are collected for culture of the organism to identify the strain of *M. bovis* responsible for the incident. Less than half of positive test reactors are found to have visible lesions or a positive culture for *M.bovis*. The Meat Hygiene Service also routinely examines all carcasses at abattoirs for macroscopic lesions of TB as part of general meat inspection.

Routine testing of herds

- 2.4 Most TB testing in Great Britain is carried out by Local Veterinary Inspectors (LVIs). These are veterinarians in private practice appointed by Defra to carry out specific statutory duties. Veterinary Officers of the SVS undertake some of the follow-up tests in herds under TB restrictions and the re-testing of inconclusive reactors. The SVS is responsible for the day to day administration of the tuberculin testing programme, the supervision of LVIs and the management of TB incidents. The latter includes notification of a new TB incident to the relevant environmental and public health officials. Where individual farmers have agreed with the local Defra DVM that they wish to pay for private testing outside of the routine testing, the farmer must notify the DVM of the results accordingly.
- 2.5 Farmers may wish to carry out private tests, for instance on purchased animals, to clarify their TB status. Additionally, more frequent testing could be viewed as providing an early indication of problems for producers of

unpasteurised cows' milk and raw milk-based products intended for consumption in that state. Pre-movement TB testing of any purchased cattle would provide an additional safeguard against the introduction of infection in the herd.

- 2.6 Most British cattle herds are routinely tested at 4-year intervals, but in some parts of the country, where the incidence of confirmed TB herd breakdowns is greater, TB testing is carried out more frequently. Cattle herds in Scotland, North Wales and most of the North and East of England remain on 4-yearly testing. There are some parts of the country where testing can be annually, 2-yearly or 3-yearly.
- 2.7 The frequency of routine TB testing is broadly based on the incidence thresholds set out in Council Directive 64/432/EEC (as amended). This testing is essentially for animal health/disease control purposes, and Defra is responsible for the testing policy. The default testing frequency in any given parish is set by the DVMs according to the number of confirmed TB herd breakdowns. In general, the higher the incidence of confirmed herd breakdowns of unexplained origin in a given parish, the shorter the interval between two consecutive routine TB tests for all the herds in that parish. Furthermore, DVMs can place individual herds on an annual TB testing regime on animal or public health grounds, regardless of the default routine testing frequency for their parish. Examples of such herds are: cattle dealers' and bull hirers' herds, herds with a regular intake of cattle from areas with a high incidence of TB, retailers of RCDM and, where this information is available to the DVM, suppliers of milk for the manufacture of unpasteurised dairy products.

Finding a TB reactor

- 2.8 Disclosure of tuberculin test reactors at a routine herd test is the most common reason for the service of TB restrictions by the SVS, but other situations may also lead to the suspension of the OTF status of a herd. These include detection by the Meat Hygiene Service of suspect lesions of TB at routine meat inspection in the abattoir; disclosure of inconclusive reactors within three years of the resolution of a confirmed TB incident; or the tuberculin tests becomes overdue. Service of the TB restriction notice (Form TB2) effectively suspends the OTF status of that herd. When a dairy herd is placed under TB movement restrictions for whatever reason the DVM will inform the relevant Chief Environmental Health Officer (CEHO). Automated letter distribution systems are being introduced but EHOs and the DVM should develop strong working relationships to ensure effective communications at a local level are established.
- 2.9 All tuberculin test reactors are sent under licence for compulsory slaughter. When reactors are slaughtered and herd restrictions applied, the DVM will make arrangements to re-test the herd at 60 day intervals until negative herd tests are obtained (one test when disease is not confirmed, two tests when confirmed). Following a programme of clear skin testing, movement restrictions will be lifted, thereby restoring the herd's OTF status. The DVM will notify the CEHO when the OTF status of a dairy herd has been regained.

Food Law Practice Guidance

Laboratory confirmation of TB

- 2.10 TB incidents (also known as herd breakdowns) are confirmed when at least one reactor animal in that herd presents with visible lesions of TB at post-mortem examination and/or when *M. bovis* is isolated by bacteriological culture from selected tissue samples. Additionally, a TB incident can also be confirmed when suspect lesions are found in carcasses of clear testing cattle during routine meat inspection and those lesions yield *M. bovis* on culture.
- As indicated in 2.9 above, all reactors are slaughtered and undergo post-2.11 mortem examination for confirmation of infection. On average, less than half of these animals are found to have visible lesions on post-mortem examination. The remainder are called "no visible lesion" (NVL) reactors. A small proportion of those NVL reactors may be due to false positive tuberculin tests, but the majority represent cattle at an early stage of infection, where the lesions of TB are too small to be detectable by visual inspection of the carcass. The SVS will collect appropriate tissue samples submission to the Veterinary Laboratories Agency, for where bacteriological culture of *M. bovis* will be attempted. In NVL reactors, a pool of apparently normal lymph nodes is collected to attempt the isolation of *M. bovis* by bacteriological culture and thus confirm the infection. In reactors with visible lesions, infection is automatically confirmed and the main reason for taking samples of the lesions is to undertake molecular typing of the *M. bovis* strain responsible for the incident. The outcomes of the post-mortem and bacteriological culture determine the number of 60day interval tests that must be carried out in the remainder of the herd before TB restrictions can be lifted. Laboratory confirmation of TB by culture will take a minimum of 6 weeks. It could take longer if samples are contaminated.
- 2.12 The DVM will notify CEHOs of all TB incidents (whether subsequently confirmed or not) in dairy herds so that checks can be made and action taken under food hygiene regulations⁴. The DVM will notify the CCDC of confirmed TB incidents in any herd, for human health screening purposes. A courtesy copy of the notification of confirmed TB is often sent to the CEHO. In the unlikely event of TB of the udder being found on postmortem examination, both the CEHO and the CCDC will be notified by the DVM.

Inconclusive Reactors

2.13 On occasions the result of the skin test on animals will be in an intermediate range between positive and negative. These animals are classed as inconclusive reactors (IRs). Cattle may react in this way for a number of reasons including stress or exposure to other diseases but experience has shown that the majority of inconclusive reactions are non specific and resolve at the first or second retest.

⁴ EC Regulations 852/2004 and 853/2004

- 2.14 In herds where there has been a recently confirmed TB breakdown (within the last 3 years), finding an IR results in the whole herd being placed under restrictions and the OTF status of the herd is suspended. CEHOs will be notified of these situations and all milk from the herd must be heat treated.
- 2.15 In herds where there is no recent history (within the last 3 years) of confirmed TB, IR animals are isolated and re-tested after 42 60 days. There are no restrictions regarding milk from the animals and OTF status of the herd is not compromised. If the inconclusive cattle retest negative, the DVM will permit the animal to rejoin the herd. If the second test is also inconclusive a third and final test will be carried out after another 42 60 days and unless this test is clear the animal will be reclassified as a reactor and slaughtered. The herd will then be classed as a confirmed TB breakdown.
- 2.16 If IRs re-test positive at either stage they are classed as reactors, OFT status is lost and the animal(s) will be slaughtered. Post-mortem examinations are carried out on all carcasses at the slaughterhouse and samples will be sent for culture.

ANNEX 3

Model form for use following loss of OTF status for milk producers

NAME OF OCCUPIER ADDRESS NAME OF LOCAL AUTHORITY ADDRESS TELEPHONE NUMBER

Milk from herds that have lost their Officially Tuberculosis Free (OTF) Status and milk from TB reactor animals

When a dairy herd is placed under TB movement restrictions, the herd effectively loses its Officially Tuberculosis Free status. This occurred to your herd when the TB2 notice was served on [xxxx] by [xxxx]. Milk from the above premises must therefore be pasteurised or subjected to a stronger heat treatment before it may be sold for human consumption, or used in the manufacture of products for human consumption. Milk heat treated in such a way will show a negative reaction to the phosphatase test. In addition, milk from any individual reactor animal must be withheld and must not be used for human consumption

Further please be advised that any person who sells or uses milk or milk-based products in breach of Article 4 (1) of Regulation (EC) 853/2004 may be convicted of an offence under the Food Hygiene (England) Regulations 2006. The legislative rules detailing the herd health requirements for raw milk production are contained in Annex III, Section IX, Chapter I of Regulation (EC) No. 853/2004. Annex III, Section IX, Chapter I, 3(a) requires that raw milk from animals that do not belong to an Officially Tuberculosis Free herd may, with the authorisation of the Competent Authority, only be used for human consumption after having undergone a heat treatment such as to show a negative reaction to the phosphatase test.

To safeguard your own health, that of your family or staff it is strongly recommended that you do not drink or use unpasteurised milk in your home.

Signed

Environmental Health Services

Date _____

ANNEX 9: EGG PRODUCTS AND LIQUID EGG

A.9.1: Introduction

This Annex provides specific guidance to Food Authorities on the enforcement of Section X, Chapter II of Regulation 853/2004. This lays down the public health rules for the manufacture and placing on the market of egg products and liquid egg for human consumption.

The Regulations lay down requirements for:

- establishments;
- raw materials for the manufacture of egg products;
- special hygiene requirements for the manufacture of egg products;
- analytical specifications; and
- labelling and identification marking.

A.9.2: Scope of the Regulations

The Regulations apply to establishments manufacturing egg products and liquid egg for human consumption, which would be food businesses involved in the production of:

- processed products resulting from the processing of eggs, or various components or mixtures of eggs, or from the further processing of such processed products; or
- liquid egg for onward transportation to approved processing establishments.

All establishments need to be approved if the Regulations apply to them.

None of the requirements in Section X, Chapter II of Regulation 853/2004 apply to retail, as defined by Regulation 178/2002, so establishments such as bakers and caterers that process eggs are not subject to any of the requirements of Regulation 853/2004.

A.9.3: Types of Approved Premises

Premises requiring approval fall into two categories:

- (i) premises where egg products are manufactured and placed on the market, i.e. where processing takes place; and
- (ii) premises where liquid egg is produced for later processing by an approved egg product manufacturer, i.e. egg producers or packing centres.

Category (ii) exists because egg packing centres may prefer to break out eggs, including cracked eggs, to produce liquid egg rather than risk breakage before they are sent to a category (i) processing establishment. Such approvals must require that the eggs are broken out as soon as possible and the resulting liquid egg frozen or chilled for transport to another approved establishment. If chilled, the storage temperature must not exceed 4°C and the storage period before processing must not exceed 48 hours. Any establishment approved for category ii) only, must comply with the same requirements for approval as egg product manufacturers in category i). When notifying the agency of approvals, the Authority should specify whether the approval is for i) or ii) and if the premise is also a packing centre.

A.9.4: Dirty Eggs

Eggs may not be broken out unless they are clean and dry. Dirty eggs may be cleaned, but Authorities must ensure that any washing, drying and disinfecting of eggs is separated from all other operations of the business.

A.9.5: Centrifuging or Crushing

The Regulations prohibit the use of centrifuges or crushing to obtain egg contents or obtain egg whites from shells for human consumption. However, centrifuges may be used for the disposal of waste, and in such cases, the centrifuge must be situated completely separately from other operations of the approved establishment. Authorised officers should satisfy themselves that centrifuged material cannot contaminate egg products intended for human consumption. Waste material must be denatured upon entry to the centrifuge, for example by use of a dye.

A.9.6: Identification Marking

The general requirements for identification marking laid down in Annex II, Section I of Regulation 853/2004 must be complied with and are set out in Chapter 5.1 of the Code. However, there are additional specific requirements for egg products. Regulation 853/2004, Annex III, Section X, Chapter II, Part V requires that consignments of egg products to be used as an ingredient in the manufacture of another product must have a label giving the temperature at which the egg products must be maintained and the period during which conservation may thus be assured.

A.9.7: Pasteurisation and Heat Treatment

The Regulations do not prescribe a time / temperature combination for the heat treatment of eggs, but they do require that the process must eliminate microbiological hazards or reduce them to an acceptable level. Processing is not required for egg white intended for the manufacture of dried or crystallised albumen destined subsequently to undergo heat treatment.

Food Authorities will need to be satisfied that the heat treatment process is sufficient to ensure a reduction in the level of micro-organisms in the egg product to any levels laid down in EC Regulations on microbiological criteria.

Where a non-standard process is proposed, the onus is on the occupier to show that adequate research has been carried out into its effectiveness. In establishments where heat processing takes place, Food Authorities should establish that the operator of the heat process has an acceptable and appropriate level of expertise.

A.9.8: Analytical Specifications

Part IV of Annex III, Section X, Chapter II of Regulation 853/2004 lays down analytical specifications that the end product must not exceed. Although there are no prescribed EU methods for testing for lactic or butyric acids, methods do exist. Where such methods are used, due consideration should be given to the reliability of the results. Where samples are tested, the results should be compared with the standards specified.

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

A.9.9: Temperature Control

The Regulations require that products that have not been stabilised so as to be kept at room temperature must be cooled to not more than 4°C. Products for freezing must be frozen immediately after processing.

