

## **APPENDIX 1**



COMMISSION OF THE EUROPEAN COMMUNITIES

Grange, 13/7/05  
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Draft

**COMMISSION DECISION**

**of [...]**

**adopting guidelines laying down criteria for the conduct of audits further to the provisions of Regulation (EC) No 882/2004 of the European Parliament and of the 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**

**”Text of EEA relevance”**

**WORKING DOCUMENT**

**DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION**

Draft

## COMMISSION DECISION

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**”Text of EEA relevance”**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Regulation (EC) No 882/2004 of the European Parliament and of the 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<sup>1</sup> and, in particular, Article 43 (1) (i) thereof,

Having consulted the Standing Committee on the Food Chain and Animal Health,

Whereas:

- (1) Under Regulation (EC) No 882/2004 of the European Parliament and of the 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, and in particular Article 4(6) thereof, the competent authorities of the Member States are required to carry out internal audits or have external audits carried out in order to ensure that they are achieving the objectives of that Regulation.
- (2) The Commission is required to draw up guidelines laying down criteria for the conduct of the audits referred to in Article 4(6) of the said Regulation and in so doing to reflect the relevant international bodies’ standards and recommendations regarding the organisation and operation of official services. Of non-binding nature, the guidelines can however provide useful guidance to the Member States in the implementation of Regulation (EC) No 882/2004.
- (3) The European Committee for Standardisation (CEN) and the International Organisation for Standardisation (ISO) have developed standards, aspects of which are appropriate for the purpose of establishing the guidelines.

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<sup>1</sup> OJ L 191, 28.05.2004, p. 1

HAS ADOPTED THIS DECISION:

*Article 1*

The guidelines laying down criteria for the conduct of the audits referred to in Article 4(6) of Regulation (EC) No 882/2004 are established as provided in the Annex

This Decision is addressed to the Member States.

Done at Brussels, [...]

*For the Commission*

[...]

*Member of the Commission*

## **ANNEX**

### **Competent Authority Audit Systems Guideline**

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### 1. PURPOSE AND SCOPE

These guidelines provide guidance on the nature and the implementation of audit systems by national competent authorities. The purpose of these audit systems is to verify whether the official controls relating to, feed and food law, and animal health and animal welfare rules, are effectively implemented and are suitable to achieve the objectives of the relevant legislation, including compliance with the national control plan.

The guidelines are drafted in terms of principles to be observed, rather than detailed methods, in order to facilitate their application to the diversity of Member State control systems. The methods chosen to apply the principles in these guidelines can differ according to the size, nature, number and complexity of the competent authorities responsible for official controls throughout the Member State.

### 2. BACKGROUND AND LEGAL BASIS – REGULATION (EC) NO 882/2004

These guidelines lay down criteria for the conduct of the audits referred to in Article 4(6) of Regulation (EC) 882/2004. In this respect the following extracts from that Regulation are relevant:

#### 1.1 Article 4(6) operational criteria for competent authorities

*“Competent Authorities shall carry out internal audits or may have external audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of this Regulation. These audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.”*

#### 1.2 Article 2(6) definition of ‘audit’

*“ ‘audit’ means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.”*

### 3. DEFINITIONS

For the purpose of these guidelines the definitions laid down in Article 2 of Regulation (EC) No 882/2004, Articles 2 and 3 of Regulation (EC) No 178/2002, ISO 19011:2002<sup>2</sup> and ISO 9000:2000<sup>3</sup> shall apply.

In particular the following definitions from ISO 19011:2002 and ISO 9000:2000 should be noted:

*“Audit criteria” mean the set of policies, procedures or requirements used as a reference against which audit evidence is compared, i.e. the standard against which the auditee’s activities are assessed.*

*“Audit plan” means the description of the activities and arrangements for an audit.*

*“Audit programme” means a set of one or more audits planned for a specific time-frame and directed towards a specific purpose.*

*“Audit team” one or more auditors conducting an audit supported if needed by technical experts.*

*“Auditee” organisation being audited.*

*“Auditor” person with the competence to conduct an audit.*

*“Corrective action” action to eliminate the cause of a detected nonconformity or other undesirable situation.*

*“Preventive action” action to eliminate the cause of a potential nonconformity or other undesirable situation.*

