Overview report
Audits of Official Controls in EU-Member States

DG Health and Food Safety

Objective

Audit of official controls

Plan

Do

Appropriate measures

Objective

Act

Audit value

Check

Ensure the effectiveness

Art. 4.6

Art. 4.2(a)

independent

compliance
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OVERVIEW REPORT
ON A SERIES OF AUDITS CARRIED OUT IN MEMBER STATES
FROM 2016 TO 2018
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 overview report describes the main conclusions in relation to a series of 25 audits carried out by the European Commission’s Directorate-General for Health and Food Safety in Member States between 2016 and 2018, 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 2 pilot missions carried out during 2015 to prepare for this audit series have also been taken into account.

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.

The vast majority of relevant Competent Authorities were found to have put 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 by Member State authorities 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.

The overall conclusion of the audit series is that effectively implemented Competent Authority audit arrangements contribute to ensuring the quality, and improving the consistency and effectiveness of official controls, provided that there is strong management commitment to the follow-up of audit recommendations.

Despite the overall positive situation it is clear that Competent Authorities implementing audits still face some challenges 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 legal requirements for independent scrutiny of the audit process, auditing effective implementation and suitability of official controls and for effective follow-up of audit results. Other areas where further improvement would be beneficial were risk-based planning of audit programmes and transparency of the audit process outside the organisation.

Improvements in these areas would further contribute to credibility, reliability, relevance and impact of audit systems.

This overview report also highlights useful practices identified in certain Member States which may be of interest to other Member States.

Finally, this report describes actions taken and planned by both the Member States and the European Commission services in response to the findings of this audit series.
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**ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT**

<table>
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<tr>
<th>Abbreviation</th>
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<td>BTSF</td>
<td>The Commission's Better Training for Safer Food training initiative</td>
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<td>DG SANTE</td>
<td>The European Commission’s Directorate-General for Health and Food Safety</td>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>IIA</td>
<td>Institute of Internal Auditors</td>
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<td>MS</td>
<td>Member State(s) of the European Union</td>
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<td>MANCP</td>
<td>Multi-Annual national Control Plan</td>
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<td>NAS</td>
<td>National Audit System(s)</td>
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<tr>
<td>The NAS Network</td>
<td>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.</td>
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<td>QM</td>
<td>Quality Management</td>
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1 OBJECTIVES

This final overview report aims to present the main conclusions at the end of a series of audits and highlights certain useful practices, which may be of interest or benefit to other Member States (MS) (see Annex III).

The audit series began with 2 pilot missions which took place in 2015. Audits were then carried out between 2016 and 2018 in 25 MS (listed in Annex II) with the objective of evaluating whether National Audit Systems (NAS) can provide confidence to their top management and to stakeholders that:

- official feed and food control systems have been set up in compliance with European Union (EU) and national legislation;
- official controls are carried out as intended;
- the control systems are suitable in achieving the objectives of the legislation; and
- audits on these control systems can provide credible, reliable and relevant results on the performance of official controls.

An interim overview report was produced after completion of the first 10 audits: http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=107

2 LEGAL BASIS AND AUDIT CRITERIA

Article 45 of Regulation (EC) No 882/2004 provided the European Commission with the mandate to carry out this audit series. The only legally binding requirement for the MS' Competent Authorities is Article 4(6) of Regulation (EC) No 882/2004, supported by Article 2(6), which provides a definition for an audit.

3 BACKGROUND

The "mad cow disease" crisis of 1996 triggered a series of events, which led into a new control framework to better ensure food safety, the interests of consumers, animal health, plant health and animal welfare. The EU overhauled the basic food safety legislation and created a new Regulation\(^1\) to improve the quality of official controls covering the whole production chain from farm to fork – the Official Feed and Food Control Regulation (Regulation (EC) No 882/2004) was adopted in 2004.

This Regulation has all the elements of a typical quality management system and has one central objective: to ensure that Competent Authorities' official controls are effective. It follows a three-layer model: firstly, the primary responsibility for safe food lies with the food business operators. Secondly, the Competent Authority must verify the food business operators' compliance with feed and food law. Thirdly, the European Commission's role is to evaluate the effectiveness of official controls carried out by MS.