A.9.10: Storage and Transport

Establishments must keep eggs and egg products separate to avoid contamination. If separate rooms are not available, egg products may be stored in separate containers and areas.

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

The Regulations do not cover egg products that are stored in separate establishments such as depots or warehouses outside approved egg products establishments. Such storage is covered by Regulation 852/2004.

A.9.11: Egg Marketing (See also Annex 10)

Egg packing centres, whether or not approved to produce liquid egg under the Regulations, are the responsibility of Defra in respect of egg quality and marketing regulations and are inspected by Egg Marketing Inspectors (EMIs).

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

ANNEX 10: EGG PACKING CENTRES

A.10.1: Introduction

This annex provides specific guidance to Food Authorities for the enforcement of Annex III, Section X, Chapter 1 of Regulation 853/2004.

In addition to the relevant requirements of Regulation 852/2004, this part of the aforementioned Regulations lay down requirements for egg packing centres covering:

- hygiene and temperature requirements for the storage and transport of eggs
- the maximum time limit in which eggs must be delivered to the consumer

A.10.2: Scope of the Regulations

The Regulations apply to establishments engaged in the following activities:

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

The production and collection of eggs at the producer's establishment are activities that take place at the primary production level. Enforcement of the Regulations at this level will be the subject of future guidance.

Under the terms of the EU hygiene legislation, egg packing centres are not classed as primary producers, as they are engaged in activities one step removed from primary production. This has been confirmed in Commission guidance. Therefore, in addition to the specific egg hygiene provisions contained in Regulation 853/2004, egg-packing centres will be subject to the appropriate provisions of Regulation 852/2004, including the Article 5 HACCP requirements and the relevant chapters of Annex II. Egg packing centres will also need to be approved, as they will be covered by Article 4(2) of Regulation 852/2004. They will also be subject to the official controls set out in Article 4 of 882/2004.

Egg packing centres will be receiving eggs from primary production units. From the packing centre, eggs will be distributed throughout the food distribution chain – to wholesalers, retailers and the catering trade. Packing centres may also be sourcing eggs from a number of different production sites and may even take bulk supplies of eggs from the wholesale market and repackage them into smaller containers. All of this is acceptable as long as the provisions of the food hygiene regulations are not breached. Packing centres have an important role to play in ensuring eggs are delivered to the consumer in good condition. Egg wholesalers, while subject to the requirements of Annex III, Section X, Chapter 1 of Regulation 853/2004, are not required to be approved as European Commission guidance has indicated wholesaling comes within the definition of retail activity, which is exempt from approval. However, if an egg packing centre sells eggs on a wholesale basis, then approval is required for the area of the establishments involved in packing eggs.

A.10.3: Specific Hygiene Requirements for Shell Eggs

The specific requirements set out in the Regulations are:

- At the producer's establishment, and until sale to the consumer, eggs must be kept clean, dry, free of extraneous odour, effectively protected from shocks and out of direct sunshine;
- Eggs must be stored and transported at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties;
- Eggs must be delivered to the consumer within a maximum time limit of 21 days of laying.

These specific requirements are self-explanatory' save for the requirement to deliver eggs to the final consumer within 21 days from laying. It is not possible to determine the age of an egg directly and any legal requirement to provide the date of lay or the age of an egg is covered in egg marketing legislation. Eggs and their packaging may be stamped with 'best before dates', 'use by dates' or 'date of minimum durability'. On the basis of this information, if an enforcement officer suspects eggs are being sold beyond the time limit required on food safety grounds, they should examine documentation from the egg producer to determine the age of an egg. He should also contact his egg-marketing inspector (EMI) for further guidance and help in taking the appropriate action. From a hygiene perspective, eggs need to be used within 28 days of lay. Retailers need to sell fresh eggs to the public within 21 days so that consumers have 7 days in which to use the eggs.

A.10.4: Non-UK eggs

Wholesalers or packers are allowed to source eggs from any country within the EU. All eggs from any EU country should comply with requirements in Annex III, Section X, Chapter 1 of Regulation 853/2004.

A.10.5: Egg Marketing

Egg producers, packing stations, and wholesalers are also subject to egg quality and marketing regulations. These regulations are the responsibility of DEFRA/SEERAD. Inspections under these regulations are carried out by egg marketing inspectors. It is recommended that enforcement officers should liaise with their respective egg-marketing inspector prior to inspecting egg packing stations and wholesalers.

A.10.6: Lion scheme and other industry-led quality assurance schemes

There are a number of industry based quality assurance schemes operating throughout the UK, particularly the 'Lion Scheme'. The Lion Quality Code incorporates food safety procedures based on the Food Hygiene Regulations but also includes additional requirements. These include compulsory vaccination against Salmonella Enteritidis of all pullets destined for flocks producing 'Lion eggs'. The Lion scheme also has a "best-before" date stamped on the shell as well as on the pack. In addition, there is the "Laid in Britain" scheme offered to independent egg producers who are members of UKEP, the UK Egg Producers Association Ltd. With these schemes, there are additional on-farm and packing station hygiene controls including a compulsory HACCP plan for packing stations. The regular inspections of egg packing and production sites by independent inspectors are part of these schemes but are different to food authorities or the EMI and the Eggs and Poultry Unit (EPU) of SEERAD inspections. Enforcement officers may wish to take into account these assurance schemes in developing a risk-based approach to inspections.

ANNEX 11: APPROVAL OF PRODUCT-SPECIFIC ESTABLISHMENTS SUBJECT TO APPROVAL UNDER REGULATION 853/2004 - TEMPLATE FORMS

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

Practice Guidance Reference	Template Form
A.11.1	Application for Approval
A.11.2	Notification of Grant of Full Approval / Conditional Approval
A.11.3	Notice of Decision Not to Grant Approval
A.11.4	Notice of Decision to Withdraw Approval / Conditional Approval
A.11.5	Notice of Decision to Suspend Approval / Conditional Approval
A.11.6	Notification of Refusal to Grant Full Approval to an Establishment which is Conditionally Approved

As stated in Paragraph 5.1.5 of the Code of Practice, although the content of these documents should be regarded as the minimum required, Food Authorities may adapt them as necessary to meet local requirements.

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

To be completed by the food business operator

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

PART 1 - Establishment for which approval is sought

Trading name	
F ollow a state	
Full postal Address	
	Postcode:

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

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

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

PART 3 – Food business operator and management of the establishment

Name and full Address of Food Business Operator	
	Postcode:
Tel (Incl. Dialling code) Fax (incl. Dialling code)	

E-mail			
Full names of managers of the establishment Job titles	1. 1.	2. 2.	3. 3.
Full Names of others In control of the business Job titles	1. 1.	2. 2.	3. 3.

PART 4 – Use of the establishment

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

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

PART 5 – Transport of products from the establishment

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

Your own vehicle(s) Contract / Private Haulier

Purchaser's own vehicle(s)

Other (please specify)

PART 6 – Supply of products from the establishment to other establishments

Which of the following will be supplied with products from the establishment (tick all that apply)?

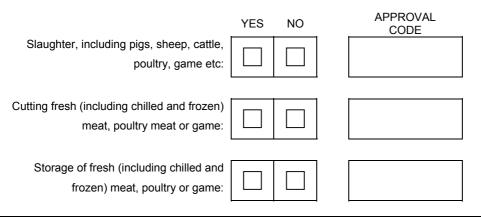
Other businesses that manufacture or process food
Wholesale packers
Cold stores that are not part of the establishment to which this application relates
Warehouses that are not part of the establishment to which this application relates
Restaurants, hotels, canteens or similar catering businesses
Take-away businesses

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Retail shops, supermarkets, stalls, or mobile vendors that you own
Retail shops, supermarkets, stalls, or mobile vendors that you do not own
Members of the public direct from the establishment to which this application relates
Other (please specify)

PART 7 - Other activities on the same site

Will any of the following activities be conducted on the same site as, or within, the establishment to which this application for approval relates?



PART 8 – Information and documentation

The following information is required in order to process your application and should be sent with this application form if possible. Please indicate which information you are sending now (N.B. information that is not sent now will still be required before your application can be determined).

A detailed scale plan of the (proposed) establishment showing the location of rooms and other areas to be used for the storage and processing of raw materials, product and waste, and the layout of facilities and equipment
A description of the (proposed) food safety management system based on HACCP principles
A description of the (proposed) establishment and equipment maintenance arrangements
A description of the (proposed) establishment, equipment, and transport cleaning arrangements
A description of the (proposed) waste collection and disposal arrangements
A description of the (proposed) water supply
A description of the (proposed) water supply quality testing arrangements
A description of the (proposed) arrangements for product testing
A description of the (proposed) pest control arrangements
A description of the (proposed) monitoring arrangements for staff health
A description of the (proposed) staff hygiene training arrangements
A description of the (proposed) arrangements for record keeping
A description of the (proposed) arrangements for applying the identification mark to product packaging or wrapping

PART 9 - Products to be handled in the establishment / activities

Which of the following activities will be conducted in the establishment? Indicate by giving the approximate quantities to be handled in kilograms or litres per week (tick all that apply).

PART 9(1) – Minced Meat and Meat Preparations

Handling minced meat

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Handling meat preparations

Full details of activities and specific products handled

How many tonnes of minced meat in total will be handled in the establishment per week on average?

How many tonnes of meat preparations in total will be handled in the establishment per week on average?

PART 9(2) – Mechanically Separated Meat

Full details of activities and specific products handled

How many tonnes of mechanically separated meat in total will be handled in the establishment per week on average?

PART 9(3) – Meat Products

Full details of activities and specific products handled

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

PART 9(4) - Live Bivalve Molluscs (Shellfish) / Fishery Products

Full details of activities and specific products handled

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

PART 9(5) – Raw Milk / Dairy Products

Raw Milk

Dairy Products

Full details of activities and specific products handled

How many litres of Raw Milk will be handled in the establishment per week on average?

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

PART 9(6) – Eggs (not Primary Production) / Egg Products

Full details of activities and specific products handled

How many tonnes of Eggs will be packed in the establishment per week on average?

How many litres of Egg Products will be handled in the establishment per week on average?

PART 9(7) – Frogs' Legs and Snails

Frogs' Legs Snails

Full details of activities and specific products handled

How many tonnes of frogs' legs in total will be handled in the establishment per week on average?

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

PART 9(8) – Rendered Animal Fats and Greaves



Rendered Animal Fats

Greaves

Full details of activities and specific products handled

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

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

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



Treated Stomachs

Treated Bladders

Treated Intestines

Full details of activities and specific products handled

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

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

PART 9(10) – Gelatine

Full Details of Activities

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

PART 9(11) – Collagen

Full Details of Activities

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

PART 9(12) - Stand-alone Cold Store

Full details of activities and specific products handled

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

PART 10 – APPLICATION

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

Signature of Food Business Operator	Date	
Name in BLOCK LETTERS		

If you need any help or advice about how to complete this form, or about the products to which the Regulation relates, or the circumstances in which approval under the Regulation is required, please contact the officer named below.

When you have completed this form and collected the other information required, please send it to:

Contact Name:

Telephone:

IMPORTANT Please notify any changes to

the details you have given on this form, in writing to the

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Fax:

E-mail:

Notification of Grant of Full Approval / Conditional Approval* of a Food Business Establishment Subject to Approval under Regulation (EC) No. 853/2004

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

PART 1 – Name and address of food business operator

TO:	IMPORTANT	
	You must notify any change to the details on this form, including any changes in the operations carried out and products handled in the establishment, in writing to the approving Food Authority at the address shown.	[Food Authority Logo]

PART 2 – Introduction

Further to your application dated for approval of your establishment in accordance with Regulation (EC) No. 853/2004, approval / conditional approval* is GRANTED in respect of the establishment shown in Part 3, and the scope of operations, activities and other matters set out in the relevant Parts of this document.

The approval code that has been allocated to this establishment is shown at the end of this document. It must be used in the format stipulated by, and when required by, Regulation (EC) No. 853/2004.

In accordance with Regulation 12 of the Official Feed and Food Controls (England) Regulations 2006, any person who is aggrieved by a decision of a Food Authority not to grant a full approval may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notice was served on you. You may wish to consult a legal adviser about the implications of this notice and your right of appeal against this Food Authority's decision on your application. The name and address of the Magistrates Court at which you should lodge your appeal is

PART 3 – Trading name and address

Trading name of establishment	
Full postal address	
	Postcode:
The establishment h 882/2004.	has been APPROVED in accordance with Article 31(2)(c) of Regulation (EC) No.
The establishment Regulation (EC) No.	has been CONDITIONALLY APPROVED in accordance with Article 31(2)(d) of 882/2004.
PART 3(1) – Conditional A	pproval (To be completed when conditional approval has been granted)

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

Regulation / Article No.	Requirement

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

Regulation / Article No.	Details of non-compliance	

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

Regulation / Article No. Measures needed to secure compliance	

In accordance with Article 31(2)(d) of Regulation (EC) No. 882/2004, this Food Authority will visit your establishment within three months of this conditional approval being granted in order to make an assessment of progress in complying with the above requirements.

