



FOOD
STANDARDS
AGENCY

SCOTLAND

Buidheann
Inbhe-Bidhe
an Alba

Food Standards Agency Scotland

Focussed Audit of Establishments

Subject to Approval under

Regulation (EC) No 853/2004

Laying Down Specific Hygiene

Rules for Food of Animal Origin

(February – May 2009)

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1.0 INTRODUCTION

Background

- 1.1 The Food Standards Agency is charged with auditing Local Authorities under the Food Standards Act 1999, and The Official Feed and Food Controls (Scotland) Regulations 2007. Such audits, including focussed audits, are a key mechanism by which the Agency can contribute to the improvement of national food safety standards by helping to improve the effectiveness and consistency of Local Authority performance.
- 1.2 Agency audits assess Local Authority conformance against relevant legal requirements, the Food Law Enforcement Standard “The Standard”, the Food Law Code of Practice, and relevant enforcement or compliance guidance issued by the Agency and other agencies. “The Standard” was published by the Agency as part of the Framework Agreement on Local Authority Food Law Enforcement and is available on the Agency’s website at:
www.food.gov.uk/enforcement/foodlaw/frameagree/.
- 1.3 Local needs and priorities result in considerable diversity in the way and manner in which Local Authorities provide their food and feed enforcement services. This is recognised by the Agency and is taken into account in the audit process.
- 1.4 Establishments that are engaged in the handling of products of animal origin are required to be approved in accordance with Regulation (EC) No 853/2004 which came into force on 1 January 2006. Responsibility rests with Local Authorities for the approval of, and delivery of, official controls in relation to establishments subject to approval under Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin in respect of which control does not fall to an official veterinarian.
- 1.5 Regulation (EC) No 178/2002 Article 17 specifically states that Food Business Operators at all stages of production, processing and distribution within the

business under their control have to ensure that foods satisfy the requirements of the Food Law relevant to their activities.

- 1.6 Regulation (EC) No 882/2004 covers in detail the Competent Authorities requirements on official controls to ensure the verification of compliance with food law, animal health and animal welfare rules.
- 1.7 Regulation (EC) No 178/2002 and Regulation (EC) No 882/2004 clearly establish that the Food Business Operators are fully responsible for the safe production of food at their establishments, and that the Competent Authorities should ensure that the requirements of food law are duly implemented.
- 1.8 These provisions apply across the UK. This focussed audit report reflects the findings of the Food Standards Agency Scotland reality checks carried out between February and May 2009. Similar audits have already been carried out in England and Northern Ireland, and are shortly to commence in Wales.

Reason for the Focussed Audit Programme

- 1.9 Following completion of the 2004/2008 Local Authority audit programme, the majority of Local Authorities received a non conformity in relation to lack of detail held within files of establishments subject to approval under Regulation (EC) No 853/2004.
- 1.10 A request was subsequently made by the Assistant Director, Science, Enforcement and Business Division, Food Standards Agency Scotland, to consider a focussed audit on delivery of official controls in establishments subject to, or approved under, Regulation (EC) No 853/2004. This audit was to include a reality check at establishments to ascertain whether the file records reflected conditions in the establishments.

Audit Objective and Scope

- 1.11 The audit looked at Local Authority systems, procedures and records that support any re-assessment and the delivery of official controls in establishments subject to, or approved under, Regulation (EC) No 853/2004.
- 1.12 Where the terms approved establishment or approval are used, this is a reference to establishments subject to Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin.
- 1.13 The scope of the audit was to assess the following:
- Efficiency of approvals and re-assessment process – i.e. ‘outcomes’ (including appropriateness of approval assessment forms)
 - Frequency of inspection as specified in the Food Law Code of Practice Scotland
 - HACCP-based controls/procedures by Enforcement Officers
 - Efficiency of routine Local Authority official controls - including inspection checklists; contemporaneous records, reports and any follow-up action as appropriate
 - Enforcement activity records (file records, reports, internal monitoring)
 - Sampling from these establishments
 - Competency of Officers (skills, qualifications, experience and training); those carrying out approvals and those implementing official controls following approval
 - Reality check at establishments

