



European
Commission



Plan

Art. 4.6

Do

Appropriate measures

Audit of official controls

independent

Add value

compliance

Objective

Act

risk

Art. 4.2(a)

Check

Ensure the effectiveness

DG Health and
Food Safety

INTERIM OVERVIEW REPORT

Audits of Official Controls in EU-Member States

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2017-6256 - MR

INTERIM OVERVIEW REPORT
ON A SERIES OF AUDITS CARRIED OUT IN MEMBER STATES
IN 2016
IN ORDER TO EVALUATE THE SYSTEM PUT IN PLACE TO IMPLEMENT
ARTICLE 4(6) OF REGULATION (EC) NO 882/2004 (NATIONAL AUDIT SYSTEM)

Executive Summary

This interim overview report describes the main conclusions in relation to a series of 10 audits carried out by the European Commission's Directorate-General for Health and Food Safety in Member States during 2016, with the objective of evaluating the systems put in place to implement Article 4(6), on audits of competent authorities, of Regulation (EC) No 882/2004 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. Findings from two pilot missions carried out during 2015 to prepare for this audit series have also been taken into account. This series is continuing in 2017 and is expected to be completed for all Member States in 2018.

Article 4(6) requires that competent authorities carry out internal audits or may have external audits carried out, and take appropriate measures in the light of their results, to ensure that they are achieving the objectives of Regulation (EC) No. 882/2004.

It was found that those competent authorities with well-organised audit systems had effectively implemented audits of official controls and could demonstrate that their audit process contributed to ensuring the quality, and improving the consistency and effectiveness of official controls, provided that there was strong management commitment to the follow-up of audit recommendations.

In most cases competent authorities were found to have put appropriate audit arrangements in place covering most official control activities falling within the scope of Regulation (EC) No 882/2004 and, in some cases, going beyond this scope. The audits carried out under Article 4(6) were, for the most part, well-accepted and appreciated by the auditees and the outputs were used to improve the consistency and effectiveness of official controls.

Some challenges remain in ensuring that audit arrangements are optimised to provide credible, reliable results that have a positive impact on the effectiveness and consistency of official controls. In particular some competent authorities had not yet fully addressed the requirements for independent scrutiny of the audit process and effective follow-up of audit results.

This interim overview report describes some challenges in organising, implementing and/or following up audits of official controls that Member States are still experiencing. In addition, certain useful practices which may be of interest to Member States are highlighted.

The final chapter of this report describes actions taken and to be taken by both the Member States and the European Commission services in response to the findings to date of this audit series.

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ABBREVIATIONS AND SPECIAL TERMS USED IN THIS REPORT

Abbreviation	Explanation
BIP	Border inspection post
CA	Competent authority
CCA	Central competent authority
DG SANTE	The European Commission's Directorate-General for Health and Food Safety
EU	European Union
MANCP	Multi-annual national control plan
MS	Member State(s) of the European Union
NAS	National Audit Systems
The NAS Network	A network of officials (auditors) from MS CA, responsible for the performance of audits of official control systems as provided for by Article 4(6) of Regulation (EC) No 882/2004. The Network meets regularly, under the chairmanship of, and facilitated by, DG SANTE to exchange experiences in implementing national audit systems on official control activities.

1 INTRODUCTION

This series of audits assessed the implementation of Article 4(6), on audits of competent authorities, of Regulation (EC) No 882/2004 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 rules¹ (hereafter: Regulation (EC) No 882/2004).

The series was undertaken because it was recognised by the European Commission's Directorate-General for Health and Food Safety (hereafter: DG SANTE) that Article 4(6) is an important component in any official control management system which, if successfully implemented, checks that arrangements in place achieve the objectives of that system and promotes its continuous improvement. The National Audit System (NAS) is thus a tool that can verify that diminishing resources are used to the best effect, by ensuring that they have been used correctly. Verification and improvement of the performance of NAS through DG SANTE audits can therefore serve as a very resource-effective way to provide assurances across the spectrum of official controls falling within the scope of Regulation (EC) No 882/2004 and to maintain and increase confidence in the performance of EU official control systems.

This audit series took place in ten Member States (listed in Annex I) during 2016. This report also includes relevant information from two pilot audits carried out in 2015 to prepare for the series. It is intended to continue the audit series in 2017 and 2018 until all Member States have been audited. This report is therefore an interim report on the progress of the series. It is intended to produce a final overview report of the series after all Member States have been audited.

This interim report aims to present the main over-arching conclusions reached in relation to the implementation of Article 4(6) as well as highlighting in Annex III the areas where Member States are still experiencing some challenges in organising, implementing and/or following up audits of official controls and certain useful practices which may be of interest to Member States.

2 OBJECTIVES, SCOPE AND AUDIT CRITERIA OF THE SERIES

The objective of the audit series was to evaluate, in each country visited, the system(s) put in place to implement Article 4(6), on audits of competent authorities, of Regulation (EC) No 882/2004.

The scope of the audits was limited to the procedures put in place to implement Article 4(6) by the competent authorities responsible for the majority of the official controls falling under Regulation (EC) No 882/2004.

The criteria used for the evaluation are set out in Article 4(6) of Regulation (EC) No 882/2004:

¹ 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, Official Journal L 165, 30.4.2004, pages 1 to 141, corrected and re-published in OJ L 191, 28.5.2004, pages 1 to 52.

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.

In addition, where applicable, the DG SANTE audit teams took into account Commission Decision 2006/677/EC setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004² (hereafter: Commission Decision 2006/677/EC). Where relevant, reference was made to Network Reference Documents produced by the informal Network of Member States National Experts on National Audit Systems (hereafter: the NAS Network), while recognising that they do not constitute an audit standard and are not legally binding.

Annex II describes the relevant legal requirements which provide the standard against which the audits were conducted, as well as the methodology used.

3 LEGAL BASIS

The audit series was carried out under the general provisions of EU legislation and, in particular Article 45 of Regulation (EC) No 882/2004.

4 OVERALL CONCLUSIONS OF THE AUDIT SERIES TO DATE

The overall conclusions in relation to the functioning of audits of official controls are presented in this section. A more detailed analysis of main findings in relation to specific aspects of the organisation, implementation and follow-up of such audits can be found in Annex III.

This audit series found that those competent authorities with well-organised audit systems had effectively implemented audits of official controls and could demonstrate that their audit process contributed to ensuring the quality, and improving the consistency and effectiveness of official controls, **provided that** there was strong management commitment to the follow-up of audit recommendations.

It was found that the audits carried out under Article 4(6) were, for the most part, well-accepted and appreciated by the auditees.

