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FOOD
STANDARDS
AGENCY

SCOTLAND

Buidheann
Inbhe-Bidhe
an Alba

Local Authority _____

Date _____

**Focussed Audit of Establishments Subject to Approval under
Regulation (EC) 853/2004**

PROTOCOL

[NOTE: These protocols should be used for focused audits of Local Authorities food law enforcement services. They should be used in conjunction with an FBO protocol and checklists]

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Authorised Officers [The Standard - para. 5]

- 5.1 The Authority shall set up, maintain and implement a documented procedure for the authorisation of officers based on their competence and in accordance with the relevant Food Safety Act Code of Practice and any centrally issued guidance.
- 5.2 The Authority, where it is responsible for the enforcement of food hygiene, food standards and/or feeding stuffs legislation, shall appoint an officer/s with specialist knowledge to have lead responsibility for that legislation. Where the Authority has specific responsibilities, for example, it is a UK point of entry or it has establishments approved under product specific legislation, it should ensure that officers have the necessary specialist knowledge.
- 5.3 The Authority shall appoint a sufficient number of authorised officers to carry out the work set out in the approved service delivery plan and they shall have suitable qualifications, training and experience consistent with their authorisation and duties in accordance with the relevant Food Safety Act Code of Practice.
- 5.4 The Authority shall set up, maintain and implement a documented training programme. The Authority shall ensure the training of all authorised officers and appropriate support staff in the technical and administrative aspects of the work in which they will be involved. Where training is provided, details of the content and objectives of the course, the duration and any assessment made of that training should be maintained on file. The training given shall depend upon the ability, qualifications, experience and responsibility of persons involved and their level of authorisation.
- 5.5 Records of relevant academic or other qualifications, training and experience of each authorised officer and appropriate support staff shall be maintained by the Authority in accordance with the relevant Food Safety Act Code of Practice.

Question	Answer	Comments/Evidence	Auditors Notes
Are all staff dealing with approved establishments appropriately authorised?	Yes/No	Document Review (PVQ Annex) Checklist	<i>Auditors should check the authorisations against the qualifications of the officers from the PVQ information.</i> <i>Authorisations should also be checked against the process set out in the Authority's own procedure. Agency and/or non-specialist IF enforcement staff should fulfil the same qualification criteria and be properly authorised by the LA, in accordance with the authorisation procedure.</i>
Are their authorisations consistent with their qualifications, training and experience and *CoP requirements?	Yes/No	Checklist Detail:	
Are officers acting in accordance with their authorisations/individual levels of qualification, training and experience?	Yes/No	Audit checks/all checklists	

(Food and Feeding Stuffs Establishments Inspections [The Standard – para. 7])

- 7.1 The Authority shall carry out food hygiene, food standards and feeding stuffs inspections of Establishments in their area, at a frequency which is not less than that determined under the inspection rating system set out in the relevant legislation, Food Safety Act Code of Practice or other centrally issued guidance.
- 7.2 The Authority shall inspect, approve, register, and license relevant Establishments in accordance with the relevant legislation, Food Safety Act Codes of Practice, centrally issued guidance and the Authority’s policies and procedures.

NOTE: Establishments includes any ship or aircraft of a description specified in the schedule to the Food Safety (Ships and Aircraft) (England and Scotland) Order 2003, the Food Safety (Ships and Aircraft) (Wales) Order 2003 [and the Food Safety (Ships and Aircraft) (Northern Ireland) Order 2004.

- 7.3 The Authority shall assess the compliance of Establishments and systems in their area to the legally prescribed standards.

NOTE: In assessing compliance, the Authority shall give due consideration to any relevant Industry Guides to Good Hygiene Practice and have regard to any other relevant centrally issued guidance. The Authority shall take appropriate action on any non-compliance found, in accordance with the Authority’s enforcement policy.