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Setting up an NAS proved to be quite challenging for many MS. Therefore, the Commission provided guidelines\(^2\) laying down criteria for the conduct of audits. Once the guidelines had been finalised in 2006, MS decided to set up a network of audit experts (the 'NAS Network') to elaborate further guidance (so-called network documents) to clarify particularly challenging issues. By 2016, the audit network had produced five guidance documents on: (1) risk-based planning of audits, (2) auditing effectiveness, (3) independence and independent scrutiny, (4) audit evidence and (5) root-cause analysis.

In addition, the Commission services organised audit training under the Better Training for Safer Food (BTSF) initiative. An initial training programme was launched in October 2013 and finished in June 2017. Two modules were designed: one for setting up an audit system and another one for conducting an audit. A total of 1296 officials had been trained under this programme. The objective of this training was to ensure that all those involved with designing or running an NAS would be familiar with the legal requirements, principles and workings of audit systems.

In 2015, the Commission decided to carry out a series of audits to evaluate how successfully MS had managed to set up their audit systems. It was considered that, if successfully implemented, the audit systems should effectively contribute to the quality of official controls and continuous improvement of control systems. If DG SANTE audits could verify effective implementation, this would be a very resource-effective way of providing assurances across the spectrum of official controls – and of maintaining and increasing confidence in the performance of EU official control systems.

The purpose of audit systems is to build confidence. They are meant to provide assurances to the top management that official controls are meeting their objectives and are continuously improved. Audit systems can also provide confidence to the consumers that Competent Authorities are controlling food business operators in an effective manner. They can also provide assurances to other stakeholders e.g. trading partners outside the EU on the safety of feed and food produced by European food business operators.

In order to achieve their objectives, audit systems must be credible, they must produce reliable results time after time, they must look into things that are relevant and must have a positive impact on the quality of official controls. Credibility, reliability, relevance and impact are the key components in building confidence. All international audit standards address these four elements in one way or another.

This audit series identified a number of practices, which may be useful for Competent Authorities in implementing particularly challenging areas (see Annex III).

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4 CONCLUSIONS

4.1 CREDIBILITY

In order to have confidence in audit results, the audit body should be credible enough to convince the auditee and top management to act upon the results. Similarly, to build and maintain stakeholders' confidence in official controls, credibility of the audit process is crucial. For the purposes of this overview report, credibility is viewed as the net effect of implementing legal requirements for independence, transparency, auditor competences and independent scrutiny of the audit process.

Independent scrutiny is essential for credibility and confidence. This is the final seal of credibility of both the audit bodies and the Competent Authorities. When implemented effectively, it also provides confidence to the Competent Authority itself that whatever audit arrangements they have put in place, they meet the expectations and top management can rely on audit results.

The main findings were as follows:

4.1.1 Independence and auditor competence

Appropriate level of independence: Competent authorities have put in place arrangements to ensure independence of the auditors, audit body and process. This was particularly the case in Competent Authorities, where top management demonstrated awareness of the audit service and strong commitment to audits.

Good basis for audit objectivity: Audit bodies mitigated properly threats to independence to safeguard objectivity of audit results.

Auditors are competent: Auditors were found to be competent and audit bodies managed properly their professional development. These form the basis for credibility and are the key conditions for carrying out high quality audits and for producing reports with impact.

4.1.2 Transparency

Good internal transparency: Audit bodies were generally transparent with their auditees and therefore, maintained good credibility towards the Competent Authority and top management.

Less external transparency: However, many Competent Authorities have overlooked transparency towards external stakeholders such as non-EU trading partners, Non-Governmental Organisations, and consumers, through, for example, the publication of information on audit activities and results. This is a missed opportunity to build and maintain consumer confidence in the official controls, which was a key issue at the time of adopting the requirements for NAS.

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3 Independent scrutiny is a regular and planned process external to the audit body and the audited organisation with particular focus on the audit process to ensure that the process is capable of producing objective results and meeting its obligations under Regulation (EC) No 882/2004.
4.1.3 Independent scrutiny

Independent scrutiny is variable and should be improved: Implementation of Independent scrutiny was sometimes less effective than other elements that affect credibility. The range of arrangements varied from none to very good. Audit service's ability to benefit from advice of the results of independent scrutiny is a significant factor in providing on-going confidence in the audit system and thereby in the quality of official controls performed by a given Competent Authority.