In relation to specific aspects of the organisation, implementation and follow-up of audits of official controls, the main conclusions arising from this series are as follows:

- The guidelines laid down in Commission Decision 2006/677/EC were generally accepted and used by the audit services to ensure that the audit process could meet the requirements of Articles 2(6) and 4(6) of Regulation (EC) No 882/2004. The guidelines proved to be flexible and practical enough to be used by a wide variety of different audit services/bodies;

² Commission Decision 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules. Official Journal L 278, 10.10.2006, pp15 to 23.

- Certain Network reference documents were also found to be well-accepted and commonly used; in particular the document on *Risk based planning for audits of official controls* and, to a lesser extent, the document on *Independence and independent scrutiny*. Thus these documents largely achieved their objective of supporting the Member States in implementing Article 4(6);
- However, the document on *Auditing effectiveness of official controls* was either less well known or found to be too abstract to be used in practice in many cases. Nevertheless, a number of examples were found where this document was used successfully as a basis for developing audits aimed at evaluating the effectiveness of official controls. Thus it can be concluded that this document has useful content but could be more user-friendly;
- In relation to the more recently adopted NAS reference documents on audit evidence and on root cause analysis, it was too soon after adoption to form an assessment of degree to which they were used and/or found to be useful by the audit bodies/services;
- In most cases competent authorities have put appropriate audit arrangements in place **covering most official control activities** falling within the scope of Regulation (EC) No 882/2004 and, in some cases, going beyond this scope. Some challenges remain in ensuring adequate audit arrangements for **small competent authorities** and for competent authorities for whom official controls carried out within the scope of Regulation (EC) No 882/2004 constitute only a **small part of their activity**. Some examples of arrangements used in such situations are highlighted in Annex III;
- The need for **independence** of audit services and auditors was well recognised by competent authorities and respected. In general, appropriate arrangements were put in place to ensure sufficient independence and mitigating measures were considered where threats to independence were identified. Some audit arrangements in limited areas could still be subject to some threats to independence – this is described in more detail in Annex III. Nevertheless, the series did not identify cases where this happened to a degree that would undermine the credibility of the arrangements in place to implement Article 4(6).
- The **maturity of the audit arrangements** evaluated during this series varied considerably. Nonetheless, all audit arrangements evaluated in the course of this series could ensure that auditors had sufficient **independence** and **competence** to effectively audit **compliance of official controls with planned arrangements**;
- With regard to **auditor competence**, the audit services audited had ensured by a variety of means that auditors had the necessary skills to audit competently. In particular, Better Training for Safer Food training courses on audits were cited as a useful tool and were widely used to ensure auditor competence and to provide training material for further dissemination of learning with the competent authorities.
- Certain elements of the above Commission Decision remain particularly challenging for Member States to address, in particular:
 - ensuring appropriate arrangements for **independent scrutiny** that consider the whole audit process, takes into account the objectives of Article 4(6) and contribute to the continuous improvement of the audit arrangement. In cases

where this has not been achieved, the competent authorities do not have the assurance regarding the independence and effectiveness of their audit services that effective independent scrutiny provides. Furthermore, the audit services do not benefit from the input that such scrutiny can provide to continuous improvement;

- implementing **risk-based planning of the audit programme** in a way that allows the audit service to demonstrate the **risk basis for the programme** and produces a programme which ensures that all areas of official controls are adequately **covered** in a reasonable timeframe and that that programme can actually be implemented as planned. Thus audit services may have a difficulty in ensuring and demonstrating to stakeholders that they are auditing the right things, at the right time. Nevertheless, a number of good examples of such risk-based planning processes were identified during this series;
- auditing of ‘effectiveness’ of official controls, which poses particular difficulties in comparison with auditing compliance with those arrangements. In particular, audit services could find it challenging to demonstrate that audit conclusions in relation to effective implementation and/or suitability of planned arrangements were arrived at in a systematic way. This creates the risk of undermining the credibility of such conclusions;
- ensuring the **audit reports** are clear and coherent, so that readers can understand exactly what was assessed during the audit and the basis for each conclusion;
- in a minority of cases, ensuring that **audit recommendations were effectively addressed**. It was noted that competent authorities who had greatest difficulties in ensuring that recommendations were addressed tended to be those that had no defined procedures for dealing with failure by auditees to address recommendations. The failure to address significant, or significant numbers of audit recommendations critically undermines the impact of the audit activity on the quality of official controls;
- reconciling the demands of implementing Article 4(6) with other demands, such as carrying out internal audit as part of a quality management system, or performing duties in relation to internal controls. Such other demands on audit services can limit or distort the targeting of the audit activities carried out in the context of Article 4(6).

It was noted that in almost all cases good **transparency** was achieved between the audit services and the services audited, ensuring good mutual understanding and promoting trust and confidence in the audit process throughout the competent authority. However, the degree of transparency of audit activities and results towards external stakeholders varied considerably. Some audit services provided little transparency to external stakeholders, which can be a missed opportunity to promote confidence in the quality of official controls.

In addition this series identified that competent authorities do not always maximise the benefit that can be derived from audits by ensuring systematic identification of potential good practices that could usefully be shared with services other than the one audited or weakness that could be system-wide.

The ability the audit service to make use of the results of independent scrutiny and the results of its own reviews of activities in order to **achieve continuous improvement of the audit process** was recognised by the DG SANTE audit teams as a significant factor in providing on-going confidence in the performance of audits of official controls and thereby in the quality of official controls performed by a given competent authority.

5 FOLLOW-UP OF THE AUDIT SERIES

5.1 FOLLOW-UP OF THE AUDITS

After each audit in the series where recommendations were made, the competent authorities were asked to submit an action plan which was assessed by the DG SANTE audit team, who sought clarifications if necessary. On-going implementation of those action plans is monitored in line with standard DG SANTE follow-up procedures. Information on further follow-up is reflected in the country profiles for each Member State, which can be found here:

http://ec.europa.eu/food/audits-analysis/country_profiles/index.cfm

5.2 ACTIONS PROPOSED TO MEMBER STATES

Member States are invited to consider the overall conclusions present in this report as well as the issues highlighted in Annex III with a view to identifying areas where this information may be useful to improve their arrangements for the audit of official controls.

Both the Member States and the Commission Services are encouraged to consider whether the NAS Network can undertake further work to assist Member States in addressing the challenges identified in Annex III.