- 7.4 The Authority shall set up, maintain and implement documented inspection procedures for the range of inspections it carries out.
- 7.5 Observations made and/or data obtained in the course of an inspection shall be recorded in a timely manner to prevent loss of relevant information. Officers’ contemporaneous records of inspections shall be legible and stored in such a way that they are retrievable.

Question	Answer	Comments/Evidence	Auditors Notes
<p>Are inspections being carried out at a frequency of not less than that set out in the Food Law Code of Practice?</p> <ul style="list-style-type: none"> • Approved establishments 	<p>Yes/No</p>	<p>Document Review. Checklist</p>	<p><i>The service plan should have identified the planned programme. The FSA’s monitoring information should identify the LA’s progress towards these targets. The auditor should verify from the computer/file records that:</i></p> <ul style="list-style-type: none"> <i>a) Establishments are being risk-rated correctly;</i> <i>b) Establishments are receiving inspections according to their risk category and no later than 28 days after they are due except in circumstances outside of the control of the Authority such as seasonal businesses.</i> <p><i>[CP – 4.1.6] & [CP – 4.1.12] Internal monitoring reports of inspections due, and inspections overdue should be requested, and auditors should verify that inspections are up to date.</i></p>

Question	Answer	Comments/Evidence	Auditors Notes
Are inspections being carried out by correctly authorised staff?	Yes/No	Checklists	
Does the Authority have documented inspection procedures?	Yes/No	Document Review	<i>The service plan should have identified the types of Establishments in the LA's area. The auditor should expect to see inspection procedures for each of the different types of Establishments. The process and content of inspection procedures should set out the LA's system of inspection including use of any checklists and aide memoirs. The Auditor should be looking for compliance with the relevant codes.</i>
Do the procedures cover:			
Food Hygiene			
Policy on announced/unannounced inspections; [PG – 4.2.2]	Yes/No		<i>General principle that inspections should be unannounced.(Regulation (EC)852/2004)</i>
<ul style="list-style-type: none"> • Use of experts; [PG 4.2.3] 	Yes/No		
<ul style="list-style-type: none"> • New Establishments inspections; 	Yes/No		<i>All registration forms reviewed and appropriate visits made to new Establishments? [CP - 4.1.4]</i>
<ul style="list-style-type: none"> • Secondary inspection criteria; 	Yes/No	Detail:	<i>Food businesses that fail to comply with significant statutory requirements must be subject to appropriate enforcement action and secondary inspections. Suggested criteria contained in [CP 4.2.5]</i>
<ul style="list-style-type: none"> • Assessment of whether to take food samples; 	Yes/No		<i>An assessment of whether to take samples, and if so what sample, should be an integral part of every primary inspection, but particularly in food manufacturing, packing and catering businesses. [CP – 4.2.2]</i>

Question	Answer	Comments/Evidence	Auditors Notes
<ul style="list-style-type: none"> Process and content of inspection (inc. reference to aide memoire/checklists); 	Yes/No		<i>Relevant inspection forms should be used. These may be LACORS inspection forms or ones developed by food authorities or their regional groups, provided they include all the elements of an inspection that are appropriate to the type of business [CP 4.1.2]</i>
<ul style="list-style-type: none"> Content and timing of inspection reports. 	Yes/No	Detail:	
Are there inspection procedures covering:			
<ul style="list-style-type: none"> Approvals; 	Yes/No		<i>The procedures should cover all categories of Approval relevant to the Establishments in the LA's area. Where no Establishments have been identified that require Approval, the procedures should contain sufficient information to assist officers to recognise such operations and appropriate references to the relevant legislation, guidance and inspection forms. The procedures should cover the inspection of Approved Establishments and the Approval process.</i>
What is the LA's policy on approvals?		Detail:	
<p>Has the approvals process been carried out in accordance with legal requirements and relevant guidance?</p> <ul style="list-style-type: none"> Pre-approval Approval assessment Follow up on issues identified at assessment Routine primary and secondary inspections 	Yes/No	Detail:	
Does the LA keep appropriate records to satisfy the requirements of Article 3(6) of Regulation EC 854/2004?	Yes/No	Detail:	
How has the LA identified all establishments requiring approval?	Yes/No	Detail:	