PART 4 – Food business operator

Name and full address of Food Business Operator	
	Postcode:

PART 5 – Scope of approval / conditional approval*

This approval/conditional approval* authorises the handling of the following type(s) of product in the establishment shown in Part 3 of this document in respect of the specific activities and products detailed below:

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

The establishment shown at Part 3 has been granted the following derogations:

Approval C	ode:	
Date Appro Conditional Appro Gran		
Sig	ned:	
Na	ame:	
Designa	tion:	
Ľ	Date:	
Name and address of Food Authority:	Contact Name:	IMPORTANT
	Telephone:	You must notify any change to the details on this form, including any
	Fax:	changes in the operations carried out and products handled in the establishment, in writing to the approving Food Authority at the
	E-mail:	address shown.

* Food Authority to delete as appropriate

Notice of Decision to REFUSE to Grant Approval to a Food Business Establishment Subject to Approval under Regulation (EC) No. 853/2004

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

PART 1 – Name and address of food business operator

то:	IMPORTANT	
	You must not use the establishment detailed in Part 3 for ANY purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004 unless this Food Authority has granted approval or conditional approval.	[Food Authority Logo]

PART 2 – Notification of decision

Further to your application dated for approval of your establishment in accordance with Regulation (EC) No. 853/2004, approval is REFUSED in respect of the establishment shown in Part 3, and the scope of operations, activities and other matters set out in the relevant Parts of this document.

The decision to refuse your application was made for the reason(s) set out in Part 4 of this document.

The establishment must therefore not be used for any purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004 <u>UNLESS THIS FOOD AUTHORITY GRANTS</u> <u>APPROVAL OR CONDITIONAL APPROVAL</u>.

In accordance with Regulation 12 of the Official Feed and Food Controls (England) Regulations 2006, any person who is aggrieved by a decision of a Food Authority to refuse to grant an approval may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notice was served on you. You may wish to consult a legal adviser about the implications of this notice and your right of appeal against this Food Authority's decision on your application. The name and address of the Magistrates Court at which you should lodge your appeal is

PART 3 – Trading name and address of the establishment		
Trading name of establishment		
Full postal address		
	Postcode:	

PART 4 – Reasons for refusal

Your application for approval has been refused because you have failed to comply with the requirements of the Regulations as indicated below.

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

Regulation / Article No.	Requirement

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

Regulation / Article No.	Details of non-compliance

Signed:	
Name:	
Designation:	
Date:	

Name and address of Food Authority:	Contact Name:	IMPORTANT
	Telephone:	You must not use the establishment detailed in Part 3 for ANY purpose which would render the
	Fax:	establishment subject to approval under Regulation (EC) No. 853/2004 unless this Food Authority has
	E-mail:	granted approval or conditional approval.

Notice of Decision to WITHDRAW the Approval / Conditional Approval* of a Food Business Establishment Subject to Approval under Regulation (EC) No. 853/2004

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

PART 1 – Name and address of food business operator

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

PART 2 - Notification of decision to withdraw approval / conditional approval*

This is formal notice that the approval / conditional approval* granted by this Food Authority (or by a predecessor Food Authority) on in respect of the establishment shown in Part 3 of this document, which is subject to approval under Regulation (EC) No. 853/2004, to handle the products of animal origin indicated in Part 4 of this document, has been WITHDRAWN in accordance with Article 31(2)(e) of Regulation (EC) No. 882/2004. The decision to withdraw the approval / conditional approval* was made for the reason(s) set out in Part 5 of this document.

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

In accordance with Regulation 12 of the Official Feed and Food Controls (England) Regulations 2006, any person who is aggrieved by a decision of a Food Authority to withdraw an approval/conditional approval* may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notice was served on you. You may wish to consult a legal adviser about the implications of this notice and your right of appeal against this Food Authority's decision on your application. The name and address of the Magistrates Court at which you should lodge your appeal is

PART 3 – Trading name and address of the establishment		
Trading name of establishment		
Full postal address		
	Postcode:	

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

Minced Meat

Meat Preparations

Mechanically Separated Meat

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

PART 5 – Reasons for withdrawal

The approval / conditional approval* has been withdrawn because you have failed to comply with the requirements of the Regulations as identified below.

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

Regulation / Article No.	Requirement

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

Regulation / Article No.	Details of non-compliance

Signed:	
Name:	
Designation:	
Date:	

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

*Food Authority to delete as appropriate

Notice of Decision to SUSPEND the Approval / Conditional Approval* of a Food Business Establishment Subject to Approval under Regulation (EC) No. 853/2004

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

PART 1 – Name and address of food business operator

TO:	IMPORTANT	
	With immediate effect, you must not use the establishment detailed in Part 3 for any purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004 or use the associated approval code on any product until such time as the Food Authority lifts this suspension.	[Food Authority Logo]

PART 2 – Notice of decision to suspend approval / conditional approval*

This is formal notice that the approval / conditional approval* granted by this Food Authority (or by a predecessor Food Authority) on in respect of the establishment shown in Part 3 of this document, which is subject to approval under Regulation (EC) No. 853/2004, to handle the products of animal origin indicated in Part 4 of this document, has been SUSPENDED in accordance with Article 31(2)(e) of Regulation (EC) No. 882/2004. The decision to suspend the approval / conditional approval* was made for the reason(s) set out in Part 5 of this document.

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

In accordance with Regulation 12 of the Official Feed and Food Controls (England) Regulations 2006, any person who is aggrieved by a decision of a Food Authority to suspend an approval or conditional approval may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notice was served on you. You may wish to consult a legal adviser about the implications of this notice and your right of appeal against this Food Authority's decision on your application. The name and address of the Magistrates Court at which you should lodge your appeal is

PART 3 – Trading name and address of the establishment		
Trading name of		

Full postal address

establishment

Postcode:

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

Minced Meat

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Meat Preparations

Mechanically Separated Meat

Meat Products

Live Bivalve Molluscs (Shellfish)
Fishery Products
Dairy Products
Eggs (not Primary Production) / Egg Products
Frogs' Legs / Snails
Rendered Animal Fats and Greaves
Treated Stomachs, Bladders and Intestines
Gelatine
Collagen

PART 5 – Reasons for suspension

The approval has been suspended because you have failed to comply with the requirements of the Regulations as identified below.

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

Regulation / Article No.	Requirement

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

Regulation / Article No.	Details of non-compliance

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

Regulation / Article No.	Measures needed to secure compliance

	igned: Name: nation: Date:	
Name and address of Food Authority:	Contact Name:	IMPORTANT
, anony.	Telephone:	With immediate effect, you must not use the establishment detailed in Part 4 for any purpose which would render
	Fax:	the establishment subject to approval under Regulation (EC) No. 853/2004 or

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E-mail:

* Food Authority to delete as appropriate

use the associated approval code on any product until such time as the Food Authority lifts this suspension.

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

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

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

PART 2 – Notification of decision

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

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

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

In accordance with Regulation 12 of the Official Feed and Food Controls (England) Regulations 2006, any person who is aggrieved by a decision of a Food Authority to refuse to grant an approval may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notice was served on you. You may wish to consult a legal adviser about the implications of this notice and your right of appeal against this Food Authority's decision on your application. The name and address of the Magistrates Court at which you should lodge your appeal is

PART 3 – Trading name and address of the establishment

Trading name of establishment	
Full postal address	
	Postcode:

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

Minced Meat

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

PART 5 – Reasons for refusal

Full approval has been refused because you have failed to comply with the requirements of the Regulations as indicated below.

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

Regulation / Article No.	Requirement

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

Regulation / Article No.	Details of non-compliance

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

ANNEX 12: APPROVAL OF PRODUCT-SPECIFIC ESTABLISHMENTS SUBJECT TO APPROVAL UNDER REGULATION 853/2004 - FOOD AUTHORITY FILES

List of Contents

The following guidance is offered to Food Authorities in order to support and improve consistency in the content and structure of files produced for establishments which require formal approval.

A properly structured file containing all the relevant information is important to the Food Authority. It provides a history of the establishment concerned and how it has developed; it provides continuity for new officers; it facilitates monitoring exercises and will assist the Food Authority in demonstrating its competence.

Each file should contain:

- The application form;
- a plan or plans of the establishment indicating:
 - i. The layout of the establishment;
 - ii. The location of equipment;
 - iii. Work flows for each product line;
 - iv. Water distribution system within the establishment including all outlets and sampling points;
 - v. Drainage layout;
 - vi. Pest control baiting and/or trapping points within the establishment and external areas;
- a synopsis of the establishment which briefly describes what type of establishment it is, products produced, volume of product, type of trade, number of employees, approval number and what it is approved for. This synopsis should be no more than one side of an A4 sheet;
- pre-approval inspection report;
- planned programme of works to achieve approval;
- approval notification document specifying:
 - i. Details of activities to which the approval relates;
 - ii. Approval number;
 - iii. Classification;
 - iv. Special hygiene direction(s);
 - v. Any derogations that have been granted;
 - vi. Any other conditions or limitations specified by the Food Authority;
 - vii. Any arrangements acceptable to the Food Authority;

Note: All relevant information and documentation to be included in file;

- labels (printed, reprinted and use of) and commercial documents bearing the identification mark;
- letter indicating the Food Authority's involvement in the planning and implementation of the establishment's hygiene training of staff;
- inspection reports on premises in chronological order;
- correspondence with establishment in chronological order;
- copies of notices or other formal action taken in chronological order;
- copy of company's emergency withdrawal plan and traceability system including names, telephone numbers, etc, of key personnel within the company;
- copy of any other documents that have been provided by, or copied at, the approved premises, including:
 - i. HACCP documentation;
 - ii. supplier information;
 - iii. product list;
 - iv. raw material, product and water test results;
 - v. process records;
 - vi. management and key contact names and contact details;
 - vii. photographs and digital images;
 - viii. product recall procedures;
- results of all samples taken by the Food Authority;
- location of any off-site facilities

ANNEX 13: APPROACH TO ENFORCEMENT - REQUIREMENT FOR FOOD SAFETY MANAGEMENT PROCEDURES BASED ON HACCP PRINCIPLES

A.13.1: Introduction

The requirement for food safety management procedures based on HACCP principles is a significant change for food businesses. The legislation is flexible and allows businesses to comply in different ways. This is particularly important for small, less developed and catering businesses where traditional HACCP is difficult to apply.

A.13.2: Enforcement Approach

Enforcement should continue to be graduated and educative.

A.13.3: Regulation 852/2004

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

Food premises that present a clear and imminent danger to public health should have formal enforcement action taken against them to secure improvement. <u>This will not change from 1 January 2006</u>.

For food premises that do not present a clear and imminent danger to public health, the focus of enforcement visits should be to help the business improve its standards of food safety. For enforcement, *in practice this means:*

• Questioning the person responsible for food safety in the premises to ensure that significant hazards are understood and controlled, and where understanding and control is lacking – helping the business to improve.

With limited time and resources, enforcers should concentrate on significant hazards to public health, ensuring that the person responsible for food safety understands these hazards and knows how to control and manage them. This is an educative approach. The expectation is that businesses improve their standards over time, taking account of the understanding they gain from the enforcement officer and other sources. Where a business does not improve – given reasonable time, after being offered guidance, improvement notices and other more formal enforcement activity can be used. This is a graduated approach.

A.13.4: Flexibility

Regulation 852/2004 will not simply add documentation and record keeping to an existing requirement for hazard analysis. In fact, the Regulation is much more flexible, and requires food businesses to establish procedures in the business that control food safety hazards, and integrate these procedures with documentation and record keeping appropriate to the size and nature of the business.

Whilst larger, more complex businesses, and businesses that have a high level of understanding of food safety management may choose to demonstrate compliance with the legislation by putting in place a traditional HACCP system, others may do so with simpler approaches that take account of this flexibility. This section describes this flexibility for small businesses.

Whilst some businesses will wish to follow the traditional 7-principle HACCP framework this may not be easily understood or implemented by others – particularly small businesses. There is no requirement to use this 7-principle approach as long as the same outcome is achieved – safe food being produced.

For enforcement, in practice, compliance <u>at a high level</u>, means:

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

Where a business is especially low-risk (e.g. sweet shop, greengrocer, market stall etc) presenting only basic hygiene hazards, it may be sufficient that the business has a guide to good hygiene practice and understands and applies it. Documentation and record keeping may not be necessary.

Further guidance on flexibility is expected from the Commission by December 2005.

The key points are:

- Flexibility applies to <u>all</u> food businesses
- The manager of a business should have the skills necessary to maintain a food safety management system proportionate to their business, and <u>not</u> simply be trained in HACCP principles. These skills can be gained in many ways, formal training is not the only route.
- Staff in a business should have the skills needed to undertake their duties and follow the food safety procedures in the business. Training for staff should be proportionate and reflect the flexibility guidance. Formal training may not be necessary to achieve the objective of having the required competencies. In practical terms, on the job training might be appropriate, attendance at a formal training event is not necessary.