5.3 ACTIONS PLANNED AND TAKEN BY THE COMMISSION SERVICES

5.3.1 Guidelines laid down in Commission Decision 2006/677/EC

Regulation (EC) No 882/2004 which is the legal basis for the above-mentioned guidelines will be replaced by Regulation (EU) No 2017/625³ with effect from 2019. The latter regulation contains essentially similar provisions to the former regarding national audit systems. However, the new regulation does not require the Commission to produce guidelines for the audit systems. Following consultation with the Member States, and supported by the findings of this audit series to date and the conclusions of this interim overview report, the

³ Regulation (EU) 2017/625 of 15 March 2017 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation). Official Journal L 95, 7.4.2017, pp 1 to 142

Commission services will produce new guidelines based on Commission Decision 2006/677/EC for the new regulation. In producing the new guidelines the Commission services will seek to provide better guidance on both the areas identified as difficult and where the auditors noted a trend of weaker performance or shortcomings.

5.3.2 NAS Network reference documents.

The NAS Network suspended selection of new topics for workshops sharing methods, techniques and good practices and the preparation of further reference documents pending the availability of this interim overview report. This report provides feedback on the usefulness and the extent of use of reference documents produced to date and also identifies a number of aspects that could be usefully addressed by this approach. The document on auditing effectiveness is found to be less useful and user-friendly and it is considered to be too early to assess the usefulness in practice of some of the more recent documents. The Network had already identified the effectiveness document as needing improvement and had begun discussion on the issue of audit reporting. It is therefore proposed that for the next NAS Network meeting a discussion on good principles for reporting audits should take place, with a view to possibly producing a reference document or a text for incorporation into the new guidelines. Other shortcomings or areas of weakness identified in the interim and later in the final overview report of this audit series will be progressively addressed by the Network.

5.3.3 Better Training for Safer Food

The current Better Training for Safer Food (BTSF) programme for audit systems finished in June and it is not proposed to extend the contract. The programme originally contained two modules, course A on how to set up an internal audit system, i.e. training on the implementation of Commission Decision 2006/677/EC, and course B on how to perform audits. Course B was later divided into two modules: B1 for basic auditing skills and B2 for more advanced audit training. Given that national audit services are rather small it could be considered that sufficient training has been provided in this area. However, in view of the fact that, in line with good practice, many auditors rotate out of audit units on a three to five year cycle it is considered that a new training programme should be put in place. In addition, such training provides auditors with opportunities to broaden their experience by interacting with auditors from other services. This is particularly important given that most auditors come from small units which means they only have opportunities to exchange views on methods and practices within a small circle.

The new training programme will not include a replacement for Course A as it is considered that sufficient training and experience is available within the Member States to establish an internal audit service, and most, if not all competent authorities now have established such services. The new training will be based on courses B1 and B2, providing basic and advanced training.

In developing the syllabus for the new training the Commission services will ensure that particular attention is paid to the addressing the issues identified in this interim overview report. In this regard, the findings of the individual reports

from this on-going audit series, that BTSF was widely used to ensure auditor competence and to provide training material for further dissemination of learning with the competent authorities, have provided good evidence to support the continuation of this training.

ANNEX I- AUDITS AND PILOT MISSIONS INCLUDED IN THE SERIES

Country	Reference Number	Link
The Netherlands	2015-7368	http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3575
Spain	2015-7369 ⁴	Not published
Belgium	2016-8822	http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3624
Malta	2016-8833	http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3694
Estonia	2016-8823	http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3710
Germany	2016-8824	Not yet published
Poland	2016-8825	http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3757
Austria	2016-8826	http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3772
Denmark	2016-8828	Not yet published
France	2016-8831	http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3758
Slovenia	2016-8830	http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3783
Ireland	2016-8834	http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3783

⁴ As this was a pilot mission, the report was not published.

ANNEX II –AUDIT CRITERIA AND METHODOLOGY

1. Legal requirements

The requirements laid down in **Article 4(6) of Regulation (EC) No 882/2004**, that:

*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***

should be read together with the definition of Article 2(6) laid down in the same Regulation:

*“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**.*

2. Commission guidelines

Further guidance on certain aspects of the requirement and definition is provided in **Commission Decision 2006/677/EC**. In particular the guidelines in the Annex to this Decision provide information on aspects to be considered when ensuring that the audit process is **systematic, transparent, independent** and subject to **independent scrutiny**. In addition, guiding principles in relation to **auditing compliance with planned arrangements, effective implementation of arrangements and their suitability to achieve objectives** are provided. Guidance is also provided, *inter alia*, in relation to **audit reporting, follow-up of the audit outcome, audit review and dissemination of best practice and auditor competence**. As reflected in the recitals of the decision: “*The guidelines are not binding but serve to provide useful guidance to the Member States in the implementation of Regulation (EC) No 882/2004*”.

2.1. Independence

In section 5.3 of the Annex of Commission Decision 2006/677/EC further guidance is provided to Member States on ‘**independence**’, including:

“Audit bodies should be free from any commercial, financial, hierarchical, political or other pressures that might affect their 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 conflicts of interest. Auditors should not audit areas or activities for which they have direct responsibility.

All relevant competent authorities should introduce safeguards to ensure that responsibility and accountability for audit and control activities, such as the management and supervision of official control systems, are kept sufficiently distinct.”

In addition, the NAS Network Reference Document on Independence and Independent Scrutiny (see section 2.8 of this Annex) provides additional guidance to Member States on threats to independence and mitigating measures.

2.2. Independent scrutiny

In section 5.4 of the Annex of Commission Decision 2006/677/EC further guidance is provided to Member States on the ‘**Independent Scrutiny of the Audit Process**’:

“In order to check whether it is achieving its objectives, the audit process should be subject to scrutiny by an independent person or body. Such independent person or body should have sufficient authority, expertise and resources to carry out this task effectively. The approaches to independent scrutiny may vary, depending on the activity or the competent authority. Where a body or a committee has been established with a view to independent scrutiny of the audit process, one or more independent persons should be members of such body or committee. Such independent persons should have access to the audit process and be empowered to contribute fully to it. Action should be taken to remedy any shortcomings identified in the audit process by the independent person or body.”

2.3. Auditor competence

Articles 2(6) and 4(6) of Regulation (EC) No 882/2004 do not lay down specific requirements regarding the **competence of auditors**. Article 6 of the same Regulation requires that staff performing official controls “receive, for their area of competence, appropriate training enabling them to undertake their duties competently” and “keep up-to-date in their area of competence and receive regular additional training as necessary”

Section 6.6 of the Annex of Commission Decision 2006/677 provides guidance on 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 skills,*
- specific technical knowledge and skills,*
- personal attributes,*
- education,*
- work experience,*
- auditor training and experience.*

It is essential to put a mechanism in place to ensure auditors are consistent and their competencies are maintained. 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 (Chapter 1 of Annex II to Regulation (EC) No 882/2004) should also be considered.”