4.2 Reliability

An audit system should follow a process which is able to produce consistent results in a systematic way. It should be based on widely accepted international standards and have arrangements in place to ensure high quality of the whole audit process. Audit systems should also be able to critically review their operations, learn and improve in time. Once an audit system meets these criteria, it has a high degree of reliability.

A systematic approach provides consistency and, when combined with transparency, increases the auditees' trust in the process. Effective quality management systems ensure that audit bodies are able to meet the expectations of auditees, management and external stakeholders. Standards increase trust and reliability and when an audit body follows generally accepted standards, it is more likely that all stakeholders accept audit results and rely on the audit process. Review of the audit process itself is an opportunity to learn and improve the effectiveness of audit systems.

The main findings were as follows:

4.2.1 Systematic approach

Audits are managed in a systematic way: Documented procedures were in place for the whole audit process including planning, conduct, follow-up and management of audits. All audit services had procedures in place for drafting audit reports, dealing with auditee comments, and final audit report approval and distribution.

Audits were part of a mostly multi-annual programme, aiming at adequate and risk-based coverage of all relevant areas of activity.

4.2.2 Quality management

Quality management is in place: Most audit bodies followed a systematic approach which had all the essential elements of a Quality Management System. In some cases, these Quality Management Systems were accredited to either ISO or Institute of Internal Auditors (IIA) standards – providing additional external assurances.

4.2.3 Use of standards

Audit processes are based on standards: Audit bodies made use of the Commission guidelines and network documents to achieve the objectives of Article 4(6). In addition to these non-binding guidance documents, some audit bodies were following either IIA or ISO standards – even if they were not seeking accreditation.
4.2.4 Monitoring and review

Audit processes are properly monitored: In general, the audit services met had sufficient tools and procedures in place to allow them to monitor the implementation of their audit process.

Review of audit process and results could be improved: There was considerable variation in the degree to which audit services systematically reviewed audit conclusions to identify possible systems-wide weaknesses and useful practices, which could be applied more widely, and ensured dissemination of this information across the Competent Authority. Many audit bodies did not use this opportunity systematically to its full potential for achieving continuous improvement.

4.3 Relevance

When audits provide conclusions on topics that matter to the management and stakeholders, audit results are relevant. Thus, all stages of the feed and food production chain and all areas of official controls should be considered in the context of a risk-based prioritisation process during the development of the audit programme. Programming audits on a risk basis means that limited audit resources are used effectively. In addition, multi-annual audit programmes should ensure that all areas of official controls are adequately covered within a reasonable time-period (generally 5 years). Audits should be capable of detecting non-compliance i.e. when official controls are not in line with legal requirements, plans, procedures or instructions. Apart from compliance, audits should be able to evaluate the effective implementation of official controls and whether control arrangements are suitable in achieving their objectives – both specific and general objectives for a control system. Audit services need to ensure and demonstrate to stakeholders that they are auditing the right things, at the right time and auditing the effective implementation of planned arrangements and their suitability to achieve objectives.

The main findings were as follows:

4.3.1 Risk-based planning

Large variation in implementation: The degree to which audit services could ensure and demonstrate that the audit programme was risk-based, varied considerably.

Other demands may interfere with risk-based planning: In some cases, reconciling the demands of implementing Article 4(6) with other demands such as quality management systems and internal controls can limit or distort the targeting of the audit activities carried out in the context of Article 4(6), reducing the extent to which audit resources are used for auditing highest risk priorities.

4.3.2 Coverage

Generally sufficient coverage: Most audit services could demonstrate that their programme achieved adequate coverage of official controls.

Other demands and lack of resources may also affect coverage: In some cases, programmes could not ensure adequate coverage of all relevant official controls within a reasonable time frame: either programmes focussed only on certain areas official controls (e.g. those covered by ISO accreditation, or those targeted by senior management); or missed some levels of the control system or the programmes could not be implemented within the audit resources available.
Linked control systems give rise to coordination issues: Coordination between different Competent Authorities’ audit programmes was an issue, which some MS had not considered at all or coordination was limited in scope.