Selection of Local Authorities and Establishments

- 1.14 The following criteria were considered when selecting Local Authorities and establishments to ensure a representative sample:
- Number and locations of all commodity types of approved establishments
 - Percentage of each approved establishment commodity types overall
 - Other intelligence, e.g Remedial Action Notices, Food Alerts, Food Incidents and Product withdrawal, Temporary Closure Notices, Allergy Alerts etc

- The Food Standards Agency Scotland audits of Local Authorities in particular those with non conformities in relation to Regulation (EC) No 853/2004
- Approval history of establishment since 01 January 2006
- FVO visits and future programme

1.15 Focussed Audits were carried out at 15 Local Authorities and covered 30 approved establishments in Scotland in the period between February and May 2009. Once again Local Authority co-operation with the Food Standards Agency Scotland and the audit process has been greatly appreciated; the co-operation on this audit of the Food Business Operators has also been much valued and greatly appreciated.

Focussed Audit Approach

1.16 The focussed audit included:

- Assessment of Local Authority procedures for re-assessment and inspection of establishments under Regulation (EC) No 853/2004
- Assessment of all records maintained by the Local Authority in relation to these establishments
- Reality checks within establishments subject to, or approved under, Regulation (EC) No 853/2004 by the Local Authority
- For consistency, standard checklists were used

1.17 The focussed audit programme did not include:

- Assessment of Food Standards related issues
- Traceability under Regulation (EC) No178/2002
- Animal By Products
- Handling and Disposal of Waste Food

1.18 Although (with the exception of food standards issues) traceability, animal by products and the disposal of waste food are considered routinely as part of an approved establishments inspection and were discussed as part of this focussed

audit, they were not looked at in detail.

- 1.19 Local Authorities received prior written notice of the audit, the Chief Officer with food safety responsibility being asked to agree the suitability and availability of the establishments selected for a visit, termed as a “reality check”. The notification letter provided background information on the arrangements for, and the nature of, the audit. Accompanying the notification letter was a Pre-Visit Questionnaire (PVQ).
- 1.20 The PVQ is designed to obtain information about the Local Authority’s policies, procedures, enforcement staff and other service information that would facilitate the audit. Local Authorities were required to complete and return the PVQ to the Agency, enclosing copies of supporting documentation, prior to the audit. The Pre-Visit Questionnaire was sent to all 32 Scottish Local Authorities. 15 Authorities were selected for this focussed audit based on the criteria detailed above.
- 1.21 The Approved Establishments were also contacted in writing to advise them of their selection for a reality check of the Local Authority approvals process. The food businesses were requested to provide information to the Food Standards Agency which would help facilitate the visit (general information on the business, a layout of the establishment and current HACCP documentation). If it was not submitted by the business, the HACCP documentation was requested from the Local Authority.
- 1.22 PVQ information provided by the Local Authority and the documentation provided by the food business operator were reviewed. An audit programme was subsequently agreed.
- 1.23 The on-site audits and reality checks were carried out by the Audit Branch using audit protocols and checklists providing the detailed framework for consistency of the on-site audit. These documents were made available to Local Authorities.

- 1.24 Auditors ensured that the Local Authority's Audit Liaison Officer was regularly briefed throughout the audit. At the end of the on-site audit, it was not always considered necessary for the Auditors to hold a closing meeting, as the Audit Liaison Officer had generally been present during the reality check and the auditors ensured that the Officers were briefed as appropriate. Individual action plans were not required as the general findings are contained within this report.
- 1.25 Auditors actively sought feedback from the Local Authority Officers during the course of the audit on any issues that the Authority wished to bring to the attention of the Agency, either for action or for future consideration.

2.0 AUDIT FINDINGS

- 2.1 The findings from the 15 Local Authority visits and 30 reality checks carried out in the period from February to June 2009 have been collated and are summarised below.
- 2.2 In addition to the files for the 30 approved establishments visited, a further 35 files were also examined, giving a total of 65 approved establishment files examined.