2.4. Systematic

In relation to **the risk-based planning of the programme of audits**, Article 3(1) of Regulation (EC) No 882/2004 requires that:

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

The definition laid down in Article 2(6) specifies, inter alia, that audits should be **‘systematic’**.

In section 5.1 of the Annex of Commission Decision 2006/677/EC further guidance is provided to Member States on the ‘Systematic Approach’, including:

“A systematic approach should be applied to the planning, conduct, follow-up and management of audits. To that end, the audit process should:

- be the result of a transparent planning process identifying risk-based priorities in line with the competent authority’s responsibilities under Regulation (EC) No 882/2004,*
- form 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 consistency between auditors and to demonstrate that a systematic approach is followed”*

In addition:

“Where more than one audit programme is envisaged within a Member State, steps should be taken to ensure that such programmes are effectively coordinated, so as to ensure a seamless audit process across the relevant competent authorities. The audit programme(s) should also cover all relevant levels of the competent authority’s hierarchy.”

Article 2(6) of Regulation (EC) No 882/2004 states that “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.”*

In section 5.1 of the Annex of Commission Decision 2006/677/EC further guidance is provided to Member States on the ‘Systematic Approach’, including:

“A systematic approach should be applied to the planning, conduct, follow-up and management of audits. To that end, the audit process should:

.....

- be supported by documented audit procedures and records to ensure consistency between auditors and to demonstrate that a systematic approach is followed,*
- include procedures for generating audit findings, including the identification of evidence of compliance and noncompliance, as appropriate, and for preparing, approving and distributing audit reports,*

- include procedures to review audit conclusions, in order to identify system-wide strengths and weaknesses in the control system, disseminate best practice and ensure the monitoring of corrective and preventive actions,
- be monitored and reviewed to ensure the audit programme's objectives have been met and to identify opportunities for improvement.”

2.5. Implementation of the audit process

Section 6.1 of the Annex of Commission Decision 2006/677/EC provides guidance on **implementation of the audit process**:

“To comply with the requirements of Article 4(6) of Regulation (EC) No 882/2004, the audit system should cover the following three points set out in Article 2(6):

*(a) **Verification of compliance with planned arrangements** in order to provide 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 largely be 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 seek 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 assessing the suitability of official controls, with regard, for example, to their frequency and the methods applied, having regard to the structure of the production chain(s) and to production practices and volume. The audit team should have substantial knowledge and understanding of system auditing, together with relevant technical input to address this audit objective.*

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

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

The primary focus of audits should be the control arrangements relating 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 of the end-product(s) and (b) compliance with other feed and food law requirements and with animal health and welfare rules. In order to achieve this, audit(s) should where possible extend beyond and across administrative boundaries.”

The Network Reference Documents on Auditing Effectiveness of Official Control Systems (February 2014 - Version 1) provides additional guidance to Member States on how the effective implementation and suitability of official controls in achieving objectives may be evaluated.

2.6. Follow-up of audit results

Article 4(6) of Regulation (EC) No 882/2004 requires, *inter alia*, that “*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*”.

In section 5.3 of the Annex of Commission Decision 2006/677/EC further guidance is provided to Member States on ‘independence’, in the context of **follow-up of audit recommendations**:

“Where the audit team makes recommendations for corrective and preventive action, the auditee should choose the methods to be applied for such action. 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.”

Section 6.3 of the Annex of Commission Decision 2006/677/EC provides guidance on **follow-up of audit outcomes**:

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

— an Action plan enables the audit team to assess whether the proposed corrective and preventive action is sufficient to address the recommendations of the audit report. Action plans should include risk-based prioritisation and time frames for completion of corrective and preventive action. A wide range of different action plans could be considered satisfactory. It is for the auditee to choose from the various options available,

— Corrective and preventive action should not be confined to addressing specific technical requirements but should, where appropriate, include system-wide measures (for example communication, cooperation, coordination, reviewing and streamlining of control processes, and so forth). A root cause analysis of any non-compliance should be conducted by the auditee in order to determine the most appropriate corrective and preventive action. 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”

Article 4(6) of Regulation (EC) No 882/2004 requires, *inter alia*, that “auditsshall be carried out in a transparent manner”.

2.7. Transparency

Section 5.2 of the Annex of Commission Decision 2006/677/EC provides guidance on **transparency**, including the following:

“In order to demonstrate the audit process is transparent, documented procedures should, in particular, include a clearly defined audit planning process, audit criteria and audit 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 the auditee. Ensuring the audit process is transparent in the eyes of other stakeholders will assist in the dissemination of information, and in particular in the sharing of best practice within and between competent authorities.

The Member States should adopt the appropriate measures to ensure their audit systems are transparent, taking national legal and other requirements into account. To that end, the Member States should consider encouraging practices that improve the transparency of the process.”

2.8. NAS reference documents

The NAS Network is a network of officials (auditors) from Member States competent authorities, responsible for the performance of audits of official control systems as provided for by Article 4(6) of Regulation (EC) No 882/2004. The Network meets regularly, under the chairmanship of, and facilitated by, DG SANTE to exchange experiences in implementing national audit systems on official control activities. During the course of these exchanges; discussions, workshops etc. good principles and practices are identified and agreed by the network. To enable dissemination of information the Network, working in plenary session and through sub-groups, and facilitated by DG SANTE, consolidates agreed principles and good practices on specific topics into Network Reference Documents.

At the time of writing of this report the NAS Network has produced the following Network Reference Documents:

- Risk Based Planning for Audits of Official Control Systems - February 2014 - Version 1;
- Independence and Independent Scrutiny - Feb 2014 – Version 1;
- Auditing Effectiveness of Official Control Systems - February 2014 - Version 1;
- Audit evidence, October 2015 - version 1;
- Root cause analysis, November 2016 – version 1.

These documents may be used as reference documents; however, they do not constitute an audit standard and are not legally binding.

The network document on **risk-based planning for audits of official control systems** clarifies what is the consensus of audit experts on the objectives of Article 4(6):

“The main objectives of audits as laid down in Article 4(6) are:

To verify:

CA's compliance with general and specific control requirements of feed and food law, plant health, animal health and welfare rules.

Compliance of official controls with planned arrangements at a national level, which may include:

Control plans of any kind (MANCP, business-, operational-, control-, monitoring-plan etc.) with the purpose of giving effect to legal requirements.

Policies, strategies, procedures, guidelines.

