

Capacity & Capability

Audit Brief & Plan

September 2024



1. Introduction

- 1.1 The power to set standards, monitor and audit the performance of enforcement authorities was conferred on Food Standards Scotland by Sections 3 and 25 of the Food (Scotland) Act 2015 and Regulation 7 of The Official Feed and Food Controls (Scotland) Regulations 2009¹.
- 1.2 Assimilated Regulation (EU) No 2017/625² on official controls performed to ensure the verification of compliance with feed or food law includes a requirement for competent authorities to carry out internal audits or to have external audits carried out.
- 1.3 To fulfil this requirement Food Standards Scotland, has established external audit arrangements in respect of competent authorities. These arrangements are intended to ensure competent authorities are providing an effective and consistent service for the delivery of official controls and are meeting the general criteria laid out in assimilated Regulation (EU) No 2017/625.
- 1.4 In developing these audit arrangements Food Standards Scotland has taken account of the European Commission guidance on how such audits should be conducted.
- 1.5 The Food Scotland Act 2015 provides Food Standards Scotland with statutory powers to strengthen its influence over enforcement activity and to ensure national priorities and objectives will be delivered at a local level. It gives Food Standards Scotland powers to carry out the following duties:
 - *set standards of performance in relation to enforcement of feed and food law*
 - *monitor the performance of feed and food law enforcement authorities*
 - *require information from Local Authorities relating to food law enforcement and inspect any records*
 - *enter authority premises, to inspect records and take samples of records*
 - *publish information on the performance of enforcement authorities*
 - *make reports to individual authorities, including guidance on improving performance*
 - *require Local Authorities to publish these reports, and state what action they propose in response*
- 1.6 The audits will be a systematic and independent examination of the delivery of food law by Local Authorities in Scotland.

¹ <http://www.legislation.gov.uk/ssi/2009/446/contents/made>

² <http://www.legislation.gov.uk/eur/2017/625/contents>

2. Aims and Scope

2.1 The aim of the audit programme will be to determine whether official control activities/food law and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve the objectives of the relevant food legislation³.

2.2 The specific aims of this audit programme are to:

- evaluate the organisational, management and information systems in place to ensure they are effective and suitable to achieve the objectives of the relevant food law.
- assess the capacity and capability of the Local Authority to deliver the food service.
- provide a means to identify under performance in Local Authority food law enforcement systems.
- assist in the identification and dissemination of good practice to aid consistency.
- provide information to aid the formulation of Food Standards Scotland policy.

2.3 Assimilated Regulation (EU) No 2017/625, states that competent authorities, in this case Local Authorities should have in place certain controls. A summary of the relevant controls for this audit programme are listed below:

1) meet certain operational criteria such as:

- having a sufficient number of staff who are suitably:
 - qualified
 - experienced
 - competent
 - authorised
- ensuring that staff are free from conflict of interest
- having contingency plans for emergencies
- having appropriate legal powers
- having suitable facilities and equipment

2) ensure that staff receive appropriate and on-going training

3) ensure effective and efficient co-ordination with other competent authorities and between different units of a single authority, as applicable

4) have procedures in place for the registration/approval of establishments

5) take appropriate action where businesses do not comply with the law

³ <https://www.foodstandards.gov.scot/business-and-industry/safety-and-regulation/regulation-legislation/scottish-food-and-feed-law-guide>

- 6) carry out internal audits or have external audits undertaken
- 7) be transparent about its monitoring and enforcement activity
- 8) prepare reports of individual controls and provide copies to businesses
- 9) have, use and update as necessary, documented procedures for carrying out controls

2.4 **Annex 1** provides the specific articles of assimilated Regulation (EU) No 2017/625, which have been included in the scope of this audit programme.

3. Audit criteria

3.1 The audit criteria is the legislation, policies, procedures or other requirements used as a reference against which audit evidence is compared, i.e. the standards against which the auditee's activities are assessed. For the purposes of this audit the main legislation references will be:

- Assimilated Regulation (EC) No 2017/625 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules as amended, extended or applied at the date of making of The Official Feed and Food Regulations (Scotland) 2009 in so far as it relates to food.
- Assimilated Regulation (EC) No 178/2002⁴ of the European Parliament and of the Council 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.
- The Official Feed and Food Control (Scotland) Regulations 2009 in so far as they relate to food.
- In addition, the Food Law Codes of Practice provides relevant guidance to Local Authorities on discharging their duties.