- Monitoring key activities in the business (critical control points) need not be numeric and can be based on sensory observation, craft skills and supervision.
- Incident recording is an appropriate and proportionate form of record keeping in many businesses
- Corrective actions must supplement incident recording.

In order to help businesses develop appropriate procedures and to adopt a graduated approach to its enforcement, it is important to understand how to judge progress. The chart below describes the components of the legislation and how an enforcement officer might judge progress towards complying with it in small businesses.

The following chart breaks down the components of the legislation into the standard 7 principles of HACCP, with some of the flexibility in the legislation identified. Although guidance materials may use this 7-principle framework, it is not necessary for this approach to be used. Provided the same outcome is achieved, safe food being produced, this can be achieved by substituting, in a simplified but effective way, some or more of the seven principles. This is clarified in the further Commission guidance on flexibility. Similarly, the terminology or 'jargon' of HACCP need not be used, and may be confusing to some businesses.

This breakdown is based on the Agency approach 'Safer food better business', but should be useable to identify compliance in a business using other similarly flexible tools, or where the business has devised its own procedures.

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

Mapping Hazard Analysis with tools such as flow-charts may not be suitable for all businesses. It is sufficient that the business has thought about its activities in a structured way. The effect of the analysis and the procedures produced should be to ensure that safe food is always produced.

The traditional HACCP approach of controlling some hazards through prerequisite programmes of Good Hygienic Practice and others through the HACCP system may not be appropriate, particularly in small businesses where it is not readily understood. Whatever the format of the guidance, the business must be managing all significant hazards including those traditionally controlled through Good Hygienic Practice.

For enforcement, in practice, this means:

• Seeing some evidence that the person responsible for food safety has thought about their business and identified significant hazards and knows how to control them – for some businesses it may be appropriate to follow standard advice from the Agency, industry guides, advice from trade bodies etc.

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

3. and Establish critical limits at CCPs;

Critical control points and their limits may not always be helpful ways of thinking about food safety for small businesses and they may instead identify generic controls - like thorough cooking, together with the ways of ensuring they know this has happened.

The legislation is flexible in stating the requirement that establishing a critical limit does not always imply that a numerical value must be fixed. This is in particular the case where monitoring procedures are based on visual observation, for example a business may rely on sensory information such as colour change, juices running clear, stews bubbling etc. Businesses must understand how these methods control hazards and be sure they are effective. This validation can be done by the business themselves (on the basis of experience), or it may be appropriate to use pre-validated procedures that follow established best practice, produced by the Agency, trade bodies or others.

For enforcement, in practice, this means:

 Seeing some evidence that the business is following procedures that include steps where the significant hazards are controlled – for many businesses it may be appropriate to follow standard advice.

4. Establish procedures to monitor the CCPs;

Management of food safety through the procedures detailed above will need to be demonstrated. This can be shown in many ways. In some larger businesses this may be achieved by monitoring protocols and record keeping. In other businesses – particularly where the person responsible spends significant time in the food preparation areas, this may be demonstrated by their ability to supervise their operation – that their procedures are being followed. It will be important to establish that if the procedures are followed, safe food will result.

Monitoring may in many cases be a purely sensory exercise, for example a regular visual verification of the temperature of cooked food by a colour change.

For enforcement, in practice, this means:

 Seeing some evidence that the business is monitoring their procedures, either using physical checks such as noting temperatures or via sensory checks such as noting that a stew or sauce is bubbling. The person responsible for food safety should be able to explain the chosen method of monitoring.

5.	Establish corrective actions to be taken if a CCP is not under control;
	It is also important that the business knows what to do when things go wrong – the corrective action that needs to be taken.
	For enforcement, in practice, this means:
	• Questioning the person responsible for food safety management to ensure adequate supervision of staff and equipment so as to assure that procedures are being followed and safe food produced, and that when things go wrong appropriate action is taken.
6.	Establish procedures to verify whether the above procedures are working effectively;
	The business will need to demonstrate that its procedures are verified and reviewed and kept up to date, and that changes to menus, types of foods and cooking methods, and new equipment are reflected. In larger businesses, verification is often achieved by third parties, but for smaller businesses it is sufficient that the business carries out periodic reviews of its procedures and methods, and takes account of good practice and safe methods.
	For enforcement, in practice, this means:
	• Seeing evidence that the procedures in a business are reviewed to ensure they continue to be appropriate and reflect changes in the business.
7.	Establish documents and records to demonstrate the effective application of the above measures;
	Documentation and record keeping are particularly onerous for smaller businesses and the new legislation is clear that this should be well balanced and limited to what is essential with regard to food safety. Records should include the corrective action that has been taken.
	For enforcement, in practice, this means:
	 Seeing documentation that is up to date and describes the main procedures or methods used in the business to control the most important hazards;
	• Seeing some periodic records that represents evidence that these procedures were followed. This does not have to record every monitoring and supervisory activity and in small caterers, exception reporting will be acceptable.
	• For simple small businesses following good hygienic practice guides, documentation and record keeping may not be necessary.

A.13.5: Role of Food Authorities

The legislation requires the industry to raise its standards to that already achieved by the best businesses. The flexibility means that all food businesses should be able to comply.

In accordance with the legislation, businesses are required to implement appropriate food safety management procedures. Different support models are appropriate for different types of business. The expectation is that larger businesses and manufacturers will continue to develop and use traditional HACCP systems. The approach developed by the Agency, Safer food, better business (SFBB) is one approach considered suitable for use by small caterers.

Proper implementation of the appropriate support model will constitute compliance with Article 5 of Regulation 852/2004. Correctly implemented, Safer food better business will allow a food business to demonstrate compliance.

Businesses should either have in place or be seen to be making progress toward having effective food safety management systems. Enforcement officers should try to educate and give businesses an understanding about what is required. For businesses that are not a threat to public health, it is expected that formal enforcement action should only be taken where the business:

- Has been given reasonable opportunity to implement food safety management;
- Has been directed to appropriate training, if needed; and
- Has been provided with appropriate guidance.

The graduated approach should seek to educate businesses and improve their standards in realisable steps. Guidance material should be broken down in such a way that the enforcer and business can agree that by their next visit, so much progress should have been made. The Agency's advice, 'Safer food, better business', is broken down into the 4Cs (cooking, cleaning, chilling and cross-contamination) and it may be appropriate to set a business one of these 'Cs' at a time. Other guidance material can also be divided into 'chunks' like this. Where fundamental skills are missing, enforcers should point businesses at sources of the competencies – guidance materials, books, courses etc. Enforcers should look to the business to make reasonable progress through the material and make appropriate changes in their practices before the graduated approach progresses from education to more formal infraction methods.

A food safety management system should give assurance that the business knows how to produce safe food, has procedures in place that assure this, and repeatedly does produce safe food. Whether a business has an effective food safety management system in place is a judgement for enforcement officers. For enforcement, in practice, this means:

• Judging whether the business has appropriate procedures in place so that it would continue to produce food safely if things went wrong – staff absences, unexpected demand etc., and seeing some evidence that this is the case.

ANNEX 14: IMPORT OF FOOD FROM THIRD COUNTRIES

GUIDANCE FOR FOOD AUTHORITIES ON THE IMPORT OF FOOD FROM THIRD COUNTRIES

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Appendix 1: Glossary of terms

A.14.1: Introduction

All local authorities have responsibilities for certain aspects of imported food controls. The purpose of this guidance is to set out and assist local authorities on the level and type of activity to achieve effective and consistent enforcement on imported food.

The guidance focuses on the principal legislation relating to the import of food not of animal origin (FNAO). From 1 January 2006, FNAO import controls are harmonised at Community level by Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (EU Regulation 882/2004). The provisions of the EU Regulation are directly applicable but are given effect at national level by the Official Feed and Food Controls (England) Regulations 2006 (and parallel legislation in Scotland, Wales, and Northern Ireland). This legislation replaced the previous legislation (principally, the Imported Food Regulations 1997) but the general approach in the new legislation is similar.

A.14.1.1: Scope

The scope of this guidance extends to imported FNAO and imported products of animal origin (POAO). It has been revised in the light of EU Regulation 882/2004 on Official Feed and Food Controls. The guidance does not cover control activities for POAO at Border Inspection Posts, where central guidance produced by Defra is available¹. However, it does provide enforcement guidance for local authorities relating to illegally introduced POAO. The guidance covers food controls only – animal feed is subject to separate enforcement guidance issued by the Food Standards Agency.

Except where a specific distinction is made this guidance applies to all local authorities, both inland and at points of entry including Port Health Authorities. For the purpose of this guidance "imported food" means food imported into the UK from outside the European Union ("third countries"); "point of entry" means a seaport, airport or international rail link at which imported food is introduced into the UK.

Local authorities (including Port Health Authorities) with a point of entry provide the first line of control on imported food to ensure it is safe and complies with EU and UK requirements. However, it is important that controls are also in place at Enhanced Remote Transit Sheds (ERTS), ships suppliers, international rail terminals, and other premises inland, as significant amounts of FNAO will not have been subject to checks at points of entry and there is a possibility that POAO may have entered the UK illegally. Further details of the roles and responsibilities of Port Health Authorities, local authorities and other government agencies and departments can be found in the Food Standard Agency's Local Authority Resource Pack on Imported Food Control².

This guidance incorporates relevant information from:

Good practice guides contained in the Syniad/APHA/FSA Benchmarking Study³ into the port health function involving port health participants from seaports, LACORS and other Government Departments.

The Food Standards Agency's Local Authority Resource Pack on Imported Food Control provided to Food Authority delegates at national update training seminars².

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

This guidance includes summaries of some statutory provisions. However, these are indicative and for general guidance only.

A.14.2: Status of this Guidance

This document should be considered as centrally issued guidance for the purpose of the Framework Agreement on Local Authority Food Law Enforcement (the latest version is available on the Agency's website). Amendments have been made to the Standard in the Framework Agreement to clarify its application to imported food control (Amendment issued in June 2004).

This guidance should also be read in conjunction with the Food Law Code of Practice previously issued under Section 40 of the Food Safety Act 1990. It has been reviewed and re-issued under the Act as well as Regulation 24 of the Food Hygiene (England) Regulations 2006, and Regulation 6 of the Official Feed and Food Controls (England) Regulations 2006. The Code of Practice provides direction and guidance on the local authority approach to enforcement generally.

A.14.3: Imported Food Legislation (FNAO)

A.14.3.1: EU Regulation 882/2004

This introduces EU-wide harmonised rules for import controls for FNAO. The requirements (at Articles 15 to 25) extend to foods not already covered by Directive 97/78/EC (POAO Veterinary Checks regime). These cover controls in relation to materials and articles in contact with food as well as cleaning and maintenance products and processes, and pesticides.

A.14.3.2: The Official Feed and Food Controls (England) Regulations 2006

The Official Feed and Food Controls (England) Regulations 2006 give effect to Articles 15 to 25 of EU Regulation 882/2004 in England only. These Regulations replace the Imported Food Regulations 1997. Parallel legislation is in place in Scotland, Wales, and Northern Ireland.

The Official Feed and Food Controls (England) Regulations 2006 include a mechanism for ensuring that where there is a serious or imminent risk to public health, control measures may be put in place. In particular, it may be

used to ensure that Emergency Decisions made at EU level are implemented without delay. It does so by giving the Food Standards Agency powers to make declarations regarding import conditions for particular products. These conditions would apply with immediate effect.

A.14.3.3: Other legislation

For certain areas, for example, contaminants, there are specific EU harmonised requirements for foods which can be applied at point of import as well as inland. These EU requirements are implemented in the UK by separate legislation but the powers to deal with non-conforming food at import are those contained in the Official Feed and Food Controls (England) Regulations 2006. Separate and detailed European Commission guidance on the contaminants legislation is available at:

http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/aflatoxin_guidance_en.pdf.

A.14.3.4: 'High risk' FNAO

EU Regulation 882/2004 (Article 15(5)) provides that the Commission may issue a list of 'high risk' FNAO. These products will be identified on the basis of known or emerging risk, and will be subject to increased import controls at the point of entry. The frequency and nature of such checks will be specified by the Commission when the products are identified. The enhanced controls provided for by these arrangements include; prior notification, import through designated ports only, and specified documentary and physical checks at points of entry.

As the Commission had not yet issued a list of 'high risk' products, it is not possible at this stage to legislate for these products at a national level. It is proposed that once the list of products has been issued by the Commission, the national legislation will be amended appropriately.

In the meantime, current safeguard measures will continue to apply and further measures may be introduced under the provisions of the EU General Food Law Regulation (178/2002) such that public and animal health protection will not be compromised by the delay. These measures provide similar enhanced requirements such as specified checks and, where relevant, entry through designated ports.