To evaluate:

Suitability of the planned arrangements in achieving the objectives of Regulation (EC) No 882/2004.

Effectiveness and consistency of the implementation of planned arrangements i.e. the capability to deliver the planned outcomes.

Whether enforcement measures are effective, proportionate and dissuasive.

To identify:

Areas for improvement in the CA control and management systems.

Audits may also play a supportive role in risk identification and analysis."

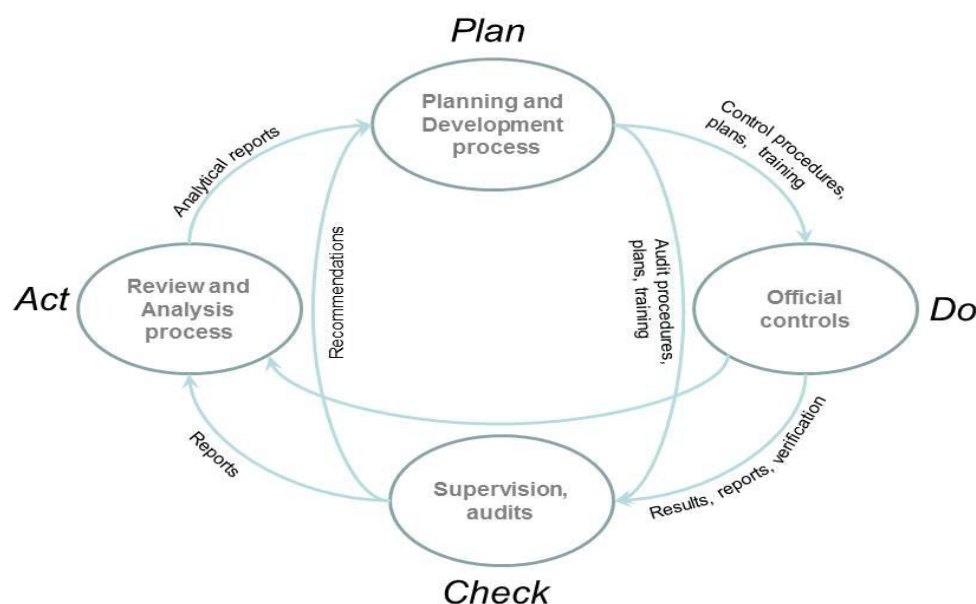
The network document "**auditing effectiveness of official control systems**" explains the audit experts' common understanding of the objectives of Regulation (EC) No 882/2004:

"Following from the definition of effectiveness, objectives of Regulation (EC) No 882/2004 have to be identified and they should be used as audit criteria. Within this document and for the purposes of assisting in auditing effectiveness according to Article 4(6), the objectives of Regulation (EC) No 882/2004 are considered to be, but not limited to:

"To ensure high quality of official controls..." (from preamble 14)

"...in verifying compliance with legal requirements" (from preamble 6, Article 1)

Ensuring implies application of the PDCA cycle:



Quality consists of:

Uniformity of controls and decisions (from preambles 12 and 14).

Consistency of controls (from preamble 14).

Effective risk-based targeting of controls (Article 3.1).

Reliable detection of non-compliance.

Turning non-compliance into compliance, when detected (Articles 54, 55)."

3. METHODOLOGY

The evaluation process of the DG SANTE audits consisted of:

- an initial desk study phase in which the relevant information already available in DG SANTE in relation to each country audited was collated and analysed. This included the Multi-Annual National Control Plan (MANCP) and associated Annual Reports, the country profile for each country, as well as relevant sectoral audit reports;
- examination of certain documentation provided by the competent authorities prior to the audit;
- meetings with the services responsible for carrying out audits under Article 4(6). The DG SANTE audit teams evaluated arrangements in place and verified their application through examination of a variety of evidence, including documentation of the audit programme development and its implementation.

Observing the performance of individual auditors during audits was not included in the scope as the DG SANTE audit teams considered that the effectiveness of an individual audit can be better judged by DG SANTE's sectoral Units' auditors in the context of relevant sectoral audits.

The evaluation focussed particularly on those elements which the DG SANTE audit teams considered essential to ensure the audit bodies can produce reliable audit results, with adequate coverage of official controls, to give assurance that the objectives of Regulation (EC) No 882/2004 are being met:

- Responsibilities for the implementation of Article 4(6);
- Status and reporting lines of auditing bodies/units;
- Arrangements for independent scrutiny;
- Procedures for the selection of auditors and management of auditor competence;
- Procedures for the development of audit programmes, with particular attention on how an adequate coverage of the audit/risk universe is ensured;
- Planning, conduct and reporting of audits, including the approach to auditing the suitability of arrangements in place for official controls to achieve the objectives of the Regulation;
- Follow-up of audit recommendations including the system in place for corrective action in cases where problems are identified during the audit activities;
- How and to what extent transparency is ensured.

In addition, the DG SANTE audit teams gathered information on particular challenges faced by the competent authorities when implementing Article 4(6).

ANNEX III - MAIN FINDINGS IN RELATION TO SPECIFIC ASPECTS OF THE ORGANISATION, IMPLEMENTATION AND FOLLOW-UP OF AUDITS OF OFFICIAL CONTROLS IN MEMBER STATES

1. Ensuring audits of official controls

The audit series found that the majority of competent authorities had put arrangements in place for audits of the official controls they performed and that, in general, these arrangements took account of the main elements described in Commission Decision 2006/677/EC. Most also aimed to take into account the NAS Network documents on *Risk based planning for audits of official control systems* and on *Independence and independent scrutiny*. A minority also took the document on *Auditing effectiveness of official control systems* into account.

Particular challenges remained in ensuring adequate audit cover in competent authorities for whom official controls under the scope of Regulation (EC) No 882/2004 constitute only a small part of their overall activity. In such cases, where the requirement for audit under article 4(6) would only apply to a very limited range of activity, developing an internal audit arrangement to address the requirement would represent an excessive and disproportionate burden. The audit series identified some cases where compliance with article 4(6) was ensured by means of periodic audits carried out by an external service provider on behalf of the competent authority. While such arrangements can satisfactorily address the requirement, where commercial service providers were used, they could be costly.

In Spain, where import controls are managed from central level, one of the competent authorities involved identified a government internal control service, the *inspección general de servicios* who could audit their activities, thereby avoiding the need to contract a commercial external service provider for this purpose.

A further challenge was identified in cases where the competence for certain official controls was delegated to a regional or local level and the individual competent authorities performing controls were therefore very small, in some cases involving a single person. These arrangements again gave rise to situations where the burden on establishing an internal audit arrangement in each small competent authority to implement article 4(6) would be excessive and disproportionate and the cost of using commercial service providers to carry out periodic audits could be prohibitive.