4.3.3 Auditing compliance vs. auditing effectiveness

Verifying compliance generally works well: All audit bodies could ensure that auditors had sufficient independence and competence to audit compliance of official controls with planned arrangements.

Auditing effectiveness poses a greater challenge: The extent to which the audit services could demonstrate ability to systematically verify effective implementation of planned arrangements and their suitability to achieve objectives varied considerably. Systematically verifying these aspects can have a strong positive impact on official controls.

One difficulty in verifying effective implementation and suitability of planned arrangements to meet objectives is that the objectives of official controls were not always explicitly defined in the planned arrangements. In the absence of explicit, concrete objectives, it is difficult for auditors to conclude on whether the objectives have been achieved or not, i.e. were controls effective.

4.4 Impact

Even if credibility, reliability and relevance of audit results can be ensured, audits can only have a positive effect on official controls if they result in corrective actions and dissemination of useful practices. This effect depends on the clarity of reports, which should include clear conclusions (and recommendations when appropriate) supported by objective evidence. Transparent reporting of audit results to external stakeholders will have an impact on other stakeholders' confidence in official controls.

Audits were found to have a positive impact on the quality of official controls and follow-up generally worked well. However, many Competent Authorities have failed to benefit from ensuring the systematic dissemination of identified cases of useful practices within their organisations and to build confidence on the part of external stakeholders (such as consumers) through publication of audit planning and an overview of audit results. The quality of audit reports is also an area for further improvement.

The main findings were as follows:

4.4.1 Follow-up

Audits generally result in corrective actions: In the majority of cases, action plans were addressing the audit findings/recommendations and corrective action was appropriate, although not always implemented within the deadlines. In a small minority of cases the Competent Authority failed to ensure that audit results were acted upon.

4.4.2 Dissemination of useful practices

Better sharing of audit results would be beneficial: This series identified that Competent Authorities do not always maximise the benefit from audits by ensuring systematic identification of useful practices or system-wide weaknesses that others in their organisations would benefit from if shared.
4.4.3 Report quality

Room for improvement with audit reports: Many audit reports were clear, logical and transparent. However, in a number of cases audit criteria and/or the outcome of the assessment was unclear. In some cases, the justification for conclusions was not evident from the findings presented.

Excessive brevity may impact clarity: Some audit bodies produced reports with a telegraphic style. While the auditor and auditee may find these easy to understand, this could pose problems for other readers, particularly during follow-up or for subsequent auditors and for managers.

4.4.4 Transparency

Good transparency with the auditees: In almost all cases, audit services achieved good transparency with the auditees and audit clients. In all cases, auditees were well-informed of the audit procedures and were allowed to comment on draft reports. This in turn increased acceptance of audit results and ensured that audit reports had an impact within the organisation.

External transparency could be improved: The degree of transparency towards other (parts of) Competent Authorities and towards external stakeholders (such as such as non-EU trading partners, Non-Governmental Organisations, and consumers) varied considerably. This is a missed opportunity to have a wider impact beyond the auditee and to increase confidence in official controls.

4.5 Overall conclusion

The overall conclusion of this audit series is that effectively implemented Competent Authority audit arrangements contribute to ensuring the quality, and improving the consistency and effectiveness of official controls, provided that there is strong management commitment to the follow-up of audit recommendations.

Despite the overall positive situation it is clear that Competent Authorities implementing audits still face some challenges 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 legal requirements for independent scrutiny of the audit process, auditing effective implementation and suitability of official controls and for effective follow-up of audit results. Other areas where further improvement would be beneficial were risk-based planning of audit programmes and transparency of the audit process outside the organisation.

Improvements in these areas would further contribute to credibility, reliability, relevance and impact of audit systems.

5 Follow-up of the audit series

5.1 Actions taken by the Member States

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 Commission services, who
sought clarifications if necessary. On-going implementation of those action plans is monitored in line with standard follow-up procedures. Information on further follow-up is reflected in regularly up-dated country profiles for each Member State, which can be found here:

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

Of the 25 MS audited, 23 received recommendations. These recommendations covered:

- Audit programmes (coverage and/or risk based planning and/or co-ordination of different audit programmes within the MS);
- Independent scrutiny;
- Implementation of audit arrangements (where none were in place for certain areas of official controls);
- Follow-up of audit recommendations;
- Ensuring audits included effective implementation and suitability of audit arrangements in their scope;
- Ensuring sufficient resource (auditors) was available to the audit service.