A.14.4: Service Planning

The Framework Agreement on Local Authority Food Law Enforcement includes service planning guidance. Section 2.3 of the framework ("Scope of the food service") and Section 2.4 ("Demands on the food service") provide for local authorities to set out the scope of the responsibilities and service

provided and to describe any external factors that may impact on their service. Where relevant, local authorities should include in these sections imported food responsibilities and the control arrangements in place.

Local authorities with a point of entry should include details of resources allocated for imported food control work in their service plans.

A.14.5: Documented Policies and Procedures

All local authorities should ensure that their written policies and procedures cover imported food having regard to the work that might reasonably be anticipated within the administrative district and jurisdiction of the authority.

Procedures relating to examination of imported food including deferred examinations under The Official Feed and Food Controls (England) Regulations 2006 should cover both food safety and food standards issues, where applicable.

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

A.14.6: Authorisation

All local authorities should ensure that at least one officer is properly authorised to undertake imported food control work and related enforcement action. One of the key issues which needs to be considered in any review of authorisations is the identification of the specific legislation where enforcement powers originate. This will affect the content and wording of authorisation documentation.

For food safety and food standards matters this should include authorisation under the Food Safety Act 1990 and under hygiene and processing Regulations issued under it, including any relevant contaminants legislation.

Officers should also be authorised to enforce relevant Regulations issued under the European Communities Act 1972 (e.g. The General Food Regulations 2004). However, the European Communities Act does not contain the specific enforcement powers, its primary function is to provide a mechanism by which Regulations can be enacted. Powers of enforcement for Regulations made under the Act are usually contained in the Regulations themselves. Therefore, the Agency's view is that all Regulations relevant to imported food control should be specifically referred to in authorisation documents, including officers' credentials. As such these should, for example, include: The Products of Animal Origin (Import and Export) Regulations 1996 as amended,

The Products of Animal Origin (Third Country Imports) (England) (No. 4) Regulations 2004,

Emergency Control Regulations e.g. The Food (Chilli, Chilli Products, Curcuma and Palm Oil) (Emergency Control) (England) Regulations 2005, and

The Official Feed and Food Controls (England) Regulations 2006.

The Agency's view is that officers do not need to be specifically authorised to enforce declarations made under Regulation 33 of the Official Feed and Food Controls (England) Regulations 2006.

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

A.14.7: Qualifications / Experience of Authorised Officers

Officers authorised to undertake imported food control work and enforcement action should be appropriately qualified, experienced and competent to carry out the range of tasks and duties they are authorised to perform, in line with the relevant requirements of the Food Law Code of Practice, and subsequent documents. Staff should be kept up to date in their area of competence and receive regular additional training as necessary.

All local authorities should have at least one officer competent in imported food controls. Relevant update training could include:

- Attendance at Food Standards Agency enforcement training on imported food control; and
- Familiarisation with the Agency's Local Authority Resource Pack on Imported Food Control²; or
- Other relevant training of an equivalent content e.g. in-house training or cascade training relating to (a) and (b) above.

A.14.8: Information

Local authorities with a point of entry in their territory should maintain up to date information on:

- The port operator.
- Access to port/Customs areas, including Enhanced Remote Transit Sheds (ERTS).
- Stakeholders, including import agents and airlines/shipping operators.

- Trade type (volume, nature, and trade routes).
- Facilities where imported food inspection can be carried out and arrangements for storage of detained/seized goods. Defra have issued further specific advice on operating procedures for sharing facilities at BIPS¹⁶.
- Equipment available for carrying out inspections and sampling of imported food.
- Details of appointed and specialist laboratories for analysis and/or examination of samples that are able to provide an appropriate service for sample analysis (in particular relation to the time-scale of analysis and issue of results).
- Health and safety requirements.
- Security requirements.

Local authorities with a point of entry, ERTS or international rail terminals should establish routine local liaison and communication with relevant local organisations for the purpose of general exchange of information on food imports and for the effective handling of incidents. These contacts could include, where appropriate:

- HMRC (Her Majesty's Revenue and Customs) including anti-smuggling and Convention On International Trade in Endangered Species (CITES) teams,
- The State Veterinary Service (SVS),
- The Health Protection Agency in England, or Scottish Centre for Infection and Environmental Health in Scotland or the National Public Health Service for Wales,
- The Horticultural Marketing Inspectorate and Plant Health and Seeds Inspectorate (Defra) in England and Wales or the Horticultural and Marketing Unit (Scottish Executive Environment and Rural Affairs Department) in Scotland,
- Port operator; import agents; Transit Shed \ ERTS operators,
- Maritime and Coastguard Agency (MCA),
- Neighbouring local authorities, particularly for joint boards and ports, which fall under the jurisdiction of more than one local authority, including County Councils for certain Trading Standards responsibilities, and
- The Medicines and Health Care products Regulatory Agency (MHRA).

Contact details and information on the roles and responsibilities of relevant central government departments and other organisations can be found in the Food Standards Agency's Local Authority Resource Pack on Imported Food Control².

Where relevant, local authorities should ensure that their officers have access to secure areas at points of entry where local, national or international aviation or maritime security rules are applicable. Information on this may be obtained from the port operator.

A.14.9: Records

A.14.9.1: Identifying and recording food importers

All local authorities should ensure that food premises and traders in their district which import food are identified and recorded in premises/trader databases and included in inspection programmes as appropriate.

Completed food premises registration forms can be used to assist identification of food premises as importers, so far as the EU Hygiene Regulation 852/2004 provides for this.

For the purposes of identifying and recording food businesses and systems falling under the official controls, local authorities / PHAs should refer to the scope of EU Regulation 882/2004 as detailed in Articles 14 and 15. Relevant activities should be identified on the appropriate files together with an indication of the type and origin of foods being imported.

To help identify food importers, local authorities may conduct desktop exercises using such information sources as local knowledge, telephone directories or Internet searches. Information from PHAs might also assist this process. Records can be refined further after visits to food premises and/or communications with food business proprietors and other local government departments as part of routine programmed activities.

A.14.9.2: Records of consignments and examinations

Local authorities with a point of entry should ensure that, where available, information relating to the number and type of food consignments is maintained together with relevant information on the checks made to determine compliance with legal requirements. Where information is recorded, the level of information about food examinations (including examinations undertaken at ERTS or international rail terminals) and deferred examinations should provide consignment traceability and permit effective internal monitoring. This information should include any identifying reference for the consignment examined, country of origin, information on the nature of the food and the checks carried out and, where any enforcement action or sampling has been undertaken, the details of the agent and/or consignor/consignee. Records of sampling checks and records relating to emergency controls should be held for up to three years.

A.14.9.3: Arrangements for points of entry without permanent local authority presence

Where there is no permanent local authority presence at an airport or seaport, and it is not considered by the authority to be a point of entry for food, the local authority should (at least once every three months) contact the port operator, HMRC and/or other commercial operators to confirm the port's status regarding food activities and/or obtain information about the volumes, types, countries of origin and customs status of food entering the port since the last such enquiry. Local authorities should keep a record of these exchanges for a period of three years.

The purpose of these arrangements is to provide local authorities with updated information on food being imported. This will enable risk-based judgements to be made on the targeting of enforcement action and to ensure that emergency controls or restrictions on certain foods are being enforced. This includes at the designated point of entry, and requirements relating to documentary checks and associated statutory sampling (further details on risk-based checks can be found in Section A9.14).

A.14.10: Reporting and Notification Arrangements

A.14.10.1: Nominated officer for imported food controls

Every local authority with a point of entry should appoint a nominated officer with the necessary competency in imported food control to be a point of contact with the Food Standards Agency on imported food matters. The details of the nominated officer or changes to the nominated officer should be notified to the Agency's Imported Food Division.

A.14.10.2: Monitoring returns

All local authorities should complete any relevant enforcement monitoring returns required by the Food Standards Agency.

In April 2005 the Food Standards Agency wrote to all local authorities seeking baseline data on imported food law enforcement activity, to be used as a measure for the Government's initiative to achieve a 'step change' in local authority delivery and co-ordination of imported food controls. In order for the Agency to monitor imported food control work, authorities should comply with future requests for such data.

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

A.14.10.3: Notification of food hazards or incidents

All local authorities should send details of any imports rejected, either at the point of entry or inland, where there is a direct or indirect risk to health to the Agency's Incidents Branch⁷ using the Rapid Alert System for Food and Feed (RASFF) notification form. This will include imports rejected for reasons such as chemical, microbiological or foreign body contamination or imports from a country which is not authorised to export that category of products to the EU.

In addition, with regard to testing for residues of veterinary medicines in Annex IV of EU Regulation 2377/90, as amended (such as nitrofurans and chloramphenicol) or those not approved for use, details of ALL positive results should be sent to the Incidents Branch using the RASFF notification form. Where available, copies of the health certificate and the airway bill or bill of lading should also be forwarded to the Incidents Branch⁷ at:

drazenka.tubin-delic@foodstandards.gsi.gov.uk or rajwinder.ubhi@foodstandards.gsi.gov.uk

Guidance on completing the RASFF notification form has already been provided to local authorities. Authorities who have access to the European Commission's Circa website, will be able to download copies of the template for the RASFF notification form⁸.

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

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

A.14.10.4: Notification of illegal imports of POAO

A notification should be made to Defra whenever illegally imported POAO are seized. From 1 April 2006, the reporting of seizures by Local Authorities (LAs)/Port Health Authorities (PHAs) have required the completion (electronically) of a common form (IIT 1 (2/06)), which is then sent by e-mail to the Department for Environment, Food and Rural Affairs (Defra) to record the information. Further details are contained in Section A.14.18 of this guidance.

A.14.11: Liaison / Referrals

Whenever inland authorities come across problems with imported food, where the point of entry for the goods can be ascertained and similar problems are likely to be found in other imported consignments, it is important to ensure that the local authority at the point of entry is informed to help target their future surveillance activities.

In certain circumstances, it may be necessary for local authorities covering points of entry to refer imported food matters to inland authorities (e.g. at ship suppliers or Channelled Goods). This would include situations where inland supervision of consignments is required and also where checks at the point of entry reveal food safety or food standards concerns and it is appropriate to refer the matter to an inland authority. Examples include:

- Where a consignment of food of non-animal origin, which is subject to emergency controls or other restrictions, has been illegally imported e.g. without being presented to the local authority at the point of entry for the required checks to be carried out.
- Where the local authority at the point of entry is aware that illegal imports of products of animal origin may have been distributed.
- Where checks on imported food reveal labelling issues which cannot be enforced at time of import.
- Where examination under The Official Feed and Food Controls (England) Regulations 2006 has been deferred.
- Where unsatisfactory test results are received for samples taken for routine surveillance and as such the consignment has been released from the port.
- Where analysis indicates that nuts are not suitable for human consumption but are referred for feed use.

Wherever practicable, inland authorities should agree to assist with these referrals and respond as appropriate without undue delay and provide feedback to the local authority at the point of entry on the outcome. To assist this process a suggested pro-forma for this purpose is available on the Agency's website⁹. Records of such referrals and details of any action taken should be maintained by authorities.

It may also be necessary for the Food Standards Agency to refer matters concerning illegally imported POAO to inland authorities. This information will normally be received from HMRC where they have intercepted illegal imports destined for commercial premises. Local authorities should respond to these referrals without undue delay and where requested provide feedback directly to HMRC. Authorities should maintain records of action taken.

A.14.12: Inland Inspection of Imported Food

Local authority procedures should ensure food (including imported food) examination forms part of food premises inspections.

During routine inspections and other visits to food business premises (e.g. complaint visits, sampling visits) officers are requested to consider the food in possession or offered for sale, and if imported, ensure it complies with relevant imported food requirements.

The Official Feed and Food Controls (England) Regulations 2006 also cover semi-finished products, materials and articles in contact with food, pesticides, and labelling issues.

When considering specific imported food inspection programmes local food authorities should not simply focus on food businesses that specialise in the supply of food to specific minority groups. They should consider food businesses within their area that routinely import food from third countries, in particular those premises that are the first destination after import. Such premises are likely to include local food manufacturers and warehouses. Any inspection programme should also be informed by food alerts and the premises compliance history.

In addition to assessing fitness for consumption, reasonable steps should be taken to check the legality of the importation of any POAO and FNAO from a third country. The Food Standard Agency's Local Authority Resource Pack on Imported Food Control provides detailed advice on points to consider when investigating the legitimacy of imports. The Agency's website¹⁰ provides the types of food imports and countries of origin where there are prohibitions and restrictions¹¹, as well as links to other relevant sites.

A.14.12.1: Deferred examination of FNAO – inland controls

The Official Feed and Food Controls (England) Regulations 2006 allow for import controls for the examination of consignments of FNAO to be deferred and undertaken by the inland Food Authority covering the ERTS or international rail terminal or at any other place of destination in the UK. Further guidance on this is given in Section A.14.