Question	Answer	Comments/Evidence	Auditors Notes
Do LA records of approved establishments match the information held by the Agency?	Yes/No	Detail:	
Are inspections carried out in accordance with the LA's procedures?	Yes/No	Audit Check/Officer interviews. Checklist	<i>Interviews with officers should test their understanding of the procedures. Ask officers to talk you through how they would undertake an inspection and how they would assess further action.</i>
Do officers determine the conformance of businesses against the relevant legislation?	Yes/No	Checklist	<i>Auditors should look at any aide-memoire or inspection checklists to ensure that the legislation is covered.</i>
Do relevant inspection forms and records of inspection findings confirm if LA checks have been carried out?	Yes/No	Detail:	

Question	Answer	Comments/Evidence	Auditors Notes
Are officer's observations and data obtained during the course of inspections legible and retrievable?	Yes/No	Officer interviews.	<i>Auditors should look at a sample of inspection notebooks/inspection sheets or computer systems.</i>
Are Inspection reports/ Informal warning letters available?	Yes/No		
Have officers reported back in writing at the end of every food inspection?	Yes/No	Checklist	<i>Auditors may need to x-check computer files with inspection records to ascertain that reports were sent after inspection.</i>
Do the reports contain the requirements laid out in the code?	Yes/No	Checklist	<i>Inspection reports: [CP -4.5.1 Annexe 6]</i>
Do informal warning letters meet the requirements of the Code?	Yes/No	Checklist	
Is there evidence of a mechanism to allow discussion of the content of informal letters, improvement notices etc?	Yes/No	Audit check.	<i>Auditors should check for any standard paragraph in letters or pamphlet given to proprietors.</i>

Documents: Examples of Management reports (eg approved establishments inspection programme, overdue inspections, Establishments according to risk), inspection procedures, enforcement procedures.

Statistics: Inspection programme statistics.

Enforcement [The Standard- para 15].

15.1 The Authority shall set up, maintain and implement a documented enforcement policy, in accordance with the relevant Food Safety Act Codes of Practice, the Enforcement Concordat and other official guidance, approved by the relevant Local Authority Member forum.

NOTE: The enforcement policy or an accurate summary should be readily available to the public and food businesses in the Authority's area.

15.2 The Authority shall set up, maintain and implement documented procedures for follow up and enforcement actions in accordance with the relevant Food Safety Act Codes of Practice and official guidance.

15.3 The Authority shall carry out food law enforcement in accordance with the relevant Food Safety Act Codes of Practice and centrally issued guidance.

15.4 All decisions on enforcement action shall be made following consideration of the Authority's enforcement policy. The reasons for any departure from the criteria set out in the enforcement policy shall be documented.

Question	Answer	Comments/Evidence	Auditors Notes
Does the Authority have a written enforcement policy? [CP – 3.1.1]	Yes/No	Document review (PVQ B6)	
Have any Remedial Action Notices and Regulation 9 detention notices been served?	Yes/No	Checklist	Currently limited to establishments "subject to approval under Regulation (EC) 853/2004"
Has the Authority acted in accordance with its: Procedure Policy Official guidance?	Yes/No Yes/No Yes/No		
Have any prosecutions or simple cautions been taken relating to the approved establishments?			

Documents: Enforcement policy, formal enforcement procedures.

Records and Inspection Reports [The Standard - para. 16]

- 16.1 The Authority shall maintain up to date accurate records in retrievable form for all food and feeding stuffs Establishments in its area and relevant checks on imported food and feeding stuffs in accordance with the relevant Food Safety Codes of Practice. These records shall include reports of all inspections and visits and the determination of compliance with legal requirements made by the authorised officer, details of action taken where non compliance was identified, details of any enforcement action taken, results of any sampling, details of any complaints and any action taken, and also relevant food and/or feeding stuffs registration, approval and licensing information.
- 16.2 All records shall be kept for at least 6 years, unless they have been marked for longer retention because of litigation or Local Government Ombudsmen review.