At the time of writing, satisfactory action plans had been received from MS in response to all of the finalised audit reports with recommendations. Action plans are published together with the audit reports (see Annex II for links). The implementation of the action plan has already been verified in several MS and will be verified in the remainder in the course of periodic up-dates of country profiles.

Presentations on the progress of the audit series, as well as on the interim overview report, were made on several occasions to the NAS Network. Feedback from MS following these presentations indicated that audit services were not limiting their actions to addressing the recommendations in the audit report but were also actively considering and seeking to address opportunities for improvement of the audit arrangements highlighted in both the individual audit report and the interim overview report.

Thus, overall the response of MS to this audit series has been very positive and active discussion of various approaches to addressing weaknesses and challenges identified in this report continue in the Network meetings.

5.2 ACTIONS PLANNED AND TAKEN BY THE COMMISSION SERVICES

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

Regulation (EC) No 882/2004 which was the legal basis for the above-mentioned guidelines was replaced by Regulation (EU) 2017/625 with effect from 2019. The latter regulation contains essentially similar provisions to the former regarding NAS. However, the new
Regulation does not require the Commission to produce guidelines for NAS. Following consultation with MS, and supported by the findings of this audit series and the conclusions of this overview report, the Commission services will produce new guidelines based on Commission Decision 2006/677/EC for the continued operation of NAS under 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.

5.2.2 NAS Network reference documents.

The NAS Network suspended selection of new topics for workshops sharing methods, techniques and useful practices and the preparation of further reference documents pending the availability of this 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. The Network has recently agreed on a number of good principles for reporting audits which, together with the lessons learnt from the NAS audit series, will be incorporated into the new guidelines, currently under discussion. Other shortcomings or areas of weakness identified in this overview report will be progressively addressed by the Network.

5.2.3 Better Training for Safer Food

The previous Better Training for Safer Food (BTSF) programme for audit systems finished in June 2017. 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. This 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. Under this programme, a total of 1296 MS' officials had been trained.

Given that national audit services are rather small it could be considered that sufficient training had been provided in this area. However, in line with good practice, many NAS auditors rotate out of audit units on a three to five year cycle. Additionally the new Official control regulation expands its requirements to new areas that may or may not have been previously covered by the NAS. It was therefore decided that a new training programme should be put in place.

The new training programme will not include a replacement for Course A as it was considered that sufficient training and experience is available within the MS 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. A total of 10 new courses were to take place by spring 2020 with a global expected
attendance of 300 participants. The first workshop of this new training series took place in October 2018.

In developing the syllabus for the new training the Commission services ensured that particular attention was paid to addressing the issues identified in this overview report. In this regard, the findings of the individual reports from this audit series, that BTSF was widely used to ensure auditor competence and to provide training material for further dissemination of learning within the Competent Authorities, have provided good evidence to support the continuation of this training.
ANNEX 1 – LEGAL REFERENCES

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<th>Legal Reference</th>
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## Annex 2 - Details of Individual Audits

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ANNEX 3 – USEFUL PRACTICES IDENTIFIED IN RELATION TO THE ORGANISATION, IMPLEMENTATION AND FOLLOW-UP OF AUDITS OF OFFICIAL CONTROLS IN MEMBER STATES

This Annex is intended to highlight some practices noted in Member States (MS) during this audit series which helped to address the challenges in implementing effective National Audit Systems (NAS). More details on the examples highlighted may be found in the individual audit reports (see Annex II for links to those reports).

It is important to note that the highlighted practices will not necessarily be transferable to all audit bodies, as each body must work within its own particular context.

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 but that 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.

One Competent Authority identified another government internal control service which 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. An approach to addressing this problem was identified:

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 bodies met displayed a good awareness and appreciation of the need to safeguard independence of the audit function and the auditors in order to ensure a credible audit body. The documents establishing audit bodies, such as legislation, internal organisation directives or audit body mandates set out the basis for the operation of the audit bodies, including requirements for independence. In most cases these 'foundation' documents were supported by practices and procedures aimed at ensuring and re-enforcing independence. In all cases, clear measures were in place to ensure that auditors did not audit activities that they were responsible for implementing.