*“Technical expert” person who provides specific knowledge or expertise to the audit team*

For the purposes of this Guideline the following definitions shall apply:

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<sup>2</sup> “Guidelines for quality and/or environmental management systems auditing”, published by the International Organization for Standardisation, 1<sup>st</sup> October 2002

<sup>3</sup> “Quality management systems – Fundamentals and vocabulary”, published by the International Organization for Standardisation, December 2000

*“**Audit Body**” means the body that carries out the audit process. This may be an internal or external entity.*

*“**Audit process**” comprises the series of activities as described in section 5.1 Systematic Approach.*

*“**Audit system**” the combination of one or more audit bodies carrying out an audit process within or across competent authorities.*

*“**Production chain**” means the full chain of production incorporating all ‘stages of production, processing and distribution’, as defined in Article 3(16) of Regulation (EC) No 178/2002.*

#### **4. GENERAL GUIDANCE**

In the event that a combination of audit systems is established within a Member State, there should be mechanisms to ensure that the audit systems cover all control activities within the scope of Regulation (EC) No 882/2004, including animal health and animal welfare, and along all stages of the feed and food production chain.

Where Competent Authority control tasks are delegated to a control body, the mandate for the conduct of audits or inspections of the control body should be included in the contractual obligations of the control body.

In addition to the specific guidance set out in this document, general guidance should be taken from ISO 19011:2002.

#### **5. NATURE OF THE AUDIT PROCESS**

##### *5.1 Systematic Approach*

A systematic approach should be taken in relation to the planning, conduct, follow-up and management of audits. To this end, the audit process should:

- Be the result of a transparent planning process, in which risk-based priorities are identified which are appropriate to fulfil the Competent Authority's responsibilities in accordance with Regulation (EC) No 882/2004;
- Be part of an audit programme that ensures adequate coverage of all relevant areas of activity and all relevant Competent Authorities within the sectors covered by Regulation (EC) No 882/2004, at an appropriate risk-based frequency, over a period not exceeding five years;
- Be supported by documented audit procedures and records to ensure that there is consistency between auditors and to demonstrate that a systematic approach is adhered to;
- Include procedures for generation of audit findings, including identification of evidence of compliance and non-compliance as appropriate, and for preparing, approving and distributing audit reports,
- Include procedures to review audit conclusions, to identify system-wide strengths and weaknesses in the control system, to disseminate best practice and to ensure follow-up of corrective and preventive action.
- Be monitored and reviewed to ensure the audit programme objectives have been met and to identify opportunities for improvement.

Where more than one audit programme is envisaged within a Member State, steps should be taken to ensure these programmes are co-ordinated effectively to ensure a seamless audit process across the relevant competent authorities for all sectors. The audit programme(s) should also ensure that all relevant levels within the competent authority's hierarchy are included.

## *5.2 Transparency.*

In order to demonstrate transparency of the audit process, documented procedures should, in particular, include a clearly defined planning process, audit criteria, report approval and distribution mechanisms.



Management and implementation of the audit process should be transparent to all relevant stakeholders. In particular, there should be full transparency between the audit body and auditee. Making the audit process transparent to other stakeholders will assist in dissemination of information, in particular sharing of best practice within and between competent authorities.

The Member States should select the appropriate measures to ensure transparency within their audit systems, taking into account national legal or other requirements where appropriate. For this purpose Member States should consider encouraging practices that contribute to the transparency of the process; some examples are listed in Table 1. In selecting the appropriate measures, the need for transparency should be balanced against the possibility of compromising the audit systems ability to achieve its objectives. In order to optimise the benefits of transparency, it should be combined with balanced reporting i.e. proper mixture of verified compliance (positive findings) and areas for improvement (negative findings).