Question	Answer	Comments/Evidence	Auditors Notes
Are records of food Establishments easily retrievable?	Yes/No	Audit check/checklists	
Are all relevant details on approved Establishments file in accordance with: Food Law (Practice Guidance) Annex 12: Approval of Establishments under Regulation 853/2004 – Food Authority Files, and Food Law Code of Practice 4.3.6 Secondary Inspections	Yes/No	Auditor check/Checklist	<p><i>Auditors should refer to Practice Guidance - Annex 12 in particular the file should contain:</i></p> <ul style="list-style-type: none"> • <i>Application form</i> • <i>Plan of establishment with layout, work flows, equip water, drainage, pest control</i> • <i>Synopsis of establishment</i> • <i>Pre-inspection approval report</i> • <i>Planned programme of work</i> • <i>Approval notification documents</i> <p><i>Relevant information on:</i></p> <ul style="list-style-type: none"> • <i>Labels and commercial documents</i> • <i>Letter indicating Food Auth involvement in hygiene training of staff</i> • <i>Inspection reports in chronological order</i> • <i>Correspondence in chronological order</i> • <i>Copies of notices or other formal action in chronological order</i> • <i>Copy of Company's emergency withdrawal plan and traceability system</i> • <i>Copy of other relevant documents eg HACCP, supplier and product information, test results etc.</i> • <i>Results of samples taken by the Food Authority</i> <p><i>Location of any off-site facilities</i></p>

Question	Answer	Comments/Evidence	Auditors Notes
Do they include relevant details?	Yes/No	checklist	<p><i>These details may be either on computer databases and/or on paper files. The information to be stored includes:</i></p> <ul style="list-style-type: none"> • <i>information on the size and scale of the business;</i> • <i>type of food activities including any special equipment;</i> • <i>processes or features, copies of correspondence including documentation associated with approvals or licensing;</i> • <i>copies of food sample analysis/examination results. In addition food hygiene:</i> • <i>assessment of compliance with HACCP requirements;</i> • <i>hygiene training by employees including any training on the implementation and operation of the food safety management system;</i> • <i>for Establishments subject to Regulation (EC) 853/2004. details of any derogations in force;</i> • <i>approved products handled and cleaning methods employed.</i> <p><i>Secondary Inspection details:</i></p> <ul style="list-style-type: none"> • <i>confirmation of operations carried out</i> • <i>approved products produced</i> • <i>assessment of effectiveness of CCp's</i> • <i>examination of CCP records</i> • <i>review of identification marks and commercial documents</i>

Internal Monitoring [The Standard - para. 19]

- 19.1 The Authority shall set up, maintain and implement documented internal monitoring procedures in accordance with the Food Safety Act Code of Practice and centrally issued guidance.
- 19.2 The Authority shall verify its conformance with this Standard, relevant legislation, the relevant Food Safety Act Codes of Practice, relevant centrally issued guidance and the Authority's own documented policies and procedures.
- 19.3 A record shall be made of all internal monitoring. This should be kept for at least 2 years.

Question	Answer	Comments/Evidence	Auditors Notes
Does the Authority have a documented monitoring procedure that covers approvals?	Yes/No	Document review	Planned inspection programme, quality & consistency [CP -7.1.2] Officers returning to food after > 3 years – should be monitored for 3 months [CP -1.2.4]
Who is responsible for carrying out the monitoring?		Name(s):	
Are records of internal monitoring maintained?	Yes/No	Detail:	
Where necessary have corrective actions been identified and implemented?	Yes/No	Audit check of records	<i>There should be evidence of corrective action where non-conformity is found. Continuing identification of the same problem could indicate that corrective action had not been effective.</i>
How have these been addressed?		Detail:	<i>e.g. training; revised procedures; discussion at Team Meetings etc.</i>

Documents: Internal monitoring procedures, copies of any internal reports following consistency and monitoring exercises.