Efficiency of approvals and re-assessment process

- 2.3 Approval can only be granted if an establishment complies with hygiene and operational requirements of relevant legislation. These include the general principles of food safety, Regulation (EC) No 178/2002¹, the hygiene of food stuffs Regulation (EC) No 852/2004², and the specific rules for food of animal origin under Regulation (EC) No 853/2004³. On receipt of an application for approval, the Local Authority is required under Regulation (EC) No 882/2004⁴ to carry out an assessment visit to verify if the establishment complies with relevant legislation. It shall then:
- a) grant full approval if it complies fully with requirements, or
 - b) grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements,
 - c) or may refuse to approve.
- 2.4 The Agency wrote to all Scottish Local Authorities in December 2005 and advised that in respect of establishments which were approved and continued to be subject to approval under Regulation (EC) No 853/2004 from 1 January 2006,

¹ Regulation (EC) No 178/2002 of the European Parliament and Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

² Regulation (EC) No 852/2004 of the European Parliament and Council of 29 April 2004 on the hygiene of foodstuffs

³ Regulation (EC) No 853/2004 of the European Parliament and Council of 29 April 2004 laying down specific rules for food of animal origin

⁴ Regulation (EC) No 882/2004 of the European Parliament and Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

food may continue to be produced in such establishments, subject to food safety requirements, and continue to be placed on the market until the establishment was re-assessed at the next programmed inspection against the requirements of the new legislation and subsequently approved (if appropriate) under Regulation (EC) No. 853/2004. Annex 1 details the approval process.

- 2.5 Local Authorities did not fully follow the approval process as advised by the Agency but adapted the process. The approval process was therefore not carried out fully or correctly in accordance with the regulations and was not consistently delivered by all Local Authorities. Examples of the different processes recorded are detailed below.
- 2.6 Approval automatically continued if the establishment was approved prior to January 2006. No formal re-assessment under the new regulations took place to determine whether approval was still appropriate.
- 2.7 Conditional approval granted prior to the Local Authority being satisfied that full approval was appropriate. However, the process of granting conditional approval as defined in article 31 of Regulation (EC) No. 882/2004 had not been followed in many cases; there are examples of conditional approval being granted for periods in excess of the initial 3 months and/or the full 6 months as required by the regulations.
- 2.8 Some Local Authorities conducted various advisory visits to the establishments but did not issue any conditional approvals; subsequently when the Local Authority was satisfied that the requirements of the regulations were being met, full approval was granted.
- 2.9 In many cases re-assessment had taken place as part of a routine inspection. However, it was not always clear from the file records that this re-assessment had taken place as it was not clearly defined or recorded within the establishment file.

- 2.10 At the time of this audit there was still one Local Authority who had a small percentage of existing businesses that had not yet been re-assessed under Regulation (EC) No 853/2004.
- 2.11 It should be noted that some Local Authorities had themselves identified the excessive timescales and had addressed the issue.
- 2.12 Once full approval or conditional approval has been granted, the 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 code. Formal approval documents (as detailed within the Food Law Code of Practice Scotland) were issued by most Local Authorities, while others notified the businesses by means of a letter advising them that they were approved under Regulation (EC) 853/2004. A small number of Local Authorities did not notify the business that they were now subject to approval under Regulation (EC) No 853/2004 (although this has since been rectified and approval documents sent out).
- 2.13 In only 1 of the 15 Local Authorities visited, specific pre-approval assessment forms were used and clearly identified the criteria and the date of the inspection that the re-assessment took place. In the other 14 Local Authorities it was not always clear when the re-assessment took place.
- 2.14 Regulation (EC) No 882/2004 (Article 31(f)) requires Competent Authorities to maintain up to date lists of approved establishments and make them available to other Member States and to the public. Following issue of either a conditional or full approval, Local Authorities are required to notify the Food Standards Agency. The Food Standards Agency Scotland is therefore responsible for ensuring that the list of Approved establishments in Scotland is kept up to date. During the course of the focussed audit it became apparent that the information held by the Agency was inaccurate and not up to date, either due to the Local Authorities not advising the Agency that establishments had been fully or conditionally approved under Regulation (EC) No 853/2004 or the Agency not processing the

information effectively. A significant exercise was then undertaken by both Local Authorities and the Agency in Scotland to update the data to improve its accuracy.

