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Regulation EC No 882/2004 Article 3 General obligations with regard to the organisation of official controls

1. Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of this Regulation taking account of:

(a) identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare;

(b) feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules;

(c) the reliability of any own checks that have already been carried out;

and

(d) any information that might indicate non-compliance.

2. 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.

3. Official controls shall be carried out at any of the stages of production, processing and distribution of feed or food and of animals and animal products. They shall include controls on feed and food businesses, on the use of feed and food, on the storage of feed and food, on any process, material, substance, activity or operation including transport applied to feed or food and on live animals, required to achieve the objectives of this Regulation.

4. Official controls shall be applied, with the same care, to exports outside the Community, to the placing on the market within the Community and to introductions from third countries into the territories referred to in Annex I.

5. Member States shall take all necessary measures to ensure that products intended for dispatch to another Member State are controlled with the same care as those intended to be placed on the market in their own territory.

6. The competent authority of the Member State of destination may check compliance of feed and food with feed and food law by means of nondiscriminatory checks. To the extent strictly necessary for the organisation of the official controls, Member States may ask operators who have goods delivered to them from another Member State to report the arrival of such goods.

7. If, during a check carried out at the place of destination or during storage or transport, a Member State establishes non-compliance, it shall take the appropriate measures, which may include re-dispatch to the Member State of origin.

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Regulation 882/2004 Article 3 General obligations with regard to the organisation of official controls

Question	Answer	Comments/Evidence	Auditors Notes
Is there a Sampling Programme that meets all the requirements of the current Food Law Code of Practice. In particular does it include sampling at relevant food establishments in the area	Yes/No	Review the Service Plan to ensure the Sampling Programme complies with the requirements of the Food Law Code of Practice. If yes is this Strategy clearly documented.	The Service Plan should have identified the planned programme and. include relevant food establishments within the LA area. The auditor should verify from the computer/file records that: a) Sampling is taking place b) The results of sampling are being recorded c) Appropriate action is taken on
Is Sampling being carried out on a risk basis as detailed in the Food Law Code of Practice • Food hygiene • Food Standards; • FLRS			sample results Internal monitoring reports of sampling activities should be requested.
Does the LA have a well-balanced Service Plan that includes Sampling			
Does the Sampling Policy & Programme cover all types of sampling work undertaken			FLCoP 38.1
Does the Sampling Policy commit the LA to providing the resources			38.2

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necessary to carry out its food sampling programme.		
Are discussions on legal interpretation and consistency		3.3
discussed at Liaison groups		
Are difficulties in enforcement reported to the Home Authority or FSS		7.7
 Does the Sampling Policy cover: Process monitoring Home Authority Inspections Complaints Special investigations Co-ordinated Programmes (local, regional or national) All samples taken 		
Does the Sampling Policy detail Consumer issues (local or national) that will influence the level of sampling		

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Regulation EC No 882/2004 Articles 4(2) to (6) Designation of competent authorities and operational criteria				
2. The competent authorities				
 (a) the effectiveness and app feed; 	ropriateness of official	controls on live animals, feed and for	bod at all stages of production, processing and distribution, and	on the use of
(b) that staff carrying out offic	al controls are free fro	om any conflict of interest;		
(c) that they have, or have ac controls and control duties			sufficient number of suitably qualified and experienced staff so	that official
			re that staff can perform official controls efficiently and effectively	y;
		ial controls and to take the measure		
.,	• • •	are prepared to operate such plans in	• •	
(g) that the feed and food bus competent authority in the			ried out in accordance with this Regulation and to assist staff of	the
	evel, efficient and effe	ctive coordination shall be ensured b	uthority or authorities other than a central competent authority, in between all the competent authorities involved, including where	-
-		ity, quality and consistency of officia etence to carry out official controls is	I controls at all levels. The criteria listed in paragraph 2 must be s conferred.	e fully
5. When, within a competent ensured between the diffe		one unit is competent to carry out off	ficial controls, efficient and effective coordination and cooperatio	on shall be
6. Competent authorities sha	all carry out internal au	dits or may have external audits car	ried out, and shall take appropriate measures in the light of their	r results, to
ensure that they are achie	eving the objectives of	this Regulation. These audits shall	be subject to independent scrutiny and shall be carried out in a t	transparent
manner.				
Question	Answer	Comments/Evidence	Auditors Notes	