4. Selection of Local Authorities for Audit and Notification

4.1 Local Authorities will be selected for audit based on information gathered via information gathering exercises and any other sources of information that become available. Supplementary evidence will then be requested as applicable, which will then be subject to a desk top review carried out by the auditors prior to the on-site visit.

4.2 The Local Authority will receive a minimum of 5 working days prior notification of the audit. Notification will be addressed to the Chief Executive and Head of Service responsible for the Local Authority's food law enforcement activity.

⁴ [\(EC\) No 178/2002](#)

5. Audit documents

- 5.1 To aid the effective operation of the audit plan audit checklists have been developed by the auditors. The checklist contains the areas to be examined and will be used to record evidence gathered during the audit. Checklists will be published on the Food Standard Scotland website, and are subject to on-going revision.

6. Audit process

- 6.1 The audit will focus on examining evidence to verify compliance with planned arrangements and assess whether the planned arrangements are suitable to achieve the objectives. This will consist of documentary evaluation and interviews. The time required to carry out the audit will be set out in a timetable and communicated to the Local Authority prior to the audit.
- 6.2 The audit will include:
- An initial opening meeting held with relevant officers of the Local Authority to address the scope, aims and arrangements for the audit. This meeting will also give the Local Authority the opportunity to raise any local sensitivity that may affect its service.
 - An assessment of the implementation of the relevant sections of the legislation listed in the Audit Brief and Plan. Auditors will make use of the audit checklist to collect evidence to assess compliance with planned arrangements, effective implementation and suitability to achieve objectives.
 - Providing feedback of findings to the designated Audit Liaison Officer⁵, or a nominated representative. This allows the auditee the opportunity to clarify any audit findings and resolve any potential points of confusion or disagreement prior to the closing meeting.
 - A closing meeting held with relevant Local Authority officers. The auditors will provide a summary of their provisional findings, in particular recommendations for improvement and areas of good practice.

Follow-up action

- 6.3 To address recommendations made by the auditors an action plan will need to be drawn up by the Local Authority. These actions should include risk-based prioritisation and specific time scales for completion of **corrective or preventative** actions. The actions to address recommendations will need agreement with the auditors.
- 6.4 There will be an expectation that Local Authorities will use root cause analysis techniques when deciding which actions will effectively address

⁵ The Audit Liaison Officer is that person of suitable seniority in the Council's food service who is responsible for acting as the auditors' main contact during the audit.

recommendations. The Food Standards Agency has developed a Root Cause Analysis eLearning module for authorised officers. It is available at: <https://rcatraining.food.gov.uk/#home> which might be of some assistance.

- 6.5 Food Standards Scotland will monitor implementation of the audit action plan. In some circumstances, follow-up assessments/re-visits to a Local Authority may be required.

7. Feedback

- 7.1 Feedback will be given by the auditors during the course of the audit and at least on a daily basis.

8. Audit Reports

- 8.1 A draft report will be issued to the Local Authority within 20 working days. The Local Authority then will be given a date to respond to the draft report and provide an action plan to addresses the recommendations made. A final report incorporating the action plan will then be produced within 10 working days.

9. Publication of audit reports

- 9.1 Information on Local Authority official control delivery performance will be placed in the public domain. A copy of the audit report and action plan (if required) will be placed on the Food Standards Scotland website at: <http://www.foodstandards.gov.scot/food-safety-standards/regulation-and-enforcement-food-laws-scotland/audit-and-monitoring>

10. Complaints and disputes

Conduct of the Audit

- 10.1 If the Local Authority is dissatisfied with any aspect of the audit, including the conduct of the audit and/or the auditors, it should initially take the matter up with the Lead Auditor and then, if necessary, the Head of Audit Assurance.