- 2.15 The re-approval process has therefore not been consistently carried out in accordance with the requirements of the regulations.
- 2.16 Many of the shortcomings found by the Audit team had not been identified by the Local Authorities.

Frequency of inspection as specified in the Food Law Code of Practice Scotland

- 2.17 During the period April 2008 until March 2009, two versions of the Food Law Code of Practice Scotland were permitted to be in use by Local Authorities. The 2006 version of the Food Law Code of Practice Scotland required a specified minimum number of primary and secondary inspections to be achieved within a 12 month period.
- 2.18 An updated version (in draft) of the Food Law Code of Practice Scotland which was issued in 2008 did not specify the frequency of inspection for approved establishments and instead required the establishments to be subjected to the risk rating scheme as described in Annex 5 of the Food Law Code of Practice Scotland. The Agency advised that Local Authorities may adopt this draft version should they wish to do so.
- 2.19 Those Local Authorities still working to the 2006 version had generally carried out the appropriate number of inspections as required. However, from the records checked, it was not always clear whether the full scope of the secondary inspection as required by the 2006 version of the Food Law Code of Practice Scotland had been covered. Recording, confirmation of operations carried out, confirmation of products produced, an assessment of the effectiveness of critical control points (CCPs), examination of CCP records, a review of the use of

health/identification marks and any commercial documents, were not always evident. In addition, details of approved products handled and the cleaning methods employed were required to be recorded by the 2006 version of the Food Law Code of Practice. The latter point has however not been specified in the current version of the Food Law Code of Practice.

- 2.20 At various times throughout the year many Local Authorities adopted the draft 2008 version of the Food Law Code of Practice Scotland which put Approved Establishments back into the risk rating scheme; these establishments were then inspected at a frequency based on risk basis.
- 2.21 Due to the Agency in Scotland allowing the use of two versions of the Food Law Code of Practice, this has meant that for the past year similar establishments in different Local Authorities were receiving differing numbers of inspections.

HACCP based controls/procedures by Enforcement Officers

- 2.22 A new application for approval was not required for establishments that were already approved prior to 1 January 2006; however some Local Authorities requested applications forms to be completed which included submitting copies of the HACCP documentation along with the application form. In all of the 30 establishments visited, the Food Business Operators HACCP documentation was retained on file by the Local Authority, either submitted as part of the application form or requested at the time of inspection. A high percentage of HACCP plans were also contained in the other 35 files checked where reality checks did not take place.
- 2.23 The 2006 and 2008 versions of the Code of Practice both require Local Authority files to include an assessment of the business progress in meeting compliance with procedures based on HACCP principles and also information on any training on the implementation and operation of the food safety management system.

- 2.24 For the first of these requirements, Local Authorities had generally assessed HACCP documentation and had accepted it as appropriate for approval and operations. However in some cases these documented food safety management systems did not appear to be robustly challenged by the Local Authorities as there was little evidence within the establishment files to demonstrate that these systems had been assessed and verified by the Officers. For example, this included lack of identification of specific hazards and causes, inappropriate CCPs and control measures, lack of detail on monitoring activities and recording and lack of specified corrective actions. Some plans had obvious gaps and missing areas in them that had not been commented on by the Local Authority.
- 2.25 The quality of HACCP plans produced by the Food Business Operators varied significantly. Food Businesses Operators did not routinely validate their HACCP plans and there was little evidence to demonstrate that Enforcement Officers had verified that HACCP plans had been validated by the Business.
- 2.26 For the second requirement there was little evidence on file to demonstrate that information was being routinely gathered, recorded or updated on the level of HACCP training by the Food Business Operator, in particular for those responsible for the development and maintenance of the HACCP plan.
- 2.27 All of the Approved Establishments visited had procedures in place based on HACCP principles but the standard of procedures examined varied. Some procedures did not contain all of the principles referred to in Article 5(2) of Regulation (EC) 852/2004 or they were incomplete, not kept up to date, evaluated or validated. Some procedures contained Critical Control Points which were really control points, or the Critical Control Points had been established without setting any critical limits to separate acceptability from unacceptability for prevention, elimination or reduction of the identified hazard. Local Authority Officers rarely made comment on the suitability or otherwise of HACCP plans.