Question	Answer	Comments/Evidence	Auditors Notes
Does the LA have access to			The LA should have appointed a PA and also
an adequate Lab for :			have access to a FE
	Yes/No		
Sampling			
1 0			
Does the LA have a			The FLCoP 2019 DOES NOT require that a
documented procedure	Yes/No		Sampling procedure should be in place,
covering sampling?			however best practice should cover:

Has the LA appointed a PA	Yes/No	Name of PA	• wł • W	e arrangements in place for deciding here and when samples are needed ho can take them 'here they go 'hat tests or examinations are required
Has the LA established a Sampling programme?	Yes/No			
Does the Sampling programme detail the intended sampling priorities Does the programme cover: 1) Numbers 2) Types of FBO 3) Risk ratings 4) Type of food produced 5) Home Authority 6) Originating Authority 7) Ensuring Food Law provisions are met.				
How are Sampling OC's verified in practice as being effective and appropriate? What checks are done to ensure OC's are free from any conflict of interest?				

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What labs do they use		
Has the LA identified the equipment and facilities it requires?	Yes/No	The Procedure should cover this
Are the equipment and facilities available?	Yes/No	Some equipment may not be required on a regular basis and some authorities may, in these circumstances, have documented arrangements to borrow necessary items from neighbouring LAs.
Does the Authority properly maintain facilities and equipment	Yes/No	Auditors should ascertain the types and quantities of equipment used by the Authority. Are all pieces of equipment adequately covered?
Eg Does this cover the implementation of: • The equipment calibration; • Recording of results & actions	Yes/No	The Procedure should cover this
Is the Authority's recording system capable of providing accurately the information required by the FSA?	Yes/No	The auditors should obtain the monitoring information received by the FSA. and cross-reference it with the LA's records.
Do the LA use SFSD (UKFSS)	Yes / No	

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Is there any Internal Monitoring of SFSD data	Yes / No	S

Regulation EC No 882/2004
Article 6
Staff performing official controls

The competent authority shall ensure that all of its staff performing official controls:

(a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner. This training shall cover as appropriate the areas referred to in Annex II, Chapter I;

(b) keep up to date in their area of competence and receive regular additional training as necessary; and

(c) have aptitude for multidisciplinary cooperation;

Question	Answer	Comments/Evidence	Auditors Notes
How are officer/Service			
sampling needs:			
 identified delivered verified maintained 			

Regulation EC No 882/2004 Article 6 Staff performing official controls				
Has the LA established a suitable sampling programme? eg • Over time • By specialist product • By food type	Yes/No			

		Regulation EC No 882/2004 Article 9 Reports	
2. These reports shall appropriate, action t	include a d hat the busi	Iraw up reports on the official controls that it has carried out. description of the purpose of the official controls, the control me iness operator concerned is to take. rovide the business operator concerned with a copy of the report i	
Question	Answer	Comments/Evidence	Auditors Notes
Are records of food samples easily	Yes/No		Records will be required for the checks on enforcement. This will go some way in determining whether they are retrievable. Auditors should examine the storage system and attempt to retrieve records themselves

Question	Answer	Comments/Evidence	Auditors Notes
Are records of food samples easily retrievable?	Yes/No		Records will be required for the checks on enforcement. This will go some way in determining whether they are retrievable. Auditors should examine the storage system and attempt to retrieve records themselves.
Do they include relevant details	Yes/No		 These details may be either on computer databases and/or on paper files. The information to be stored includes: information on the size and scale of the business; type of food activities including any special equipment; copies of food sample analysis/examination results.:

		Regulation EC No 882/2004 Article 9 Reports	
Is sampling carried out in accordance with the LA's procedures?	Yes/No		Officers should evidence their understanding of the procedures. The methods used to undertake an inspection and how they would assess further action should be clear and consistent with FLCoP.
Do officers determine the conformance of sample results against the relevant legislation?	Yes/No		Look at any aide-memoire or inspection checklists to ensure that the legislation is covered. Does SFSD and Certs match?
Is there evidence of a mechanism to allow discussion or monitoring of the results of sampling?	Yes/No		Check for any standard paragraph in letters or pamphlet given to proprietors.