Disputes concerning the outcome of the audit

- 10.2 If the Local Authority is dissatisfied with the draft audit report, it should first raise the matter with the Lead Auditor (within 20 working days of receipt.) Informal negotiation between the Local Authority and the Lead Auditor may then take place.
- 10.3 If matters are not resolved at this level and the Local Authority remains dissatisfied, it can raise the issue with Head of Audit Assurance, within a further 10 working days, so that further informal negotiation may take place.
- 10.4 If, after this stage, the Local Authority remains dissatisfied, it may refer the matter to the Deputy Chief Executive, Food Standards Scotland within a further 10 working days.

10.5 Pending the resolution of any dispute, it is expected that the Local Authority would implement those elements of its action plan not subject to dispute to ensure other improvements are not delayed.

Annex 1: Assimilated Regulation EU 2017/625 - Roles and Responsibilities of Competent Authorities

| Assimilated Regulation 2017/625 | Article statement |
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| <p>Article 4 Designation of competent authorities</p> | <ol style="list-style-type: none"> 1. For each of the areas governed by the rules referred to in Article 1(2), Member States shall designate the competent authority or authorities on which they confer the responsibility to organise or perform official controls and other official activities. 2. Where, for the same area, a Member State confers the responsibility to organise or perform official controls or other official activities on more than one competent authority, at national, regional or local level, or where the competent authorities designated in accordance with paragraph 1 are allowed by that designation to transfer specific responsibilities for official controls or other official activities to other public authorities, the Member State shall: <ol style="list-style-type: none"> (a) ensure efficient and effective coordination between all authorities involved, and the consistency and effectiveness of official controls or other official activities across its territory; and (b) designate a single authority, in conformity with Member States' constitutional requirements, responsible for coordinating the cooperation and the contacts with the Commission and with other Member States in relation to the official controls and other official activities performed in each of the areas governed by the rules referred to in Article 1 (2). 3. Competent authorities responsible for the verification of compliance with the rules referred to in point (i) of Article 1 (2) may confer certain responsibilities related to official controls or other official activities to one or more organic control authorities. In such cases, they shall attribute a code number to each of them. 4. Member States shall ensure that the Commission is informed of the contact details and of any changes regarding: <ol style="list-style-type: none"> (a) the competent authorities designated in accordance with paragraph 1; (b) the single authorities designated in accordance with point (b) of paragraph 2; (c) the organic control authorities referred to in paragraph 3; (d) the delegated bodies referred to in Article 28(1). <p>The information referred to in the first subparagraph shall also be made available by Member States to the public, including on the internet.</p> |

| Assimilated Regulation 2017/625 | Article statement |
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| <p>Article 5 General obligations concerning the competent authorities and the organic control authorities</p> | <p>1. The competent authorities and the organic control authorities shall:</p> <ul style="list-style-type: none"> (a) have procedures and/or arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities; (b) have procedures and/or arrangements in place to ensure the impartiality, quality and consistency of official controls and other official activities at all levels; (c) have procedures and/or arrangements in place to ensure that staff performing official controls and other official activities are free from any conflict of interest; (d) have, or have access to, an adequate laboratory capacity for analysis, testing and diagnosis; (e) have, or have access to, a sufficient number of suitably qualified and experienced staff so that official controls and other official activities can be performed efficiently and effectively; (f) have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls and other official activities efficiently and effectively; (g) have the legal powers to perform official controls and other official activities and to take the action provided for in this Regulation and in the rules referred to in Article 1(2); (h) have legal procedures in place in order to ensure that staff have access to the premises of, and documents kept by, operators so as to be able to accomplish their tasks properly; (i) have contingency plans in place, and be prepared to operate such plans in the event of an emergency, where appropriate, in accordance with the rules referred to in Article 1(2). <p>2. Any appointment of an official veterinarian shall be in writing and shall set out the official controls and the other official activities and related tasks for which the appointment has been made. Requirements imposed on staff of competent authorities that are provided for in this Regulation, including the requirement on freedom from any conflict of interest, shall apply to all official veterinarians.</p> <p>3. Any appointment of an official plant health officer shall be in writing and shall set out the official controls and the other official activities and related tasks for which the appointment has been made. Requirements imposed on staff of competent authorities that are provided for in this Regulation, including the requirement on freedom from any conflict of interest, shall apply to all official plant health officers.</p> <p>Competent authorities, organic control authorities and delegated bodies shall develop and implement</p> |