In Ireland, where certain controls in relation to food of animal origin, animal welfare and animal by-products in small establishments fall under the responsibility of the local authorities, a system of peer to peer auditing between the local authorities was established with the support of the central authority with overall responsibility for official controls on food. The latter carried out additional periodic audits on the relevant local authority activities. The combination of the two approaches ensured good audit coverage of the official controls.

2. Audit arrangements

2.1. Independence

In general the audit services met displayed a good awareness and appreciation of the need to ensure independence of the audit function and the auditors in order to ensure a credible audit service. Many audit services met made reference to the NAS Network document on Independence and Independence Scrutiny in relation to managing threats to independence and mitigating measures.

Those audit services that used technical experts to support their audit teams were aware of the need to ensure that the audit teams' independence was not compromised by such use and in general, adequate arrangements had been put in place to address this risk. In relation to the use of technical experts to support audit teams, in highly specialised areas and/or small countries, the sourcing of suitable experts who were sufficiently independent of the activities being audited could prove problematic and this was cited, in some cases, as a reason why technical experts were not used.

In certain cases where audit services were small and the same auditor could regularly audit the same auditee, auditors met showed good awareness of the familiarity risk to their objectivity and the need to maintain an independent mind.

The issue of independence of audit activities arose regularly in relation to arrangements whereby central level (which may have responsibility for control policy, planning and co-ordination of official controls and/or drafting of working procedures) audits the 'delivery' level where controls are actually carried out. Such audit arrangements were often in place for import controls at Border Inspection Posts (BIPs). Such arrangements bring the advantages that the central level auditors have a thorough knowledge of the procedures that should be followed and can therefore effectively audit compliance with the procedures. In addition, such audit arrangements usually permit a much higher audit intensity that would be achieved if BIPs were being considered as one element in a much larger audit universe. However, with such arrangements it can be argued that the auditors, as those responsible for control policy, planning and co-ordination of official controls and/or drafting of working procedures, cannot audit these elements of the official controls as this would constitute 'self-review'. This is a particular problem in relation to auditing effective implementation and/or suitability of planned arrangements, where the auditors are responsible to developing those planned arrangements.

This challenge was addressed in some competent authorities by using a combination of audit approaches. For example, in France, the responsible technical bureau at central level carried out regular audits at all BIPs, aiming to audit all of them every three years. The central level was in turn audited in relation to various aspects of its performance (planning, training) in the context of horizontal 'process audits'.

In several cases, competent authorities with similar arrangements argued that the DG SANTE audits could provide the additional layer of independent audit necessary to ensure that the central elements of the official controls are audited and that effective implementation and suitability of audit arrangements were audited without any 'self-review' risk. This was not an argument that was fully accepted by the DG SANTE audit teams since competent authorities are not able to determine when and on what topics they receive DG SANTE audits and can therefore not reply on these audits to ensure

adequate audit coverage within a reasonable time period of all relevant areas of official controls. It was, however, accepted that DG SANTE audits actually carried out could be taken into account when competent authorities were determining if audit coverage of a particular audit activity was sufficient.

2.2. Independent scrutiny

Given that the requirement for independent scrutiny of audit arrangements has been in place since 2006, it was a surprising finding of this series that many audit services were still struggling to put suitable arrangements in place.

The main two challenges were the cost and the identification of suitable persons to carry out such scrutiny. In a few cases, scrutiny was limited to only a part of the audit process, such as risk-based planning or approval of the programme of audits. The DG SANTE audit teams did not consider that such arrangements fully address the objectives of independent scrutiny, as this process should examine the entire audit process.

Most audit services that had arrangements in place used either audit committees with one or more independent members or external audits.

In a few cases where audit committees were used, those committees had been set up for broader internal control purposes and were tasked with carrying out the independent scrutiny required by article 4(6) as a small part of their scope. This created the risk that the committee did not necessarily include persons with sufficient knowledge of the objectives of article 4(6) and of the audit process to be able to carry out a full and appropriate evaluation of the audit process and contribute to its continuous improvement.

Where periodic external audits were used for the purposes of independent scrutiny, the cost of hiring external commercial service providers to carry out this scrutiny was in some cases a limiting factor.

In Spain, the DG SANTE audit team noted that some competent authorities involved identified a regional government internal control service, who could carry out an independent scrutiny of their activities, thereby avoiding the need to contract a commercial external service provider for this purpose.

A number of cases were seen where competent authorities had ISO accredited quality management systems and relied upon the external ISO audit carried out for accreditation purposes to provide independent scrutiny of the article 4(6) audit arrangements. The DG SANTE audit teams found that in some such cases the documentation of the external ISO accreditation audit demonstrated clearly that the audit arrangements were considered in the light of article 4(6) and that the external audit provided outputs which contributed to the improvement of the article 4(6) audit arrangements. In other cases, however, the documentation associated with the external ISO accreditation audit provided no evidence of any assessment of the internal audit process against the objectives of article 4(6) and/or provided no outputs that contributed to the continuous improvement of the audit process.

Thus, in relation to using external ISO accreditation audits as a means of independent scrutiny, the DG SANTE audit teams concluded that such audits can serve this purpose if their outputs can demonstrate that:

- The audit process was assessed against the relevant requirements and against the objective of article 4(6);
- The depth of the assessment was sufficient to give assurance that the independence and appropriateness of the audit arrangements were properly evaluated and a positive conclusion in relation to these aspects can give assurance that the audit process can provide credible, reliable results;
- Where necessary, outputs (feedback, recommendations) contributing to the improvement of the audit process were provided.

2.3. Auditor competence

In general, auditors met by the DG SANTE teams were found to have received adequate, appropriate training for their activity and display a good knowledge of audit principles and techniques. Most audit bodies/services had benefitted from the Better Training for Safer Food courses on audit and also provided on-going training opportunities for their staff.

A variety of different approaches were taken to ensuring auditor competence, including:

- Seeking to recruit people with previous audit experience and/or qualifications;
- Providing formal audit training to recruits with relevant technical/sectoral experience;
- Providing on-the-job training to new recruits, mainly by having them accompany experienced auditors during a number of audits;
- A mixture of all three approaches described above.

All of the approaches described above were found to be successful in ensuring sufficient auditor competence.

Maintenance of competence and further professional development were ensured by a variety of means, including by participation in training and/or participation in NAS Network meetings

Some audit services identified additional means of further professional development, such as periodic participation in audits for other services or in benchmarking exercises or exchanges with similar services in other Member States.