Table 1: Examples of practices that contribute to the transparency of an audit process

<b>Audit Body Practices</b>	<b>Auditee</b>	<b>Within Competent Authority</b>	<b>Across Competent Authorities (within MS)</b>	<b>Public and other Stakeholders</b>
Access to documented Audit Body procedures	✓	✓	✓	
Consultation on the planning of the audit programme	✓	✓	✓	
Publication of audit programme	✓	✓	✓	✓
Submission of an audit plan	✓	✓		
Opportunity to comment on the draft audit report	✓	✓		
Distribution of the final audit report	✓	✓	✓	
Publication of auditee's comments on the draft report		✓	✓	✓

Publication of the final audit report	✓	✓	✓	✓
Publication of summaries of the final audit reports and of an annual report	✓	✓	✓	✓
Publication of the auditee's action plan	✓	✓	✓	✓
Publication of follow-up results	✓	✓	✓	✓

### 5.3 Independence

The Audit Body should be free from any commercial, financial, hierarchical, political and other pressures that might affect its judgment or the outcome of the audit process. The audit system, audit body and auditors should be independent of the activity being audited, and free from bias and conflict of interest. Auditors should not audit areas or activities for which they have direct responsibility.

The Central Competent Authority should provide safeguards to ensure adequate segregation of responsibilities and accountabilities between audit activities and other activities such as management of official control systems or their supervision.

Where the audit team makes recommendations for corrective and preventive action the decision as to the methods of such action should reside with the auditee. Active audit team involvement in follow-up should be limited, to assessing the suitability of the action plan and the effectiveness of the corrective and preventive action. Auditees should not be in a position to impede the audit programme, findings or conclusions. They should be consulted in relation to the draft report and their comments should be considered by the audit body. Where appropriate, those comments should be taken into account in a transparent manner.

The following aspects of the audit process can assist in safeguarding the independence of both the audit body and the audit team:

- A clear and documented mandate, with adequate powers, to conduct the audits
- No involvement by the audit body and the audit team in the management or supervision of the control systems being audited

- For an external audit, the audit body and audit team should be external to, and independent of, the organisational hierarchy of the auditee.
- For internal audits, the following general principles should apply to ensure the independence and transparency of the process:
  - Audit Body and audit team appointed by top management,
  - Audit Body and/or the audit team report to top management,
  - Transparent check to ensure no conflict of interest exists for both the audit body and the audit team.

An independent Audit Body should be positioned externally or separately from the management of audited activities. An internal audit body should report to the most senior management level in the organisational structure.

Where technical expertise, required for the audit, is only available within a Competent Authority, measures should be taken to maintain the independence of the audit team. Where control activities are organised on a regional basis, it may be possible to exchange technical specialists to ensure their independence.

#### *5.4 Independent Scrutiny of the Audit Process*

In order to confirm that the audit process is achieving its objectives, it should be subject to scrutiny by an independent person or body. The independent person or body should have sufficient authority, expertise and resources to carry out this task effectively. Different approaches to independent scrutiny may be adopted, for different activities or Competent Authorities. Where a body or a committee has been established to provide independent scrutiny of the audit process, one or more independent persons should be a member of this body or committee. The independent person should have access to, and be empowered to contribute fully to, the audit process. Action should be taken to rectify any shortcomings in the audit process identified by the independent person or body.

## 6. IMPLEMENTATION OF THE AUDIT PROCESS

### 6.1 Guiding Principles: a) Compliance with Planned Arrangements; b) Effective Implementation; c) Suitability to Achieve Objectives

In order to comply with the requirements of Article 4(6) of Regulation (EC) No 882/2004, the audit system should ensure that the following three elements, as defined in Article 2(6), are covered:

- a) Verification of **compliance with planned arrangements** in order to give assurances that official controls are carried out as intended, and that any instructions or guidelines given to staff carrying out the controls are followed. This may be largely addressed by document review, but will also require on-site verification. The audit team will require good generic audit knowledge and skills to address this audit objective.
- b) Verification of the **effective implementation of planned arrangements**. In order to assess effectiveness, that is the extent to which planned results are achieved, on-site operational implementation must be included. This should include an assessment of the quality and consistency of the controls and should involve on-site audit activities. The audit team will require the relevant technical expertise in order to address this audit objective.
- c) The audit system should also make every effort to assess whether the **planned arrangements are suitable to achieve the objectives** of Regulation (EC) No 882/2004, and in particular the single integrated multi-annual national control plan. This should include an assessment of the appropriateness of, for example, the nature, frequency and methods of official controls in relation to the structure, practices and volume of the production chain(s). Substantial knowledge and understanding of systems auditing, along with appropriate technical input, on the part of the audit team is essential to address this audit objective.