Some examples of practices which helped protect and demonstrate independence are provided below:

Many audit bodies required auditors and even technical experts supporting audit teams to sign declarations of freedom from conflict of interest before beginning an audit engagement. This provided a useful prompt for signatories to consider any possible conflict of interest that might arise.

Some audit bodies defined rotation practices to ensure that the same auditor did not repeatedly audit the same auditee.

Some audit bodies made use of observers to help ensure and demonstrate that auditors carried out their work in an objective manner.

In Latvia and Slovakia, the heads of some internal audit units routinely participated in internal audits as second auditors, *inter alia* to mitigate any pressure that might be felt by lead auditors.

2.2. Independent scrutiny

This audit series found that many audit bodies were still struggling to put suitable arrangements for independent scrutiny in place. The two main challenges were the cost and the identification of suitable persons to carry out such scrutiny.

The Nordic co-operation model on independent scrutiny of NAS was developed by Denmark, Finland, Iceland, Norway and Sweden and involved those countries providing **independent scrutiny of each other's audit systems**. The scrutiny was conducted on the basis of a common agreed approach by a team of two persons drawn from two countries other than the one undergoing scrutiny. This approach proved to be very cost-effective for the audit bodies involved. The five countries planned to continue to develop and further refine the approach.

Some Competent Authorities' audit bodies identified a regional government internal control service which could **carry out an independent scrutiny of their activities**, thereby avoiding the need to contract a commercial external service provider for...
In France, the audit body in the Directorate-General for Food was subject to independent scrutiny by the 'Ministerial Internal Audit Mission' of the Ministry for Agriculture, Agri-food and Forestry, and in Bulgaria, this scrutiny was provided by the 'Internal Audit Directorate', which is an independent administrative and financial control organ within the Bulgarian Food Safety Agency, reporting directly to the Executive Director. In each case, care was taken to ensure the services used were sufficiently independent of the audit body, and of official controls, to bring 'fresh eyes' to the scrutiny of the audit arrangements and it was ensured that the requirements of Regulation (EC) No 882/2004 and the guidelines in Commission Decision 677/2006/EC were taken into account when the scrutiny was conducted.

The Danish Agrifish Agency has arrangements with the National Audit Office of Denmark (NAOD) to carry out independent scrutiny of the audit process.

Independent scrutiny can also be carried out using an audit committee with a sufficient number of independent experts with relevant knowledge of audit. Establishing and maintaining such a committee can be expensive for small Competent Authorities. The Sea Fisheries Protection Agency in Ireland used a pre-existing internal control committee, reinforced with external independent members with relevant audit expertise, to provide independent scrutiny for its audit arrangement.

As many Competent Authorities have ISO accreditation of their quality management systems, some considered that external ISO audit could provide independent scrutiny. This audit series found that this could meet the objectives of independent scrutiny, but only if the external auditors were aware of the relevant requirements for the audit arrangements, took them into account in their audit and reported transparently on the degree to which those audit arrangements achieved the objective of Article 4(6) of Regulation (EC) No 882/2004.

It was found that the Planning and Control Division of the Lithuanian State Plant Service, as well as the Cypriot Internal Audit Body of the Department of Agriculture had put in place independent scrutiny through ISO accreditation audits which took proper account of the requirements of Regulation (EC) No 882/2004 and the guidance in Commission Decision 677/2006/EC. These arrangements for independent scrutiny produced outputs which could provide some assurance as to the performance of the audit bodies and contribute to continuous improvement of those bodies.
2.3. Auditor competence

In general, NAS auditors were found to have received adequate, appropriate training for their auditing tasks and displayed a good knowledge of audit principles and techniques. A number of useful practices for ensuring auditor competence were identified:

Many MS’ audit bodies describe in their procedures the qualification requirements for auditors and lead auditors and procedures for monitoring qualifications and maintenance of competence.

Most audit bodies had benefitted from the Better Training for Safer Food (BTSF) courses on auditing and also provided on-going training opportunities for their staff.

The Bulgarian Agency translated the NAS reference documents and provided them to all auditors. In addition, the audit body holds regular meetings with the entire pool of auditors and experts on their contents.