The decision to defer rests with the local authority covering the point of entry and they need to liaise with the receiving authority to ensure that appropriate checks will be carried out and as such the procedure relies on co-operation between authorities. Receiving authorities should wherever possible agree to any reasonable request for a deferred examination. Under The Official Feed and Food Controls (England) Regulations 2006, the enforcement authority at the place of destination would become responsible for enforcement of the import controls once the point of entry authority had deferred examination to the place of destination.

Inland local authorities should ensure that any available information on imported food, which is sampled, detained, seized or destroyed, wherever practicable is recorded in relevant in-house records or databases.

A.14.13: Sampling of Imported Food

A.14.13.1: Considerations for sampling

Routine imported food sampling considerations, for local authority surveillance and enforcement purposes, should take account of:

- any statutory requirements for sampling laid down in European Commission Decisions or Emergency Control Regulations (usually this will occur at a point of entry),
- any agreed LACORS/Food Standards Agency sampling programmes,
- any sampling required following a Food Alert or RASFF notification,
- information from any EU, LACORS, regional liaison group, local or other sampling survey, and

• any imported food where there is no history or information on the product.

Commodities sampled under Emergency Control Decisions or Emergency Control Regulations should be detained until the enforcement authority receives the results unless otherwise stated in the implementing rules.

Local authorities should also take into account local priorities, including consumer complaints relating to imported food, and their local business profile when considering sampling, and include these in their sampling programmes. Sampling policies and programmes should be reviewed from time to time to assess the need to include national or regional imported food priorities/surveys and the UK's National Control Plan.

Local authorities should take into account any specific central guidance on sampling or other matters set out by the Agency or Defra (Scottish Executive Environment and Rural Affairs Department (SEERAD) in Scotland, National Assembly for Wales Agriculture Department (NAWAD) in Wales), or LACORS.

A.14.13.2: Qualifications / experience / training of officers carrying out sampling

Samples for microbiological examination or chemical analysis should be taken by authorised officers, having been properly trained in the appropriate techniques including relevant EU protocols and Food Standards Agency guidance, and being competent to carry out the duties assigned to them. Sampling should only be undertaken by officers meeting the relevant qualification and experience requirements described in the Food Law Code of Practice.

A.14.14: Food of Non-Animal Origin (FNAO)

This section applies to local authorities with a point of entry, checks undertaken at ERTS or international rail terminals, and deferred examinations under The Official Feed and Food Controls (England) Regulations 2006.

The advice in this section also applies to composite products which contain a small amount of product of animal origin and which are outside the Veterinary Checks regime covered by Directive 97/78/EC.

A.14.14.1: Identification

It is important that authorities with a point of entry are aware of the volume and nature of foods entering the port. Local authorities overseeing seaports where enquiries with the port operator indicate that food is imported should check 100% of ships' manifests for imported food. 100% checks should continue until enquiries with the port operator reveal no food imports for a continuous period of three months, and further food imports are not reasonably foreseeable. Thereafter contact should be made with the port operator at least once every three months to check the status of food imports.

Local authorities overseeing airports, ERTS and international rail terminals should set up, implement and maintain documented procedures on the arrangements in place to identify imported food.

This might include:

- Liaison with HMRC regarding food imported directly from third countries or via other Member States or ports under T1 arrangements (see glossary);
- Liaison with transit shed operators to obtain copies of cargo manifests;
- Random checks of transit sheds/ERTS handling imported food with a view to verifying the information arrangements in place;
- Informal notification systems in co-operation with importers or their agents.

A.14.14.2: Prohibition

It is an offence under Regulation 27 of The Official Feed and Food Controls (England) Regulations 2006 for any person to import a product that does not comply with the food safety requirements set out in the EU Food Law Regulation (178/2002) or with the requirements of Articles 3 to 6 of EU Hygiene of Foodstuffs Regulation (852/2004). This prohibition applies to products being imported either direct from a third country or from a third country through another EU Member State.

A.14.14.3: Examination

Imported food should be subjected to risk based checks. EU Regulation 882/2004 requires systematic documentary checks, random identity checks and where appropriate physical checks. A systematic documentary check does not imply 100% checking of commercial documents but there should be risk based planned arrangements in place. However, documents required to accompany any consignment by food law, such as under Emergency Control Decisions, are likely to require 100% checking. Physical checks might include: checks on the food itself, checks on the means of transport, checks on the packaging, checks on the temperature controls, organoleptic testing, and chemical or microbiological examination, or any other check necessary to verify compliance with EU food safety requirements. Such checks may also take into account any guarantees that the Competent Authority of the third country has given and which have been assessed by the Commission. The arrangements and follow up actions should be set out in relevant service policies and procedures.

Physical checks should be carried out under appropriate conditions inclusive of standards of hygiene and at a place with access to appropriate control facilities allowing investigations to be conducted properly. Samples should be handled in such a way as to guarantee both their legal and analytical validity.

Where an authorised officer reasonably requires facilities and assistance to carry out checks on a product, the importer may be asked to provide these. The Official Feed and Food Controls (England) Regulations 2006 also allow an authorised officer to require that physical checks and identity checks take place at a specified place, where necessary for proper examination.

Checks should be informed by:

- Statutory requirements for documentary checks and associated sampling laid down in relevant Emergency Control Decisions and Emergency Control Regulations,
- The risk associated with different types of food safety issues,
- Knowledge of the product e.g. new or unusual,
- Any requirements following a Food Alert or RASFF notification,
- The history of compliance for the product, country of origin and exporter/importer,
- The controls that the food business importing the food has carried out,
- Any guarantees that the Competent Authority of the third country of origin has given under the third country pre-export checks provisions in EU Regulation 882/2004 (details under Section A.14.15 below),
- Any existing co-ordinated programmes e.g. at the request of or under the direction of other food control/advisory bodies,
- Adequacy or sufficiency of documentation e.g. discrepancies which need further investigation, and
- Suspicion of non-compliance.

Checks may also be influenced by information received from inland authorities regarding non-compliant food or from other control authorities or the port operator who may have concerns about a consignment.

Checks on imported food should also take into account any guidance issued by the Food Standards Agency. Such guidance may cover foods for which specific documentary checking regimes have been laid down or foods with restricted points of entry and/or testing regimes laid down in Commission Decisions or Regulations. Local authorities with points of entry which are not designated to handle certain FNAO products subject to Emergency Control Decisions may wish to ensure relevant port operators, local HMRC, or agents/importers are aware of any restrictions. Arrangements should also be in place to deal with any such consignments which may arrive at the point of entry.

Officers should give the owner, importer or importer's agent a receipt for, or a record of, all samples taken and a copy of the results in the case of non-compliance.

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

A.14.14.4: Deferred examinations of FNAO

The Official Feed and Food Controls (England) Regulations 2006 allow for the examination of consignments of FNAO to be deferred and undertaken by the Food Authority covering the ERTS or international rail terminal or at any other place of destination in the UK. Deferred examinations may be considered where the local authority at the point of entry has a valid reason why an examination needs to be deferred, but it is anticipated this is likely to be in exceptional circumstances only.

Either the local authority covering the point of entry or the importer can request deferred examination. However, the final decision on whether to defer examination rests with the local authority covering the point of entry. In coming to any decision liaison with the receiving authority should be carried out to ensure that appropriate checks will take place and deferral should therefore be based on full co-operation and agreement between authorities.

Where products are subject to Emergency Control Decisions or Emergency Control Regulation measures which require designated points of entry, deferred examination is unlikely to be appropriate but there may be circumstances where there are overriding health and safety considerations. In such cases the Food Standards Agency should be informed. In all cases high risk food should be subject to relevant document and identity checks before being deferred for physical checks.

When any examination is deferred, the Official Feed and Food Controls (England) Regulations 2006 require that the importer should provide a written undertaking that the consignment has been sealed and will not be opened until it reaches its specified destination and opening has been authorised by the receiving authority. The local authority at the point of entry should notify the receiving authority by the most expeditious means available that the food has not been examined and forward to the authority a copy of any written undertaking given by the importer.

Deferred examinations under The Official Feed and Food Controls (England) Regulations 2006 should be carried out in accordance with Regulation 26 of the Regulations - only an outline has been provided in paragraphs 14.15 to 14.18.

A.14.15: Third Country Pre-Export Checks

EU Regulation 882/2004 includes provisions for the Commission to grant third countries reduced import checks on imported FNAO. Such arrangements will be restricted to those countries where the Commission is satisfied that

effective official controls are in place to carry out the appropriate pre-export checks immediately prior to export to the EU. Details of relevant products and third countries will be notified to local authorities, as appropriate.

This status can be repealed by the Commission in the light of information or experience. Where such arrangements are in place local authorities at points of entry should check relevant certification and consignments to validate such assurances. Particular consideration should be given to consignments accompanied by certification from non-accredited laboratories. Where authorities have concerns relating to any such arrangements based on checks carried out they should notify the Food Standards Agency.

A.14.16: Charges

EU Regulation 882/2004 provides that mandatory fees may be introduced for 'high risk' FNAO imports by means of implementing rules when these products are identified at Community level. This is dependent on the Commission putting forward proposals..

Commission Emergency Control Decisions may in some cases provide for charges. Commission Decision 2006/504/EC, on special conditions governing certain foodstuffs imported from certain third countries due to possible contamination of these products by aflatoxins, allows for charging for certain provisions. Commission Decision 2005/402/EC, on measures regarding chilli, chilli products, curcuma and palm oil, allows for recovery of costs for certain provisions relating to these products.

A.14.17: Enforcement

Where, for the purpose of examination at points of entry, or deferred examination at ERTS, international rail terminals or other place of destination, an authorised officer considers that a consignment needs to be inspected to confirm compliance, Article 18 of EU Regulation 882/2004 and Regulation 29 of the Official Feed and Food Controls (England) Regulations 2006 allow the product to be detained pending the results of any examination associated with the official controls.

Where an authorised officer has detained a food consignment pending any results of examination, they should notify in writing the person importing the food or any person in possession of the food who is entitled to be in possession of it. The notification should specify that the food should not be removed from the place stated, until the officer's examination of the food has been completed. The person on whom any notification is given should be informed in writing by the authorised officer.

Article 18 of EU Regulation 882/2004 and Regulation 29 of the Official Feed and Food Controls (England) Regulations 2006 do not specify a time limit for examination and investigation of consignments. They give an option of whether to detain or not, if non-compliance is suspected. However, such examinations, and/or detention periods, should be expedited as quickly as practicable such as to avoid unreasonable disruption to the trade.

Where samples are submitted for analysis or examination, and the consignment is detained pending the results, local authorities should inform the analyst or examiner of that fact and also ensure that the consignment is stored appropriately and securely. The importer or the importer's agent should be informed of the analysis/examination results as soon as possible.

If it appears to an authorised officer upon inspection or examination of food, that a batch, lot or consignment of food fails to comply with food safety requirements (Food Safety Act 1990 Section 8 as amended), Regulation 30 of The Official Feed and Food Controls (England) Regulations 2006 allows, after having heard from the importer, for the officer to serve a Notice requiring:

- Destruction of the relevant batch, lot or consignment
- The food be subjected to special treatment
- Re-dispatch of the food outside the European Community
- Another use of the food for purposes other than those for which they were originally intended

In practice, the options specified in the Notice should be drawn up after appropriate consultation with the person importing the food. The person on whom any Notice is served should be informed in writing by the authorised officer of any relevant appeal provisions at the time that the Notice is served. The Notice served should allow 60 days for compliance by the responsible person. Where the official control allows for re-dispatch, if after a 60 day period re-dispatch does not take place, the consignment should be destroyed, unless delay is justified.

Regulation 34 of The Official Feed and Food Controls (England) Regulations 2006 allows for costs associated with such action to be recovered from the person responsible for the consignment.

Special treatment may include such treatment or processing to ensure the food complies with EU requirements, or the requirements of the third country to where it is to be re-dispatched. Special treatment may also include processing for purposes other than human or animal consumption. Where special treatment is permitted liaison should take place with any other relevant enforcement authority or organisation to ensure the necessary processing has been carried out. This process may also be used where a non-conforming product is being imported specifically for the purpose of undergoing treatment to comply with EU law.

A consignment should only be re-dispatched outside the EU where the importer has agreed to the proposed destination and has informed the Competent Authority for the third country why it has been rejected for import into the EU. Where the consignment is being re-dispatched to a country other than that of origin, the Competent Authority for the country of destination should provide notification to the Competent Authority controlling the product

that it is willing to accept the consignment. The consignment should be officially detained pending re-dispatch.

Any decision on the approval of alternative usage of rejected goods should be informed by any relevant guidance issued by the EU or the Food Standards Agency on the appropriateness of alternative use or re-exportation.

Where official controls indicate that a consignment is injurious to health or unsafe, the consignment should be detained until it is either destroyed or undergoes appropriate measures to protect health.

Where there is no evidence to suggest that a deliberate attempt has been made to import non compliant goods, and adequate control arrangements are in place, ports may consider Voluntary Surrender as an option for dealing with such consignments. In accordance with Food Law Code of Practice, where food is voluntarily surrendered for destruction, a receipt should be issued and the description of the food should include the phrase "voluntarily surrendered for destruction" with the person surrendering the food or their representative signing the receipt.