| Assimilated Regulation 2017/625 | Article statement |
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| | training programmes for the purpose of ensuring that staff performing official controls and other official activities receive the training referred to in points (a), (b) and (c). |
| Article 5 (continued) | <p>4. Staff performing official controls and other official activities shall:</p> <p>(a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to perform official controls and other official activities in a consistent manner;</p> <p>(b) keep up-to-date in their area of competence and receive regular additional training as necessary; and</p> <p>(c) receive training in the subject matters set out in Chapter I of Annex II and on the obligations of the competent authorities resulting from this Regulation, as appropriate.</p> <p>5. When, within the services of a competent authority, more than one unit is competent to perform official controls or other official activities, efficient and effective coordination and cooperation shall be ensured between the different units.</p> |
| Article 6 Audits of the competent authorities | <p>1. To ensure their compliance with this Regulation, the competent authorities shall carry out internal audits or have audits carried out on themselves and shall take appropriate measures in the light of the results of those audits.</p> <p>2. The audits referred to in paragraph 1 shall be subject to independent scrutiny and carried out in a transparent manner.</p> |
| Article 9 General rules on official controls | <p>1. Competent authorities shall perform official controls on all operators regularly, on a risk basis and with appropriate frequency, taking account of:</p> <p>(a) identified risks associated with:</p> <p>(i) animals and goods;</p> <p>(ii) the activities under the control of operators;</p> <p>(iii) the location of the activities or operations of operators;</p> <p>(iv) the use of products, processes, materials or substances that may influence food safety, integrity and wholesomeness, or feed safety, animal health or animal welfare, plant health or, in the case of GMOs and plant protection products, that may also have an adverse impact on the environment;</p> <p>(b) any information indicating the likelihood that consumers might be misled, in particular as to the nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production of food;</p> |

| Assimilated Regulation 2017/625 | Article statement |
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| <p>Article 9 (Continued)</p> | <p>(c) operators' past record as regards the outcome of official controls performed on them and their compliance with the rules referred to in Article 1(2);</p> <p>(d) the reliability and results of own controls that have been performed by the operators, or by a third party at their request, including, where appropriate, private quality assurance schemes, for the purpose of ascertaining compliance with the rules referred to in Article 1(2); and</p> <p>(e) any information that might indicate non-compliance with the rules referred to in Article 1(2).</p> <p>2. Competent authorities shall perform official controls regularly, with appropriate frequencies determined on a risk basis, to identify possible intentional violations of the rules referred to in Article 1(2), perpetrated through fraudulent or deceptive practices, and taking into account information regarding such violations shared through the mechanisms of administrative assistance provided for in Articles 102 to 108 and any other information pointing to the possibility of such violations.</p> <p>3. Official controls that are performed prior to the placing on the market, or the movement of certain animals and goods in view of the issuance of the official certificates or official attestations required by the rules referred to in Article 1 (2), as a condition for the placing on the market or the movement of the animals or goods shall be performed in accordance with both of the following:</p> <p>(a) the rules referred to in Article 1(2);</p> <p>(b) the applicable delegated and implementing acts adopted by the Commission in accordance with Articles 18 to 27.</p> <p>4. Official controls shall be performed without prior notice, except where such notice is necessary and duly justified for the official control to be carried out. As regards official controls upon request from the operator, the competent authority may decide whether the official controls are to be performed with or without prior notice. Official controls with prior notice shall not preclude official controls without prior notice.</p> <p>5. Official controls shall be performed as much as possible in such a manner that the administrative burden and operational disruption for operators are kept to the minimum necessary, but without this negatively affecting the effectiveness of those controls.</p> <p>6. Competent authorities shall perform official controls in the same manner, while taking account of the need to adapt the controls to the specific situations, irrespective of whether the animals and goods concerned are:</p> <p>(a) available on the Union market, whether originating in the Member State where the official controls are</p> |