Efficiency of routine Local Authority official controls - including inspection checklists, contemporaneous records, reports and any follow up action as appropriate

- 2.28 There are a variety of inspection forms in use to record inspection details of approved establishments. Examples are detailed below.
- 2.29 LACORS Regulation (EC) No 852/2004 inspection forms supplemented by subject specific (known as “bolt on’s”) Regulation (EC) No 853/2004 inspection forms. Comment was made by some Enforcement Officers that these checklists were cumbersome and not particularly user friendly. This was evident from the fact that many of these checklists contained within the establishment files were only partially completed.
- 2.30 Some Local Authorities had developed their own inspection checklists covering Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004 which were developed in consultation with their Officers. These were generally comprehensive and fully completed.
- 2.31 Other examples include using Regulation (EC) No 852/2004 forms only which did not cover the requirements of Regulation (EC) No 853/2004 and the reverse of this where specific Regulation (EC) No 853/2004 checklists were used which did not cover Regulation (EC) 852/2004. In one Authority, Officers were using a catering checklist for recording information at approved establishments.
- 2.32 Officers completed these inspection checklists and aides memoire to varying degrees, some being only partially completed.
- 2.33 In one Local Authority, the format of the aide memoire used did not allow for a full picture of the findings and scope of the inspection to be recorded. In particular, details on HACCP principles, assessment of the CCPs and the Food Business Operator records examined were not routinely recorded unless a non-compliance

was identified.

- 2.34 In all cases examined, Officers reported back in writing to the Food Business Operators following inspection, either by leaving a summary report or by writing a letter; these reports and letters generally met the requirements of Annex 6 of the Food Law Code of Practice Scotland.

Enforcement activity records (file records, reports, internal monitoring)

- 2.35 Generally file records in relation to establishments subject to Regulation (EC) No 853/2004 had significantly improved since the 2004/2008 audit programme. Many Local Authorities requested the information as detailed in Annex 12 of the Food Law Practice Guidance Scotland which provides guidance in order to support and improve consistency in the content and structure of files for approved establishments.
- 2.36 In some cases Local Authorities also took the opportunity to ask the Food Business Operator to complete an application form for approval as a means of gathering appropriate information. (Annex 11.1 of the Food Law Practice Guidance).
- 2.37 It should be noted that the information requested as part of the application form for approval differs slightly from that detailed in Annex 12 of the Food Law Practice Guidance. If these were aligned more closely it would potentially assist with information gathering.
- 2.38 Internal monitoring had generally been carried out, although it had not been fully effective in all cases. Some files were found to be badly organised or incomplete and these items had not always been identified by the Local Authority as part of their internal monitoring process.

Sampling from these establishments

- 2.39 It was evident that microbiological and chemical sampling is taking place as part of Local Authority routine sampling programmes. Many Local Authorities concentrate their sampling on locally produced products at or near to the time of production. In most cases Food Business Operators are being notified of the results whether satisfactory or unsatisfactory.
- 2.40 In some Local Authorities sampling at approved establishments is carried out only if the establishments or product coincided with a survey or if there was a known problem or complaint which required investigating or monitoring.
- 2.41 However, there was little evidence of Food Business Operator sampling taking place. Comment and reason for this was made on the cost of sampling and local availability of laboratories. Many businesses relied on the results of the samples taken by the Local Authority as a means of validating their HACCP plans.

Competency of Officers (skills, qualifications, experience and training), those carrying out approvals, and those implementing official controls following approval

- 2.42 Generally satisfactory evidence of good levels of knowledge of legislation and Approved Establishment procedures and establishments were identified. In some Local Authorities it was a policy that two officers conducted the inspection, these officers then consulted with each other before producing a single report.
- 2.43 In many cases Local Authority Officers concentrated their resources on conducting a physical inspection of the approved establishment, basing their reports on the requirements of Annex II General Hygiene requirements of Regulation (EC) 852/2004. The audit team identified deficiencies in structure, layout, maintenance and cleaning during the audits, many of which were not raised by the Local Authority. Only in a few cases did the Local Authority

Officers assess and verify procedures based on HACCP principles, confirming that controls were in place and operating correctly.