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Regulation EC No 882/2004 Article 10 Control activities, methods and techniques

- 1. Tasks related to official controls shall, in general, be carried out using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.
- 2. Official controls on feed and food shall include, inter alia, the following activities:
- (a) examination of any control systems that feed and food business operators have put in place and the results obtained;
- (b) inspection of:
- (i.) primary producers' installations, feed and food businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of feed and food;
- (ii.) raw materials, ingredients, processing aids and other products used for the preparation and production of feed and food;
- (iii.) semi-finished products;
- (iv.) materials and articles intended to come into contact with food;
- (v.) cleaning and maintenance products and processes, and pesticides;
- (vi.) labelling, presentation and advertising;
- (c) checks on the hygiene conditions in feed and food businesses;
- (d) assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and HACCP, taking into account the use of guides established in accordance with Community legislation;
- (e) examination of written material and other records which may be relevant to the assessment of compliance with feed or food law;
- (f) interviews with feed and food business operators and with their staff;
- (g) the reading of values recorded by feed or food business measuring instruments;
- (h) controls carried out with the competent authority's own instruments to verify measurements taken by feed and food business operators;
- (i) any other activity required to ensure that the objectives of this Regulation are met.

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Regulation EC No 882/2004 Article 10 Control activities, methods and techniques			
Question	Answer	Comments/Evidence	Auditors Notes
Does the Authority have FLCoP documented sampling procedures that are: • Current • Correct • Available • Understood • Reviewed	Yes/No		The service plan should have identified the types of premises in the LA's area. The auditor should expect to see sampling procedures for each of the different types of premises.
Is there a reference or Policy on: announced/unannounced sampling 	Yes/No		General principle that inspections should be unannounced.(Regulation (EC)882/2004 A3.2)
• Use of experts; [PG 4.2.3]	Yes/No		
Assessment of whether to take food samples;	Yes/No		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]

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Is sampling carried out in accordance with the LA's procedures?	Yes/No	Interviews with officers should test their understanding of the procedures. Ask officers to talk you through how they would undertake sampling and how they would assess further action.
Do officers determine the conformance of a sample against the relevant legislation?	Yes/No	Auditors should look at any aide-memoire or inspection checklists to ensure that the legislation is covered.

Regulation EC No 882/2004 Articles 11 (1) to (3) and (5) to (7) Methods of sampling and analysis

- 1. Sampling and analysis methods used in the context of official controls shall comply with relevant Community rules or,
- (a) if no such rules exist, with internationally recognised rules or protocols, for example those that the European Committee for Standardisation (CEN) has accepted or those agreed in national legislation; or,
- (b) in the absence of the above, with other methods fit for the intended purpose or developed in accordance with scientific protocols.
- 2. Where paragraph 1 does not apply, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol.
- 3. Wherever possible, methods of analysis shall be characterised by the appropriate criteria set out in Annex III.
- 5. The competent authorities shall establish adequate procedures in order to guarantee the right of feed and food business operators whose products are subject to sampling and analysis to apply for a supplementary expert opinion, without prejudice to the obligation of competent authorities to take prompt action in case of emergency.
- 6. In particular, they shall ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substrate.
- 7. Samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity.

Question	Answer	Comments/Evidence	Auditors Notes
Does the Authority have a documented sampling policy? [(2019 Code @ 38.2)	Yes/No	Document review/PVQ	Auditors will need to take account of the LA's range of responsibilities when assessing the completeness of the sampling policy, procedures and programme e.g. specific imported food/Approved Premises responsibilities.
Does the Authority have any sampling procedures?	Yes/no		
Does the sampling policy take into account:			
A risk based approach?	Yes/No		
Home Authority premises?	Yes/No		
Originating Authority premises?	Yes/No		

Regulation EC No 882/2004 Articles 11 (1) to (3) and (5) to (7) Methods of sampling and analysis		
Process monitoring?	Yes/No	
Complaints?	Yes/No	
 Surveys – national & regional? 	Yes/No	
Special investigations?	Yes/No	

Does the sampling procedure cover:		Document review	
Equipment required?	Yes/No		
• Procurement of samples?	Yes/No		
Sample size?	Yes/No		Procedures may reference centrally issued protocols that cover sample size/method of sampling, or those drawn up by food liaison groups.
 Method of sampling (hot, cold, frozen, solid, liquid, bulk etc)? 	Yes/No		
Equipment required?	Yes/No		
 Sealing, labelling, bagging? 	Yes/No		
Documentation?	Yes/No		