| Assimilated Regulation 2017/625 | Article statement |
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| Article 9 (continued) | <p>performed or in another Member State;</p> <p>(b) to be exported from the Union; or</p> <p>(c) entering the Union.</p> <p>7. To the extent strictly necessary for the organisation of the official controls, Member States of destination may require operators that have animals or goods delivered to them from another Member State to report the arrival of such animals or goods</p> |
| Article 10 Operators, processes and activities subject to official controls | <p>1. To the extent necessary to ascertain compliance with the rules referred to in Article 1(2), competent authorities shall perform official controls on:</p> <p>(a) animals and goods at any stage of production, processing, distribution and use;</p> <p>(b) substances, materials or other objects which may influence the characteristics or health of animals and goods and their compliance with applicable requirements, at any stage of production, processing, distribution and use;</p> <p>(c) operators as regards activities, including the keeping of animals, equipment, means of transport, premises and other places under their control and their surroundings and on related documentation.</p> <p>2. Without prejudice to the rules concerning existing lists or registers established on the basis of the rules referred to in Article 1(2), the competent authorities shall draw up and keep up-to-date a list of operators. Where such a list or register already exists for other purposes, it may also be used for the purposes of this Regulation.</p> <p>3. The Commission shall adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the setting out of categories of operators to be exempted from the list of operators referred to in paragraph 2 of this Article where their inclusion in such a list would constitute a disproportionate administrative burden for them compared to the risk related to their activities.</p> |
| Article 12 Documented control procedures | <p>1. Competent authorities shall perform official controls in accordance with documented procedures. Those procedures shall cover the subject areas for control procedures set out in Chapter II of Annex II and shall contain instructions for staff performing official controls.</p> <p>2. Competent authorities shall have control verification procedures in place.</p> <p>3. Competent authorities shall:</p> |

| Assimilated Regulation 2017/625 | Article statement |
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| Article 12 (Continued) | <p>(a) take corrective actions in all cases where the procedures provided for in paragraph 2 identify shortcomings; and</p> <p>(b) update the documented procedures provided for in paragraph 1 as appropriate.</p> <p>4. Paragraphs 1, 2 and 3 shall also apply to delegated bodies and organic control authorities.</p> |
| Article 13 Written records of official controls | <p>1. Competent authorities shall draw up written records of every official control that they perform. Those records may be on paper or in electronic form.</p> <p>Those records shall contain:</p> <p>(a) a description of the purpose of the official controls;</p> <p>(b) the control methods applied;</p> <p>(c) the outcome of the official controls; and</p> <p>(d) where appropriate, action that the competent authorities require the operator concerned to take as a result of their official controls.</p> <p>2. Unless the purposes of judicial investigations or the protection of court proceedings require otherwise, the operators subject to an official control shall be provided upon request with a copy of the records provided for in paragraph 1, except where an official certificate or official attestation has been issued. The operator shall be promptly informed in writing by the competent authorities of any case of non-compliance identified through the official controls.</p> <p>3. Where official controls require the continuous or regular presence of staff or representatives of the competent authorities on the operator's premises, the records provided for in paragraph 1 shall be produced with a frequency that enables the competent authorities and the operator to be:</p> <p>(a) regularly informed of the level of compliance; and (b) promptly informed of any case of non-compliance identified through the official controls.</p> <p>4. Paragraphs 1, 2 and 3 shall also apply to delegated bodies, organic control authorities and natural persons to which certain official control tasks have been delegated.</p> |
| Article 14 Methods and techniques for official controls | <p>Official control methods and techniques shall include the following as appropriate:</p> <p>(a) an examination of the controls that operators have put in place and of the results obtained;</p> <p>(b) an inspection of:</p> |