Other general issues

- 2.44 Identification marks were found in a variety of formats and in many cases do not comply with the format required by the regulations. There may be some ambiguity as the model approval document (Annex 11.2 of the Food Law Practice Guidance) does not detail fully the form of the identification mark.
- 2.45 Traceability, withdrawal and recall were not clearly defined in many food safety management systems and procedures for each or any of the three actions were not in place in some cases; traceability was generally therefore weak at all stages in approved establishments. Some businesses had however tested their procedures and recorded the results. Generally Local Authorities did not verify that the traceability systems in place complied with the traceability requirements within the regulations.
- 2.46 Registration documents for Live Bivalve Molluscs were incomplete, with examples found where there was no indication of classification of waters or quantity of product. These documents were not examined or requested by the Local Authority during the visit.
- 2.47 Physical condition of establishments varied considerably, from a very high standard of construction, cleanliness, maintenance and decoration to examples which were clearly not able to comply with the requirements of the regulations. In some cases the physical inspection failed to assess and report on the compliance with the regulations.
- 2.48 Products of Animal Origin (with the exception of primary products) were identified by Local Authority Officers in approved establishments as having originated in unapproved establishments, contrary to the requirements of the regulations. This

situation was accepted as allowable and was not recorded as a breach of regulations.

- 2.49 Inconsistent approaches to approving establishments were found. In one case the Local Authority separately approved two establishments with different processes under the same ownership who shared a common HACCP plan. In another case the Local Authority approved one establishment that was carrying out different processes in two clearly defined establishments in different locations under the same ownership with separate HACCP plans. It is not clear what the acceptable format is.
- 2.50 There have been longstanding requests from Local Authorities for better Food Standards Agency/central guidance on regulation and interpretation of issues. This has been raised by Local Authorities both directly and via auditors. Although the Agency has produced a significant quantity of guidance a more concentrated approach is required to identify gaps, produce guidance to address these gaps and then confirm that the guidance has been applied and found to be appropriate in practice by enforcers.

UK Audits

- 2.51 Findings from the audits carried out in England reflect the findings of the Scottish audits. For example, failure to follow the re-approval process was also evident during the audits in England. Local Authorities did not follow the statutory approvals process, choosing alternatives e.g. by conducting 'desktop approvals', particularly, but not exclusively, following the post-January 2006 need to re-approve existing approved premises. Also, the granting of full approval to businesses where sometimes significant non-compliances have been identified (e.g. no HACCP), not using the 'conditional approval' mechanism where appropriate as a lever for improvement, and failing to use formal enforcement to ensure full compliance where necessary.

2.52 In England frequent inconsistencies were also identified between Local Authority records of their approved premises and those held centrally by the Food Standards Agency. Agency restructuring in London, which has rationalised the data collection, will provide for better central data management.

3.0 CONCLUSIONS

- 3.1 The re-approval process following introduction of the new EU Consolidated Hygiene Regulations in January 2006 has not been carried out by Local Authorities in accordance with the requirements of the regulations. Clear guidelines were not issued by the Agency to ensure that all Local Authorities were aware of their responsibilities in relation to the re-approval process.
- 3.2 Local Authority files had generally improved considerably since the 2004-2008 core audit programme in content and detail; some however were using inappropriate forms to record inspection outcomes, and in a few cases internal monitoring had not identified the inadequate scope of inspections being carried out or that the files did not contain all of the information required.
- 3.3 Comprehensive coverage of the requirements of the regulations was not always evident, with areas such as HACCP training, traceability, cleaning methods, prerequisite programmes and shelf life validation frequently not being covered.
- 3.4 In many cases the auditors identified inadequate Approved Establishment HACCP plans which did not appear to have been verified by the Local Authorities as there was little evidence within the establishment files or during the reality checks to demonstrate that these systems had been assessed by the Officers.
- 3.5 Local Authority Officers were found to generally concentrate their inspections on physical inspection of the approved establishments; however these frequently failed to identify and raise clear breaches of the regulations.
- 3.6 Documentation examined during the reality check on identification marking, prerequisite programme documents or registration documents in relation to Live Bivalve Molluscs were generally not thorough, detailed or effective.
- 3.7 Food businesses operators are infrequently taking samples as a method of

validating HACCP plans or verifying shelf life of products. Local Authorities then do not appear to be targeting their sampling programmes at end of shelf life products, taking them usually at or near to production date.