The extent of the use of technical experts varied considerably – some audit services used them regularly, some only occasionally and some never used them. The need for additional expertise also varied, depending on the range of official controls audited and the previous technical experience of the auditors. The DG SANTE teams did identify some cases where the decision not to use, or lack of provision to use technical experts

could limit the auditor's ability to fully assess effective implementation and/or suitability of planned arrangements.

2.4. Development of the programme of audits

The DG SANTE teams consider three aspects in relation to the development of audit programmes:

- Did the programmes developed ensure adequate coverage of official controls within a reasonable time period?
- Were the programmes risk-based and if so, could the risk-basis be demonstrated?
- Where two or more competent authorities were carrying out official controls, was there sufficient co-ordination between their audit programmes to ensure a seamless coverage by the audit programmes of official controls (i.e. to avoid gaps and overlaps)?

Most audited services met could demonstrate that their programme achieved of adequate coverage of official controls. In a minority of cases it was found that programmes did not ensure adequate coverage of all relevant official controls within a reasonable time frame, either because:

- Programmes focussed only on a subset of official controls (e.g. those covered by ISO accreditation, or those targeted by senior management); or
- The programmes developed could not be implemented within the audit resources available.

In some cases 'coverage' of official controls did not include relevant activities carried out at central level, such as planning/programming and/or coordination of controls, or issue of documented procedures.

In relation to ensuring that the programme was risk-based and demonstrating this risk-basis, the degree to which this was achieved varied considerably between the audit services met. Nevertheless some good examples of methodologies used for this purpose were demonstrated to the DG SANTE audit teams, in particular in Belgium and Ireland.

With regard to co-ordination between different competent authorities' audit programmes, this was something which had not been considered, or was limited in scope, in some Member States visited. Conversely some examples a good practice in coordination were noted: in Austria all audit related aspects of controls falling under the responsibility of the Länder are discussed at specific working groups and meetings of the head of the Länder services.

Similarly in Spain, while responsibility for implementation of audits of most official controls lay with the autonomous communities, strong co-ordination activities by the central competent authorities ensured that a common approach to ensuring coverage, with audits based on the commonly defined programmes of official controls, was used nationally.

2.5. Implementation of the audit process

2.5.1. Documented Procedures

In general, most audit services had adequate documented procedures in place to ensure consistent and transparent performance of audit activities. The most common exception was in relation to procedures for development of risk-based audit programmes, where in some cases procedures were still quite new and under active development and therefore not always fully documented.

Some examples were seen of very extensively documented audit arrangements, including not just procedures for each step of the audit process but comprehensive supporting documents, including templates, records and guidance documents.

2.5.2. Compliance with planned arrangements

All audit services met demonstrated that they had adequate arrangements in place to ensure that they could verify compliance with planned arrangements. These arrangements included sufficient auditor competence, appropriate documented procedures and sufficient access to people, documentation, information and facilities in order to allow a proper evaluation of the degree to which official controls were performed in compliance with planned arrangements. Thus audit bodies/services could provide management within their competent authorities with reliable information on the extent to which official controls were carried out as foreseen.

2.5.3. Verification of the effective implementation of planned arrangements and their suitability to achieve objectives

The extent to which the audit services met could demonstrate that they were able to verify effective implementation of planned arrangements and their suitability to achieve objectives varied considerably. Some audit services largely limited their activities to verifying compliance with planned arrangements; this was particularly true for recently established audit services and for those with a strong emphasis on internal audit of quality management systems in the context of achieving and maintaining ISO accreditation.

For those that did include verification of effective implementation of planned arrangements and their suitability to achieve objectives in the scope of their audit activities, the degree to which this was done in a systematic manner and could be demonstrated in audit reports varied considerably:

- In some cases audit procedures and/or audit objectives referred to the effective implementation of planned arrangements and/or their suitability to achieve objectives but findings and conclusions did not;
- In some cases no explicit mention of verification of effective implementation of planned arrangements and their suitability to achieve objectives was made in audit objectives but certain audit findings and/or conclusions clearly addressed these elements;

- In some cases, broad statements were made in relation to the effectiveness of official controls, but the basis for these statements was not evident in the audit findings;
- In a few cases auditors could demonstrate from audit procedures, audit working documents and audit objectives, findings and conclusions that effective implementation of planned arrangements and their suitability to achieve objectives were systematically evaluated.

Overall, demonstrating that effective implementation of planned arrangements and their suitability to achieve objectives have been verified remains challenging for audit services. The adoption of the NAS Network document on Auditing Effectiveness of Official Control Systems in February 2014 has not entirely addressed this difficulty.

Some audit services met also highlighted that while audit findings, conclusions and recommendations in relation to compliance are usually accepted by auditees, those made in relation to effective implementation and/or suitability can be disputed more easily as such assessments can be seen as more subjective. In addition, recommendations in relation to effective implementation and/or suitability of planned arrangements can be more challenging to address (see section 2.6 of this Annex).

A further difficulty for audit services in verifying effectively implementation and suitability of planned arrangements to meet objectives is that the objectives of official controls are not always explicitly defined.

One competent authority in Ireland has implemented targeted audits of sectors (e.g. cold stores). This practice intended to assess the overall state of implementation of areas of legislation in particular sectors nationally, but in some cases included very useful findings about the effectiveness of official controls and led directly to actions to improve those controls.

Competent authorities are also required, under Article 8(3) of Regulation (EC) No 882/2004 to put in place procedures to verify the effectiveness of their official controls. This is a separate and distinct requirement from Article 4(6): arrangements under article 8(3) usually involve those directly responsible for the official controls and may take the form of on-going activities, such as line supervision, while audits are carried out by persons independent from the activity audited and are carried out periodically. These two separate activities can and should complement each other: at the very least the outputs of each can be used by the other. In a few competent authorities, the audit services considered that verification of compliance with planned arrangements was sufficient during an audit because the arrangements in place to implement Article 8(3) ensure that such planned arrangements would be effectively implemented and suitable. The DG SANTE audit teams took the view that this could represent a missed opportunity to use the 'fresh eyes' of audit to periodically examine the effective implementation and suitability of these planned arrangements.

2.5.4. Audit reporting

All audit services had procedures in place for drafting audit reports, receipt and consideration of auditee comments, and final audit report approval and distribution.