| Assimilated Regulation 2017/625 | Article statement |
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| <p>Article 14 (Continued)</p> | <ul style="list-style-type: none"> (i) equipment, means of transport, premises and other places under their control and their surroundings; (ii) animals and goods, including semi-finished goods, raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals; (iii) cleaning and maintenance products and processes; (iv) traceability, labelling, presentation, advertising and relevant packaging materials including materials intended to come into contact with food; (c) controls on the hygiene conditions in the operators' premises; (d) an assessment of procedures on good manufacturing practices, good hygiene practices, good farming practices, and of procedures based on the principles of hazard analysis critical control points (HACCP); (e) an examination of documents, traceability records and other records which may be relevant to the assessment of compliance with the rules referred to in Article 1(2), including, where appropriate, documents accompanying food, feed and any substance or material entering or leaving an establishment; (f) interviews with operators and with their staff; (g) the verification of measurements taken by the operator and other test results; (h) sampling, analysis, diagnosis and tests; (i) audits of operators; (j) any other activity required to identify cases of non-compliance. |
| <p>Art 34, (1) to (2) and (4) to (5) Methods used for sampling, analyses, tests and diagnoses</p> | <ol style="list-style-type: none"> 1. Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with Union rules establishing those methods or the performance criteria for those methods. 2. In the absence of the Union rules as referred to in paragraph 1, and in the context of official controls and other official activities, official laboratories shall use one of the following methods according to the suitability for their specific analytical, testing and diagnostic needs: <ul style="list-style-type: none"> (a) available methods complying with relevant internationally recognised rules or protocols including those that the European Committee for Standardisation (CEN) has accepted; or relevant methods developed or recommended by the European Union reference laboratories and validated in accordance with internationally accepted scientific protocols; |

| Assimilated Regulation 2017/625 | Article statement |
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| <p>Art 34, (1) to (2) and (4) to (5) (Continued)</p> | <p>(b) in the absence of the suitable rules or protocols, as referred to in point (a), methods which comply with relevant rules established at national level, or, if no such rules exist, relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; or</p> <p>relevant methods developed and validated with inter or intra-laboratory methods validation studies in accordance with internationally accepted scientific protocols.</p> <p>3. Where laboratory analyses, tests or diagnoses are urgently needed and none of the methods referred to in paragraphs 1 and 2 of this Article exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory designated in accordance with Article 37(1) may use methods other than those referred to in paragraphs 1 and 2 of this Article until the validation of an appropriate method in accordance with internationally accepted scientific protocols.</p> <p>4. Wherever possible, methods used for laboratory analyses shall be characterised by the relevant criteria set out in Annex III.</p> <p>5. Samples shall be taken, handled and labelled in such a way as to ensure their legal, scientific and technical validity.</p> |
| <p>Article 35 Sampling</p> | <p>1. The competent authorities shall ensure that operators, whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls, have the right to a second expert opinion, at the operator's own expense.</p> <p>The right to a second expert opinion shall entitle the operator to request a documentary review of the sampling, analysis, test or diagnosis by another recognised and appropriately qualified expert.</p> <p>2. Where relevant, appropriate and technically feasible, having regard in particular to the prevalence and distribution of the hazard in the animals or goods, to the perishability of the samples or the goods and to the amount of available substrate, the competent authorities shall:</p> |

| Assimilated Regulation 2017/625 | Article statement |
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| | <p>(a) when taking the sample, and if so requested by the operator, ensure that a sufficient quantity is taken to allow for a second expert opinion and for the review referred to in paragraph 3, should this prove necessary; or</p> <p>(b) where it is not possible to take a sufficient quantity as referred to in point (a), inform the operator thereof.</p> |
| <p>Article 105</p> <p>Assistance without request in the event of non-compliance</p> | <p>1. When the competent authorities in a Member State become aware of a case of non-compliance, and if such non-compliance may have implications for another Member State, they shall notify such information to the competent authorities of that other Member State without being requested to do so and without undue delay.</p> <p>2. The competent authorities notified in accordance with paragraph 1 shall:</p> <p>(a) acknowledge receipt of the notification without undue delay;</p> <p>(b) where the notifying competent authority so specifies, indicate within ten working days from the date of receipt of the notification:</p> <p>(i) what investigations they intend to carry out; or</p> <p>(ii) the reasons why they consider that no investigations are necessary; and</p> <p>(c) where investigations referred to in point (b) are considered necessary, investigate the matter and inform the notifying competent authorities without delay of the results and, where appropriate, of any measures taken.</p> |
| <p>Article 138</p> <p>Actions in the event of established non-compliance</p> | <p>1. Where the non-compliance is established, the competent authorities shall take:</p> <p>(a) any action necessary to determine the origin and extent of the non-compliance and to establish the operator's responsibilities; and</p> <p>(b) appropriate measures to ensure that the operator concerned remedies the non-compliance and prevents further occurrences of such non-compliance.</p> <p>When deciding which measures to take, the competent authorities shall take account of the nature of that non-compliance and the operator's past record with regard to compliance.</p> |