- 3.8 Local Authority Officers interpreted the application of the regulations in considerably different ways. Strict adherence to the detail within the regulations was not common practice, which lead to a wide variation of standards within the establishments.
- 3.9 Live Bivalve Molluscs establishments were found to be carrying out very little end product testing. The regulations however do not specify the frequency of testing.

4.0 RECOMMENDATIONS

- 4.1 Measures to ensure consistency of approval assessments and decisions should be formalised by the Agency across Scotland. All key documents used in the approval process, including the approval assessment aide-memoire, should be centrally developed to ensure consistency of approach.
- 4.2 Application of HACCP knowledge and enforcement requires to be further improved, with measures put in place to ensure consistency across Local Authority boundaries.
- 4.3 Good practice and inspection outcomes should be widely disseminated to allow Local Authorities to be aware of alternative enforcement techniques.
- 4.4 Guidance and training on specific enforcement issues at approved establishments should be improved and increased to ensure greater levels of consistency.
- 4.5 Agency monitoring of specific enforcement issues at approved establishments should be improved and increased to ensure greater levels of consistency. This will also be applicable to establishments subject to Regulation (EC) No 852/2004.
- 4.6 Reality checks should form part of future audit programmes and consideration should be given to the period of notice for audit.
- 4.7 The requirement to have certain and specific information retained on file should be considered during the next review of the Code of Practice. At present this information is detailed within the Food Law Practice Guidance Scotland and not within the Code of Practice itself. The information requested as part of the application form for approval is different from that detailed in annex 12 of the Food Law Practice Guidance Scotland which details general information to be held by the Local Authority. If these were aligned more closely it would assist

with information gathering and retention.

- 4.8 More detailed guidance and training is required on traceability, withdrawal and recall for both Food Business Operators and Local Authorities.
- 4.9 The Agency should ensure that the list of approved establishments is accurate and kept up to date.
- 5.0 In relation to Live Bivalve Molluscs, more thorough examination of registration documents should be carried out by Local Authorities.

Annex 1

Approval Process issued to Local Authorities in December 2005

At the first inspection after 1 January 2006 the Competent Authority shall approve the establishment for the activities concerned only if the food business operator has demonstrated that it complies with the relevant requirements of food law (Regulation EC. 852/2004 and Regulation EC 853/2004. **(Regulation (EC) No 882/2004 Article 31, (2) (c))**

The Competent Authority may grant conditional approval if it appears that the establishment meets all the infrastructure⁵ and equipment requirements. It shall grant full approval only if it appears from a new official control of the establishment, carried out **within three months** of granting conditional approval, that the establishment meets the other relevant requirements of food law. If clear progress has been made but the establishment still does not meet all of the relevant requirements, the Competent Authority may prolong conditional approval. **However, conditional approval shall not exceed a total of six months. (Regulation (EC) No 882/2004 Article 31(2) (d))**

It is recognised that for new establishments since 1 January 2006 where the business has not previously traded, it would be appropriate to grant conditional approval until the Food Authority is satisfied that the HACCP system has been verified. For establishments approved under previous regulations prior to implementation of the new regulations in January 2006, verified HACCP systems should have already existed and it would therefore not be appropriate to grant conditional approval on this basis.

Notification of Approval (Food Law Code of Practice Paragraph 5.1.15)

Once full approval or conditional approval has been granted, the 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 code.

When full approval is granted following conditional approval, the Authority should notify the food business operator in writing. Such notification should also include details of the nature and scope of the approval and any conditions or limitations that apply, and confirmation that the approval code allocated to the establishment may continue to be used. **(Regulation (EC) No 853/2004 Annex II, Section 1B).**

A new application for approval is not required for establishments that were already approved prior to 1 January 2006. With the exception of the application form, the approval process should be followed for both new businesses after 1 January 2006 and for those previously approved under the now revoked legislation.

⁵ 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 (Code of Practice Guidance A.3.4).