Imported food failing food safety requirements may also be subjected to Food Safety Act 1990 provisions to ensure appropriate action is taken. Such provisions include detention and seizure powers, applied in accordance with the Code of Practice.

Officers should have regard to The Official Feed and Food Controls (England) Regulations 2006, The Contaminants in Food (England) Regulations 2007 and any relevant Emergency Control Regulations, which may provide for specific detention powers and notice provisions in relation to certain foods. Any designated port should have adequate facilities to ensure products can be sampled effectively, hygienically and under appropriate conditions.

Arrangements should be in place to ensure that detained or seized FNAO is stored appropriately, particularly to avoid cross contamination of other goods. Food which is to be destroyed or disposed of should be dealt with so as to ensure that there is no possibility of it re-entering the food chain e.g. deep burial at an approved waste disposal site. Copies of waste disposal notes should be kept on file.

A.14.18: Products of Animal Origin - Enforcement

A.14.18.1: Illegally introduced POAO

POAO should be imported in accordance with the Products of Animal Origin (Third Country Imports) (England) Regulations 200. These require that POAO are imported through a designated Border Inspection Post (BIP) and are subject to veterinary checks. A Common Veterinary Entry Document (CVED)¹² is issued for consignments which pass the veterinary checks and this should accompany the consignment to the first premises after import, where it should be retained for a period of one year. POAO are considered to

be illegally introduced (smuggled) where they have not been presented at the BIP of entry, for clearance.

HMRC became responsible in April 2003 for detecting smuggled POAO in Customs controlled areas including ERTS. However, local authorities still have responsibilities relating to goods presented at Border Inspection Posts and also inland where officers come across illegal POAO in the course of their routine enforcement activities (MHS are responsible for illegal POAO found at premises under their control). Defra have produced guidance clarifying the roles and responsibilities, including relevant contact details, of enforcement agencies involved in the control of illegal imports of POAO¹³. The Food Standards Agency has also produced Enforcement Guidance on Illegal Meat for Enforcement Officers¹⁴.

All local authorities should set up, implement and maintain arrangements to effectively deal with illegally introduced POAO. Due to the nature of the enforcement activity which might require prompt action, officers should be properly authorised, template notices should be available, and effective mechanisms for any likely sampling or examination should be in place. Consideration should be given to necessary arrangements for the transport, storage, facilities and the necessary control arrangement for the destruction of POAO by high temperature incineration.

Where an authorised officer, in the course of their duties, comes across POAO at premises under Customs control i.e. in a port area or an ERTS, which they have reason to believe has been illegally introduced, they should notify HMRC and if needed for adequate interim control of the consignment, issue a detention notice under Regulation 5(3) of the POAO (Third Country Imports)(England) Regulations 2006.

Where illegal imports of POAO are found inland in an area/premises outside customs control, the local authority has responsibility for the enforcement action. Where an authorised officer is satisfied that a POAO has been illegally introduced, they should serve a notice under Regulation 24 of the POAO (Third Country Imports) (England) Regulations 2006on the person having charge of any consignment or product. An authorised officer should by such notice, take charge of the consignment or product and either:

- Have it re-dispatched, by the mode of transport by which it was first introduced into the EU, to a destination in a third country within sixty days; or
- Have it re-dispatched for rendering or incineration in accordance with relevant animal by-products legislation.

Although the final decision rests with the enforcing authority, in most circumstances it is unlikely to be appropriate or practical to re-dispatch the products. If re-dispatch was appropriate this would need to be carried out through the relevant importer and subject to appropriate control.

A.14.18.2: POAO Presenting a risk to public or animal health

Where an authorised officer, either at a port of entry or inland, considers that a consignment or product from a third country presents a risk to animal or public health, they should serve a notice under Regulation 25 of the POAO (Third Country Imports) (England) Regulations 2006on the person having charge of the consignment or product. The product should then be destroyed without undue delay in accordance with relevant animal by-products legislation.

A.14.18.3: Detention of POAO inland

Where an officer wishes to detain any POAO inland in order to investigate further to establish its safety or compliance, voluntary co-operation could be sought in the first instance. In situations where this is not possible or is inappropriate due to risk, there is a provision under Regulation 25 of the POAO (Third Country Imports) (England) Regulations 2006 for an authorised officer to serve a notice on the person having charge of the consignment to detain the product until such a time any further notice allows the product to be removed, provided that the officer is is satisfied that further checks need to be carried out.

Where Third Country POAO has been imported correctly through a BIP in another Member State, but are found to be non-conforming, for example, they are not marked with the approval number of the establishment of origin, as opposed to being deliberately smuggled, provisions under the Products of Animal Origin (Import and Export) Regulations 1996 as amended may be used. Part III of these Regulations applies to intra-community trade and includes goods, which originate in a third country but have received full clearance in a Member State i.e. they are in free circulation. Regulation 16 covers consignments posing a risk to health or illegal consignments. Under 16(3), where an authorised officer has reasonable grounds for believing that any POAO does not comply with animal or public health conditions relating to import into Great Britain or the European Community, a Notice may be served to prohibit the movement of the consignment. Regulation 16(4) provides that a notice should then be served ordering the destruction of the goods, or public and animal health considerations permitting, use of the goods for other purposes as may be specified in the notice, including returning them (with the authorisation of the Competent Authority of the country of origin) to their country of origin. If the consignment fails to comply with legislation due to an irregularity in documentation only, the notice shall grant the consignor a period of seven days to produce the correct documentation before action is taken (Regulation 16(5)).

A.14.18.4: Reporting

From 1 April 2006, the reporting of seizures by Local Authorities (LAs)/Port Health Authorities (PHAs) have required the completion (electronically) of a

common form (IIT 1 (2/06)), which is then sent by e-mail to the Department for Environment, Food and Rural Affairs (Defra) to record the information. An option remains for the form to be completed manually, if that method is preferred, and sent to Defra by fax/post. Details of where to e-mail/fax/post the completed form are included on the form itself. The form is located on the secure parts of the following websites which cannot be accessed without password permission:

Association of Port Health Authorities (APHA): http://www.apha.org.uk

Chartered Institute of Environmental Health (CIEH): http://www.ehcnet4.net/govt/defra/iit/iitrept.php

Local Authorities Coordinators of Regulatory Services (LACORS): http://www.lacors.gov.uk/lacors/ViewDocument.aspx?docID=7866&docType= C

This system replaces the Illegal Import of Animal Product Seizures (ILAPS) database. From 1 April 2006, it has no longer been possible for LAs/PHAs to record new seizure information on to the ILAPS database. However, all current users (with password access) from LAs/PHAs can retain 'for information only' access, so that details of all their previously recorded seizures can be viewed. Defra will retain 'for information only' access to ALL seizure details previously recorded on ILAPS. Anyone trying to log in to the ILAPS database to record new seizure information will receive a message advising them that this is not now possible and informing them briefly what they need to do now.

Where definite information as to the route/people involved is available, LAs/PHAs should also pass information to Her Majesty's Revenue and Customs (HMRC) via the Food Standards Agency for evaluation and possible future investigation action at the frontier. Please contact 0207 276 8018 or e-mail: imported.food@foodstandards.gsi.gov.uk for advice on submission of intelligence data. HMRC should also be involved at the earliest possible stage in any formal LA investigation into illegal imports found inland.

HMRC will also pass intelligence referrals to the FSA for the use of LAs when they come across consignments destined for retail/commercial establishments in Great Britain. LAs should then investigate these establishments to determine if any other illegal imports/activity has taken place and then feed back any information obtained to HMRC.

A.14.19: References

imported.food@foodstandards.gsi.gov.uk

Tel: 020 7276 8018

This guidance can be found on the Agency's website <u>www.food.gov.uk</u>

¹ For information and guidance on international trade in animal products see Defra's website <u>http://www.defra.gov.uk/animalh/int-trde/imports/index.htm</u>

² Food Standards Agency Imported Food Control Resource Pack (available on the Agency's website at:

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

³ Benchmarking the Port Health Function, The Syniad Benchmarking Centre (<u>martin.goodman@wlga.gov.uk</u>)

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

⁴ <u>http://www.food.gov.uk/enforcement/foodlaw/frameagree/</u>

⁵ Local Authority Delegated Powers, Authorisation of Officers and Use of Credentials, LACORS.

⁶ Imported Food Division – Tel. 020 7276 8018 , fax 020 7276 8024, email imported.food@foodstandards.gsi.gov.uk

⁷ Incidents Branch – Tel. 020 7276 8448, fax 020 7276 8446, email

drazenka.tubin-delic@foodstandards.gsi.gov.uk or rajwinder.ubhi@foodstandards.gsi.gov.uk

⁸ <u>www.forum.europa.eu.int/Public/irc/sanco/Home/main</u>

⁹<u>www.food.gov.uk/multimedia/worddocs/referralsproforma.doc</u>

¹⁰ <u>www.food.gov.uk/imports</u>

¹¹ <u>www.food.gov.uk/multimedia/pdfs/foodstuff_controls.pdf</u>

¹² This document was introduced on 1 March 2004 and is standardised throughout EU Member States. The predecessor of the CVED was the Certificate of Veterinary Checks (CVC).

¹³ Enforcement guidance for anti-smuggling activity against illegal imports of meat and other products of animal origin. For further information, contact <u>andy.green@defra.gsi.gov.uk</u>, or phone 020 7904 8233.

¹⁴ Food Standards Agency Illegal Meat. Enforcement Guidance for Local Authority officers in England July 2004. This can be found at: <u>http://www.food.gov.uk/foodindustry/guidancenotes/meatregsguid/illegalmeatguidance</u>

¹⁵ The BIP Manual. Published by DEFRA. Available at: http://www.defra.gov.uk/animalh/int-trde/imports/vetchecks.htm#manual

Appendix 1 : Glossary of Terms

BIP	EU Border Inspection Post situated at a seaport or airport or international rail or road link – designated point of entry for products of animal origin from third countries.
CITES	Convention on International Trade in Endangered Species, enforced by HM Revenue and Customs.
Consignment	Consignments can consist of one type of product, or a number of different types of products, which is covered by the same health certificate and/or airway bill or bill of lading. See also legal definition in POAO Regs.
ERTS	Enhanced Remote Transit Shed. Customs approved warehouse facilities where imported goods are held in temporary storage under Customs control. They are intended to facilitate entry of goods for Customs purposes and may be some distance from the seaport or airport, so may therefore fall under the jurisdiction of another local authority. May be referred to as "temporary storage facilities".
High risk FNAO	Products subject to special import conditions / emergency controls. These are laid down in specific Community and domestic legislation concerning individual products/groups of products and/or countries of origin.
Manifest	Document/computer file describing all cargo carried on a ship, cargo train or aircraft.
PHA	Port Health Authority. These are specially constituted local authorities with a remit of administering a range of environmental health functions in docks/seaports.
T1 arrangements	A transit declaration made to HM Revenue and Customs. T1 signifies that the goods are not in Free Circulation i.e. they are still subject to Customs control.

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Stage: Consultation	Version: #1	Date: 20 September 2007	
Related Publications:			

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What is the problem under consideration? Why is government intervention necessary?

The Hampton report highlighted the need for regulators to operate a risk based approach when deciding the appropriate regime to protect public health. The finite resources available to Local Authority regulators need to be targeted at higher risk premises. The current system of inspection by Local Authorities and monitoring of this action by the Food Standards Agency, does not allow the Local Authority to make best use of local resources or the FSA to formally recognise those official controls and interventions

What are the policy objectives and the intended effects?

To make focused amendments to the Code of Practice to reflect the principles of better regulation and to reduce the administrative burdens to business and local authorities, while maintaining the protection of public health and consumers other interests.(this would include premises requiring approved under EU 852/2004)

This would lead to:

the introduction of the concept of Interventions and the redefining of Official Controls; and moving all food establishments into a risk based inspection regime.

What policy options have been considered? Please justify any preferred option.

Option1: Do nothing

Option 2: Adopt the limited proposed changes to Code of Practice and undertake a full scale review of the Code of Practice once the initial changes have been accepted by the Food Enforcement community. (This is the preferred option as this would coinside with other agency work streams)

Option 3: Undertake a full review of the Code of Practice now to address any issues with the Code that are raised by our stakeholders within the enforcement community and the general public.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? Once the full consultation has been completed, estimated costs submitted by stakeholders will be considered and the introduction of interventions will be moinitored over the next year.

Ministerial/CEO Sign-off For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the Food Standards Agency Chair*:

* for non-legislative Impact Assessments undertaken by non-ministerial departments/agencies

Partial Regulatory Impact Assessment

1. Title of proposal

Review of the Food Law Code of Practice

2. Purpose and intended effect

Objective:

- 2.1 To make focused amendments to the Code of Practice to reflect the principles of better regulation and to reduce the administrative burdens to business and local authorities, while maintaining the protection of public health and consumers other interests.
- 2.2 The key proposals within this review are:
 - the introduction of the concept of Interventions and the redefining of Official Controls; and
 - moving all food establishments into a risk based inspection regime.