| Assimilated Regulation 2017/625 | Article statement |
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| <p>Article 138 (Continued)</p> | <p>2. When acting in accordance with paragraph 1 of this Article, competent authorities shall take any measure they deem appropriate to ensure compliance with the rules referred to in Article 1(2), including, but not limited, to the following:</p> <ul style="list-style-type: none"> (a) order or perform treatments on animals; (b) order the unloading, transfer to another means of transport, holding and care of animals, quarantine periods, the postponement of the slaughter of animals, and, if necessary, order that veterinary assistance be sought; (c) order treatments on goods, the alteration of labels or corrective information to be provided to consumers; (d) restrict or prohibit the placing on the market, the movement, the entry into the Union or the export of animals and goods; and prohibit their return to the Member State of dispatch or order their return to the Member State of dispatch; (e) order the operator to increase the frequency of own controls; (f) order certain activities of the operator concerned to be subject to increased or systematic official controls; (g) order the recall, withdrawal, removal and destruction of goods, authorising, where appropriate, the use of the goods for purposes other than those for which they were originally intended; (h) order the isolation or closure, for an appropriate period of time, of all or part of the business of the operator concerned, or its establishments, holdings or other premises; (i) order the cessation for an appropriate period of time of all or part of the activities of the operator concerned and, where relevant, of the internet sites it operates or employs; (j) order the suspension or withdrawal of the registration or approval of the establishment, plant, holding or means of transport concerned, of the authorisation of a transporter or of the certificate of competence of the driver; (k) order the slaughter or killing of animals provided that this is the most appropriate measure to safeguard human health as well as animal health and welfare. <p>3. The competent authorities shall provide the operator concerned, or its representative, with:</p> <ul style="list-style-type: none"> (a) written notification of their decision concerning the action or measure to be taken in accordance with paragraphs 1 and 2, together with the reasons for that decision; and (b) information on any right of appeal against such decisions and on the applicable procedure and time limits |

| Assimilated Regulation 2017/625 | Article statement |
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| Article 138 (Continued) | <p>with respect to such right of appeal.</p> <p>4. All expenditure incurred under this Article shall be borne by the responsible operators.</p> <p>5. The competent authorities, in the case of issuance of false or misleading official certificates or in the case of abuse of official certificates, shall take appropriate measures, including:</p> <p>(a) the temporary suspension of the certifying officer from its duties;</p> <p>(b) the withdrawal of the authorisation to sign official certificates;</p> <p>(c) any other measure to prevent a reoccurrence of the offences referred to in Article 89(2).</p> |
| Article 148 Relation with Regulations (EC) No 852/2004 and (EC) No 853/2004 regarding approval of food business establishments | <p>1. Competent authorities shall establish procedures for food business operators to follow when applying for the approval of their establishments in accordance with Regulations (EC) No 852/2004 and (EC) No 853/2004.</p> <p>2. Upon receipt of an application for approval from a food business operator, the competent authority shall make an on- site visit.</p> <p>3. The competent authority shall approve an establishment for the activities concerned only if the food business operator has demonstrated that it complies with the relevant requirements of food law.</p> <p>4. The competent authority may grant conditional approval if it appears that the establishment meets all the infrastructure 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 the conditional approval. However, conditional approval shall not exceed a total of six months, except in the case of factory and freezer vessels flying the flag of Member States, for which such conditional approval shall not exceed a total of 12 months.</p> <p>5. The competent authority shall keep the approval of establishments under review when carrying out official controls.</p> |