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Sealing, labelling and bagging?	Yes/No		
Storage and transport?			
Question	Answer	Comments/Evidence	Auditors Notes
Results and further action?	Yes/No		
Traceability/continuity of evidence?	Yes/No		
Link with Food Alert procedure	Yes/No		
Contact with PA/FE/HPS	Yes/No		[PA = Public Analyst. FE = Food Examiner. HPS = Health Protection Scotland]
Does the LA have a documented sampling programme? [CP – 6.1.2]	Yes/No		
If YES, was the programme developed in consultation with the PA/FE? [CP – 6.1.2]	Yes/No		
Is the programme in accordance with the sampling policy?	Yes/No		
Is the sampling programme being implemented?	Yes/No		Auditors should note that SFSD will also give an idea of activity prior to the audit. If the LA has not met its programme, any review carried out with the PA/FE should be checked to determine the reasons.
Has appropriate action followed sample results that were not considered satisfactory?	Yes/No		The auditor will need to examine records of sampling activity. Where samples have been unsatisfactory, the premises files/interviews with officers should establish whether appropriate action has been taken. The PA/FE

			reports will give an indication whether the food met legal requirements and if further investigation was necessary.
Are all microbiological food samples submitted to an Official Control laboratory?	Yes/No	5	Details of the Public Analyst and the Food Examiner should be within the service plan information The List of official labs can be found at <u>http://www.food.gov.uk/enforcement/foodsampl</u> ing/foodcontrollabs#h_4

Regulation EC No 882/2004 Article 54 Action in case of non-compliance

- 1. When the competent authority identifies non-compliance, it shall take action to ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance.
- 2. Such action shall include, where appropriate, the following measures:
- (a) the imposition of sanitation procedures or any other action deemed necessary to ensure the safety of feed or food or compliance with feed or food law, animal health or animal welfare rules;
- (b) the restriction or prohibition of the placing on the market, import or export of feed, food or animals;
- (c) monitoring and, if necessary, ordering the recall, withdrawal and/or destruction of feed or food;
- (d) the authorisation to use feed or food for purposes other than those for which they were originally intended;
- (e) the suspension of operation or closure of all or part of the business concerned for an appropriate period of time;
- (f) the suspension or withdrawal of the establishment's approval;
- (g) the measures referred to in Article 19 on consignments from third countries;
- (h) any other measure the competent authority deems appropriate.
- 3. The competent authority shall provide the operator concerned, or a representative, with:
- (a) written notification of its decision concerning the action to be taken in accordance with paragraph 1, together with the reasons for the decision; and
- (b) information on rights of appeal against such decisions and on the applicable procedure and time limits.
- 4. Where appropriate, the competent authority shall also notify the competent authority of the Member State of dispatch of its decision.
- 5. All expenditure incurred pursuant to this Article shall be borne by the responsible feed and food business operator.

Question	Answer	Comments/Evidence	Auditors Notes
Has the Authority followed or had regard to the Scottish Regulators Code of Compliance following a sample failure?	Yes/No		
Does the Authority have a written enforcement policy? [CP – 3.1.1]	Yes/No		

		Regulation EC No 882/2004 Article 54 Action in case of non-compliance	
Has the appropriate Member forum approved the policy?	Yes/No	Date: Forum:	The committee minutes should be available to verify this approval. The forum chosen should ensure that the policy is made public.
Does the Enforcement Policy cover			
• Enforcement options and the circumstances in which they should be used;	Yes/No		
The internal appeals mechanism;	Yes/No		
The Scottish Regulators SCoP and the principles of better regulation	Yes/No		
 Emphasis on: reasonable proportionate risk based consistent with good practice 	Yes/No		14.3. National Food and Feed Compliance Spectrum
Include reference to the involvement of home and originating authorities;	Yes/No		

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		Regulation EC No 882/2004 Article 54 Action in case of non-compliance	
Include reference to the FL Code of Practice requirements in deciding to report to the Procurator Fiscal.			 (143) In considering whether to initiate enforcement action, Food Authorities should take account of the following: Reports to the Procurator Fiscal – A Guide For Non-Police Reporting Agencies,
Human Rights Act.	Yes/No	<u> </u>	
How are officers aware of the contents of the policy?	Yes/No		
Is there evidence of it being implemented?	Yes/No		This evidence may be in the form of coversheets on prosecutions or notes in relation to follow up on inspections demonstrating that the policy has been considered, or it may be obtained through officer interview
Have any monitoring found any enforcement decisions made outside the enforcement policy guidelines?	Yes/No		
Have these reasons been documented?	Yes/No		

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Regulation EC No 882/2004 Article 54 Action in case of non-compliance		
Has the policy or a summary been published?	Yes/No	
Is it made available to the public and businesses? And how is this done?	Yes/No	

Question	Answer	Comments/Evidence	Auditors Notes
Does the LA have	Yes/No		
documented procedures for			
formal follow up/			
enforcement actions?			

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