Background

- 2.3 In the 2004 Budget, the Chancellor asked Philip Hampton to consider the scope for reducing administrative burdens by promoting more efficient approaches to regulatory inspection and enforcement, without compromising regulatory standards or outcomes. The report on the Hampton Review on Regulatory Inspections and Enforcement was published in March 2005. The recommendations in the Hampton report which this review is addressing are:
- 2.3.1. Comprehensive risk assessments should be the foundation of all regulators' enforcement programmes;
- 2.3.2. There should be no inspection without reason, and data requirements for less risky business should be lower than for riskier businesses;
- 2.3.3. Resources released from unnecessary inspections should be redirected towards advice to improve compliance;
- 2.3.4. There should be fewer, simpler forms.

The full document can be found at: <u>http://www.hm-</u> <u>treasury.gov.uk/independent_reviews/hamptonreview/hampton_index.cfm</u>

2.4. The existing Code of Practice¹ requires that Local Authorities record numbers of inspections only, whilst other activities to increase compliance (which

¹ <u>http://www.food.gov.uk/enforcement/foodlaw/foodlawcop/copengland</u>

would be in line with the Hampton report recommendations) are not currently monitored or reported by the Food Standard Agency.

- 2.5 In addition the current interpretation of Official Controls within the Code is unnecessarily constrained and regulatory work other than inspections are not explicitly recognised as Official Controls as defined by European legislation 882/2004.
- 2.6 Establishments that are required to be approved under European Regulation 852/2004 (specific hygiene rules for food of animal origin) currently have their inspection frequency prescribed in section 4.3.4 of the Food Law Code of Practice. These are not based on a risk assessment process.
- 2.7 The Local Authorities have expressed concern that these establishments are not being inspected on a risk basis, and consequently resources are not been directed at the most high risk premises

Rationale for government intervention

- 2.8 The Hampton report highlighted the need for regulators to operate a risk based approach when deciding the appropriate regime to protect public health. The finite resources available to Local Authority regulators need to be targeted at higher risk premises. This will ensure that establishments which are of high risk to public health and which do not comply with Food Law are closely monitored and the appropriate enforcement action is taken if necessary.
- 2.9 The current system of inspection by Local Authorities and monitoring of this action by the Food Standards Agency, does not allow the Local Authority to make best use of local resources or the FSA to formally recognise those official controls and interventions that improve compliance. This can only be achieved by changing the Code of Practice
- 2.10The requirement for premises approved under EU 852/2004 to be inspected on a basis, other than one informed by a risk rating system, would not be in line with the recommendations of the Hampton report. Local Authorities have pressed for this imbalance to be addressed.

3. Consultation

- Within government
- 3.1 The FSA is consulting with the Department for Business, Enterprise and Regulatory Reform Better Regulation Executive, the Small Business Service, LACORS, and representatives from Trading Standard and Environmental Health Bodies and all food authorities.
 - Public consultation
- 3.2 The consultation package is being sent to the Chartered Institute of Environmental Health, consumer groups, and industry and business groups.

Annex E

The package is also being placed on the agency's website for wider access by interested parties.

4. Options

4.1 The FSA has identified three options;

Option1: Do nothing

<u>Option 2:</u> Adopt the limited proposed changes to Code of Practice and undertake a full scale review of the Code of Practice once the initial changes have been accepted by the Food Enforcement community.

<u>Option 3</u>: Undertake a full review of the Code of Practice now to address any issues with the Code that are raised by our stakeholders within the enforcement community and the general public.

- 4.2 Option 1, 'Do nothing' would mean the current Code of Practice remaining in force. The Agency would not be implementing the Hampton recommendations and risk not fulfilling its commitment to Local Authorities [to update the Code in line with Hampton principles]. Failure to make changes to the Code of Practice will put the delivery of the new monitoring system, due to See be delivered by April 2008, at risk. link: http://www.food.gov.uk/enforcement/ocddata/
- 4.3 <u>Option 2</u>, making limited changes to Code would enable the FSA to bring in changes to the Code of Practice that were agreed with the Agency's key stakeholders in the field of Food Law enforcement, while staying within the agreed time-frame of the Agency's Changes to Local Authority Enforcement (CLAE) project. This will provide more flexibility to enforcers to direct resources at non-compliant businesses. Once the initial changes have been made a second stage of the review of the Code can begin following stakeholder discussions.
- 4.4 Under this option the Agency will continue to monitor the level of compliance in food businesses to determine whether the changes have increased the number of businesses that are broadly compliant with food law. Part of the consultation process will be to seek opinion as to whether stakeholders agree that the changes will facilitate an increase in compliance.
- 4.5 <u>Option 3</u>, undertaking a full review of the Code would enable the Agency to address a wider range of issues in relation to the Code of Practice such as the risk rating scheme in Annex 5. The Agency would not be able to deliver changes quickly, as a full review of the code would take up to 2 years to complete, missing current timescales agreed with stakeholders in delivering the Hampton report recommendations.

5. Costs and benefits

• Sectors and groups affected

- 5.1 The key groups affected are 469 local authorities, around 570,000 food businesses and the general public, plus any voluntary organisations and charities subject to local authority regulation in respect of food legislation.
- 5.2 It is not anticipated that the policy proposal will have any race equality impacts, or that it will have any effect on environmental or social issues.

Costs

Option 1: Do nothing

5.3 There are no incremental costs as this option represents the status quo.

Option 2: Adopt limited changes

- 5.4 The financial costs to the local authorities associated with the introduction of official control regime would change due to the fact that under the previous Code there was a requirement for inspections to take place at each visit to the establishment, at a frequency dependent on the risk presented to public health. Under the proposed version of the code the requirement to undertake an inspection at every visit has been removed and there is discretion given to the visiting officer to undertake an alternative form of intervention.
- 5.5 Local authorities will incur a cost from reading the revised Code. This is estimated for front line Environment Health Officers to take approximately one working day (7 hours and 30 minutes). Given an hourly rate of pay of £16.84 for Environmental Health Officers (ONS ASHE Survey 2006 up-rated by 30% to account for overheads) this will give an average cost of £126.30 for local authorities across the UK. Multiplied across 469 local authorities in the UK, gives a total one-off cost to UK local authorities of £59,200.
- 5.6 Local Authorities will also incur a separate cost associated with Food Service Managers understanding and adapting their service or work plans to reflect the change in requirement that the revision brings; this is estimated to take one working week (37 hours and 30 minutes). Given an hourly rate of pay of £22.18 for Business and Public Service Professionals (ONS ASHE Survey 2006, up-rated by 30% to account for overheads), this will give an average cost of £831.68 for local authorities across the UK. Multiplied across 469 local authorities in the UK, gives a total one-off cost to UK local authorities of £390,100.

The Agency would welcome evidence of the estimated costs associated with food service managers understanding and adapting their service or work plans to reflect the introductions of interventions. 5.7 A number of changes to the registration forms within the code will present a cost saving in the time spent by businesses completing these forms. Based on information provided by industry, the Agency estimates that it takes 1 hour and 30 minutes to gather the information required, complete and submit the current registration form. Based upon the hourly rate of pay for Managers being £15.86 (according to FSA consultation with industry) the time-cost of providing this information is £23.79, including overheads takes this figure to £27.49. The Agency estimates that half of this cost can be attributed to activities that would occur through normal business operations, even in the absence of such a requirement to provide such data (the 'business-as-usual' element). Therefore the administrative burden of the current requirement equates to £13.75 per business. By reducing the required level of detail that a business needs to supply on the registration form, the Agency estimates that the time taken to complete the forms could be reduced by 50%, reducing this administration burden by £6.87, to £6.87. There are an estimated 61,000 new food establishments in the UK every year; this therefore, represents a (negative) cost to UK business of -£419,200 per annum; this is the total reduction in the administration burden.

The Agency would welcome comments and evidence of the estimated time and cost of gathering the information required to complete and submit the new registration form

Option 3: Undertake a full review of the Code of Practice

5.8 The Agency anticipates that all costs associated with Option 2 would also apply to option 3. However, without knowing the outcome of a full review, total costs cannot be estimated.

Although not an incremental cost with respect to the status quo (Option 1), it is worth noting that there will be additional costs of pursuing Option 3 with respect to the alternative of pursuing Option 2. These would be due to the anticipated saving given in option 2 being delayed as a full review of the Code of Practice would take up to two years to complete. This would incur additional costs, as the review of the Code is being undertaken as part of wider change management programme (CLAE project²)

The Agency would welcome comments and evidence of the estimated costs undertaking a full review of the Code of Practice

Benefits

² <u>http://www.food.gov.uk/enforcement/clae/</u>

Option 1: Do Nothing

5.9 There are no identifiable incremental benefits from doing nothing.

Option 2: Adopt Limited Changes

- 5.10 The Agency believes that the introduction of the proposed changes to the Code of Practice will have a positive effect on both public health and the costs associated with compliance to Food Law for both Local Authority enforcers and business operators. Research carried out by the Agency indicates that Food Authorities would benefit from the provision of a variety of different interventions, which they could use in a more responsive way, to drive up compliance within food establishments. See link: http://www.food.gov.uk/science/research/researchinfo/choiceandstandardsres earch/enforcementresearch/e03programme/projlist/e03003/
- 5.11 The returning of premises requiring approval under Regulation (EU) 853/2004 to the risk rating system should reduce the number of inspections Local Authority regulators are required to undertake as the food establishment will be given an inspection frequency based on their estimated risk to public health rather than the prescribed frequencies specified in section 4.3.4 of the existing Code of Practice. This has the potential to represent significant time-savings to local authorities. Compliant businesses will also benefit from reduced number of inspections.

The Agency would welcome comments and evidence of the estimated benefits of option 2.

5.12 The Agency anticipates that both changes will enable local authorities to direct their front line EHO resources to premises identified as presenting a higher food safety risk and increase the number of establishments that are considered to be compliant with food law. This should also bring about a concurrent increase in consumer confidence.

Option 3: Undertake a full review of the Code of Practice

- 5.13 A full review of the Code would allow the Agency to address many other issues within the code that have been raised by our stakeholders. This single review approach would mean that local authority regulators will only need read and understand one set of changes, and make one set of changes to their work practices.
- 5.14 This would enable the Agency to address a wider range of issues, i.e. undertaking an in-depth review of the risk rating system at Annex 5. This system is used by all local authorities to determine the minimum inspection frequencies laid down in their service plans. Stakeholders have raised many issues relating to the interpretation and weighting given to some aspects of the risk rating.

- 5.15 The Agency will also like to review the current qualification requirements of Food Officers, in light of comments raised by stakeholders and the devolved administrations. A full review of the Code would enable the Agency to review current qualification requirements.
- 5.16 There are a number of other minor amendments needed to the Code of Practice, and the Agency would be able to consult widely on these issues, and consider gathering evidence that would support any proposed changes.

The Agency would welcome comments and evidence of the estimated benefits of option 3.

6. Small Firms Impact Test

5.13 The Agency is aware of the possible impact that this work could have on small businesses and believes it may benefit those which are already broadly compliant, by reducing the number of inspections and interventions they receive. We do not envisage that the proposed changes will have any additional burden on the small business community but business will have an opportunity during the public consultation to tell if any of the proposed changes give cause for concern.

The Agency would welcome views on the impact that these changes have on small businesses

7. Competition assessment

7.1 The Agency has considered the competition assessment, and does not anticipate that changes will lead to competition issues. Information provided as a result of this consultation will enable the Agency to review the competition filter.

8. Enforcement, sanctions and monitoring

- 8.1 The proposed changes to the Code of Practice will lead to a change in methods of enforcement used by the Local Authorities. The Agency will be consulting publicly as to whether the proposed methods are likely to drive up compliance in food establishments and whether the Local Authorities will be able to adopt the new range of enforcement interventions.
- 8.2 It is intended that the changes to the Code will allow Local Authority enforcers a more flexible approach and will give them the option of replacing inspections with alternative interventions, aimed at driving up compliance, with the intention of reducing the burden of inspection on both the business and the enforcing authority.
- 8.3 This will enable enforcers to take a more risked based approach to the targeting of resources and use a range of alternative interventions with

businesses that have demonstrated a history of compliance, redirecting resources at higher risk premises.

- 8.4 Returning premises requiring approval under regulation (EU) 852/2004 into a risked based inspection program will reduce the number of inspections required and allow greater targeting of enforcement resources.
- 8.5 The changes proposed should not require any change to regulatory sanctions currently being used in the enforcement of Food Law.
- 8.6 The Agency will be able to monitor the effect of these changes on business compliance through its new systems of monitoring local authority compliance scores, and new audit arrangements.

List of Interested Parties

All Local Authorities LACORS CIEH WHICH? TSI BRC DEFRA DH