In order to determine whether the **planned arrangements are suitable to achieve the objectives** as set out in c) above, the following should be considered:

*Audit criteria* should include strategic objectives derived from Regulation (EC) No 178/2002, Regulation (EC) No 882/2004 (including the single integrated multi-annual national control plan), and national legislation.

**Primary focus** of the audits should be the control arrangements related to the critical points for control in the production chain(s). The emphasis should be on assessing whether planned arrangements are capable of delivering sufficient guarantees on (a) the safety and other feed and food law requirements of the end-product(s) and (b) animal health and welfare rules. In order to achieve this, audit(s) should where possible extend beyond and across administrative boundaries.

## 6.2 Audit Reporting

Audit reports should include clear conclusions derived from the audit findings, and where appropriate, recommendations.

- **Conclusions** should address the compliance of the system with the planned arrangements, the effectiveness of the implementation, and the suitability of the planned arrangements to achieve the stated objectives, as appropriate. They should be based on objective evidence. In particular, where conclusions are drawn as to the suitability of the planned arrangements to achieve the stated objectives, evidence may be obtained from the compilation and analysis of results from several audits. In this case conclusions should extend beyond the boundaries of individual establishments, units of authorities or authorities.
- **Recommendations** should address the end-result to be delivered rather than the means of correcting non-compliances. Recommendations should be based on solid conclusions.

## 6.3 Follow-up of Audit Outcome

Where appropriate, an action plan should be drawn up and delivered by the auditee. It should propose time-bound corrective and preventive actions to address any weakness identified by the audit or audit programme. The audit team should assess the action plan and may be involved in verifying its subsequent implementation.

- An **Action plan** enables the audit team to assess whether the proposed set of corrective and preventive actions is sufficient to address the recommendations of the audit report. Action plans should include risk-based prioritisation and timeframes for completion of corrective and preventive action. A wide range of different action plans could be considered as satisfactory. It is for the auditee to make the choice amongst the various options available.
- **Corrective and preventive actions** should not be limited to addressing specific technical requirements, but they should, where appropriate, include system-wide measures (e.g. communication, cooperation, coordination, reviewing and/or stream-lining of control processes, etc.). A root-cause analysis of any non-compliance should be conducted by the auditee, in order to determine the most

appropriate corrective and preventive actions. Any differences of opinion between the auditee and audit team should be resolved.

- **Close-out:** Mechanisms should be established to ensure that action plans are appropriate, and that corrective and preventive actions are effectively completed in a timely manner. Procedures for verifying the close-out of the action plan should be agreed between the auditee and the audit team.

#### *6.4 Audit Review and Dissemination of Best Practice*

The implications of audit findings for other sectors and for other regions should be considered, particularly in Member States where controls are delegated to a number of competent authorities, or are decentralised. In particular, examples of best practice should be disseminated. For this purpose, reports should be made available to other sectors and regions within a Member State, and to the Commission. Audit results should also be considered during the planning process for the audit programme, and in the context of the review of the single integrated multi-annual national control plan.

#### *6.5 Resources*

Member States should ensure that competent authorities have sufficient resources, with the appropriate authority, to establish, implement and maintain an effective audit system.

Human and related resources required to manage, monitor, and review the audit process should be made available, taking into account that all competent authorities and their control activities should be audited over a period not exceeding five years. General guidance on the resources required for auditing may be obtained from ISO 19011. In order to have all the necessary expertise to fulfil the purpose and scope of the audit and audit programme(s), the audit team may include a combination of general or technical specialist auditors and technical experts. Care should be taken to maintain the objectivity and independence of the audit team especially where technical experts are required. To that end rotation of auditors or audit teams may assist in achieving this.

#### *6.6 Auditor Competence*

Auditor competence and selection criteria should be defined under the following headings:

- Generic knowledge and skills – audit principles, procedures and techniques; management/ organisational
- Specific technical knowledge and skills
- Personal attributes
- Education
- Work experience
- Auditor training and experience

It is essential that there is a mechanism put in place to ensure consistency of auditors and maintenance of competencies. The competencies required by audit teams will vary depending on the area they are auditing within the control or supervision systems. As regards the technical knowledge and skills required by auditors, the training requirements for staff performing official controls (Regulation (EC) No 882/2004, Annex II, Chapter 1) should also be considered.