Many examples of clear, logical and transparent audit reports were seen. Nevertheless, the DG SANTE audit teams identified a number of problems in relation to audit reports:

- In a few cases audit reports were written in telegraphic style which would only be understood by the auditor and auditee, which limited their usefulness to any other readers and could pose problems during follow-up or for subsequent auditors, as it would not necessarily be clear to them what issues were actually identified at previous audits or what was assessed as satisfactory;
- In a number of cases it was not always entirely clear what elements of the audit criteria had actually been assessed and what the outcome of that assessment was. This was particularly the case where the audit criteria cited included numerous pieces of legislation, but not all elements of that legislation were assessed in the scope of the audit actually conducted;
- In some cases the basis or justification for conclusions was not evident from the findings presented;
- As highlighted in section 2.5.3 of this Annex, in some cases where effective implementation and suitability of planned arrangements were actually assessed during audits, the auditors struggle to make this clear in the report.

Some useful practices in relation to audit reporting were also identified. In particular, a number of audit services systematically identified weaknesses and strengths or potential good practices in their reports, which facilitated subsequent identification and dissemination of information on potentially system-wide weaknesses or good practice which could be of general use in the competent authority (see section 2.5.5 of this Annex).

Conversely several competent authorities considered that the identification of good practice examples in audit reports as a challenge, as this is based on a subjective assessment of a single auditee. Such practices may not be readily generalizable across a competent authority and it may be found that a practice considered initially as good may not necessarily work well under different circumstances.

2.5.5. Review of audit conclusions and dissemination of best practice

The degree to which audit services systematically reviewed audit conclusions to identify possible systems-wide weaknesses and good practices which could be applied more widely, and ensured this information was disseminated across the competent authority, varied considerably.

The good practices identified by the DG SANTE audit teams included:

- The use of report formats that led auditors to systematically consider whether their findings might have an application beyond the service being audited and to record such issues in a transparent way;
- The regular, planned systematic review of audit reports to identify possible systems-wide weaknesses and potential good practices that could be used more widely across the competent authority;

- Mechanisms for active communication across the competent authority of the outcome of the reviews, which could include both once-off events, such as presentations to management committees or at training events, and more permanent communication, such as making the information available on dedicated parts of intranets.

The DG SANTE teams considered actively harvesting this type of information from audit reports and ensuring that it is brought to the attention of all who could benefit from it represents an effective way to maximise the benefit that the competent authority gains from having an audit service. Thus, relying on passive communication, such as simply placing all audit reports on a shared intranet would not necessarily be the most effective means of maximising the benefits to be derived from an audit service and could therefore represent a missed opportunity.

2.5.6. Monitoring and review of the audit process

In general the audit services met had sufficient tools and procedures in place to allow them to monitor the implementation of their audit process.

In relation to review of the audit process, while most audit services produced an annual report, in some cases this was predominantly an activity report and no review of the audit process, its strengths and weaknesses, was included. This represents a missed opportunity for continuous improvement.

Other audit services met could demonstrate that a regular (usually annual or bi-annual) in-depth review of the audit process took place and that this process yielded outputs that led to the improvement of the audit process.

Some audit services also had systematic procedures to receive feedback from auditees, which was used to improve the audit process.

2.6. Follow-up of audit recommendations

All competent authorities had put in place arrangements to ensure that responsibility for production, assessment and follow-up of the implementation of action plans in response to audit findings/recommendations was clearly allocated and procedures for action plan production and follow-up were defined. In most cases, it could be demonstrated that the majority of audit findings/recommendations were addressed, although not always within the deadlines originally proposed.

A minority of competent authorities did not ensure that audit recommendations were effectively addressed. This was particularly in the case of audit recommendations in relation to effective implementation and/or suitability of planned arrangements, which tend to be more demanding to address in comparison with recommendations on compliance with planned arrangements. It was noted that competent authorities who had greatest difficulties in ensuring that recommendations were addressed tended to be those that had no defined procedures for dealing with failure of the auditee to address recommendations.

The DG SANTE audit teams considered that ultimately the impact of the audit arrangements is determined by the effectiveness and appropriateness of the corrective actions implemented in response to audit findings/recommendations. Thus those few

cases where significant numbers of audit recommendations remained unaddressed over long periods of time undermined confidence in the assurance that the implementation of audit arrangements would normally give in relation to the quality of official controls.

A number of useful practices in relation to follow-up of audit recommendations were noted:

- A number of audit services carried out periodic dedicated follow-up audits to check the effectiveness of measures taken in the light of audit findings or made systematic provision for follow-up of previous recommendations to be included in the scope of subsequent audits;
- A number of competent authorities used root cause analysis, carried out either by the auditees or the auditors and auditees in co-operation, to ensure that underlying causes of deficiencies identified by audits were determined and addressed. This could pose some difficulties for auditees who did not necessarily have the skills to carry out such root cause analysis. Some actions aimed at addressing this challenge were noted:
 - The Veterinary Internal Audit Unit of the Irish Department of Agriculture, Food and the Marine, developed guidance on root cause analysis for auditees responsible for development of action plans in response to audit recommendations;
 - The Irish Sea Fisheries Protection Agency used a group of representatives drawn from their central service and all of their Port Offices to evaluate all audit reports and recommendations, develop service-wide action plans aimed at addressing underlying causes of deficiencies identified and identify managers responsible for implementing corrective action;
- A number of audit services had defined clear procedures to be followed where no, or inadequate action plans were provided by auditees, and this could not be resolved between auditee and auditor. These procedures ensured that senior management were fully aware when adequate measures had not been taken in response to audit findings and could ensure that whatever action was taken, if considered necessary.

2.7. Transparency

It was noted that in almost all cases good transparency was achieved between the audit services and the services audited. In all cases auditees were well-informed of the audit procedures and were allowed to comment on draft reports. In most cases final audit reports were made available within the competent authority. In almost all cases, the audit programme was available to all personnel within the competent authority.

However, the degree of transparency of audit activities and results towards external stakeholders varied considerably. This was often a reflection of normal administrative practices within the country concerned. Some audit services published detailed information about audit activities on a regular basis, even publishing audit reports when

their content was suitable for such publication others provided little transparency to external stakeholders.

Member States are required to include information on the audit activity undertaken within the scope of Article 4(6) in the annual reports on the implementation of their multi-annual national control plans. The amount of information contained in these reports varied, with quite detailed information being presented in some cases. However, not all annual reports are published.

The DG SANTE audit teams considered that the degree to which audit services make information in relation to general audit activities and specific audits public can legitimately vary depending on the nature of the audit activity. It would not always be appropriate, for example, to publish audit reports that would allow the identification of specific individuals carrying out controls or of food businesses. However, the failure to provide any information on audit activities to external stakeholders can be a missed opportunity to promote confidence in the quality of official controls, based on the assurance provided by an effective audit function.

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