A number of MS’ audit bodies have participated in exchanges between NAS services, as part of benchmarking activities. The Internal Audit Unit of the Belgian Federal Agency for the Safety of the Food Chain also sets for its auditors the objective of participating in an audit in an external body once every 3 years, in order to broaden their experience.

The auditor in the Organisation for the Safety and Quality of the Food Chain of Luxembourg periodically carries out audits for BELAC, the Belgian accreditation body, in order to maintain and broaden auditing competence.

2.4. Development of the programme of audits

The audit series considered three aspects in relation to the development of NAS 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)?

In relation to coverage, in general most audit bodies could achieve a satisfactory level. Performance in relation to risk-based planning of audit programmes and co-ordination was more variable.

Regarding risk-based planning of audit programmes, some potentially useful practices were identified:
In relation to risk-based planning of audit programmes, some good examples of methodologies used for this purpose were seen, in particular in Belgium, Ireland, Denmark and Bulgaria. Their methodologies are described in more detail in the individual audit reports. In addition, the Portuguese General Inspection for Agriculture, Sea, Environment and Spatial Planning Ministry had developed a comprehensive risk analysis methodology to be used in the preparation of the NAS audit programme which, although not implemented at the time of the Commission services' audit, was found during follow-up of that audit to be in use.

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 MS visited. Conversely, some examples of effective coordination were noted:

Perhaps not surprisingly, in countries where many competences for official controls are delegated to regional levels, well-developed co-ordination mechanisms for the multiple audit arrangements were in place, in particular in Austria and Germany. These arrangements involve, inter alia, the creation of forums where the regional auditing bodies can come together to co-ordinate their activities, develop common practices and procedures and exchange experience. One competent authority also set up an electronic co-operation platform (e-room) to allow the regional audit bodies to continue to work together to develop common guidance on topics where this was found to be necessary.

In Italy, for the official control areas falling under the responsibility of the Ministry of Health, Office III at central level co-ordinates the audit programme across the sectoral offices at central level, to ensure an appropriate coverage of the Regions. In addition, this Office also co-ordinates the operation of the Regional audit system through reports to the "Technical Coordination Table" (where Regions are represented), organising training and developing a common reporting mechanism for the Annual Report on the implementation of the Multi-Annual National Control Plan (MANCP).

2.5. Implementation of the audit process

2.5.1. Documented Procedures

In general, most audit bodies had adequate documented procedures in place to ensure consistent and transparent performance of audit activities. 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.

In addition to audit procedures and supporting templates, the audit bodies of both the Bulgarian Food Safety Agency and the Romanian National Sanitary Veterinary Food Safety Authority also developed and used very good thematic audit
checklists.

The Portuguese Directorate-General for Food and Veterinary Matters provided the audited services with a “Good auditing practices manual for auditees”.

The Veterinary Internal Audit Unit of the Irish Department of Agriculture, Food and the Marine, had developed very comprehensive documented procedures and supporting models, checklists, guidelines and templates. In addition to procedures for their own work, they had developed guidelines for managers completing action plans in response to audit recommendations, to help to improve the quality of root cause analysis undertaken.

2.5.2. Auditing techniques

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

Some examples of well-developed approaches to systematically and transparently auditing effective implementation and/or suitability of planned arrangements were noted:

The audit approach in the Finnish Food Safety Authority mostly addressed matters related to the effective implementation of planned arrangements and their suitability to achieve objectives (both in the context of Regulation (EC) No 882/2004 as well as other strategic objectives set by the agency). During the preparation stage there is an extensive use of "lean" methodology tools, specifically:

- Root-cause analysis,
- value chain analysis (a tool to analyse which activities within an organisation are the most valuable),
- problem-solving using the plan-do-check-act (PDCA cycle) approach.

This philosophy was also built into the performance of the audits which put extensive focus on the system-level view combined with a process-based approach. The preparation phase of the audit also included confidential information-gathering sessions with external stakeholders and a detailed analysis of the risks in the sector.

The documented audit procedures of the Bulgarian Food Safety Agency included detailed guidance on auditing techniques in their audit procedure including the methodology to assess whether official controls are carried out effectively and whether they are suitable to achieve the objectives of both Regulation (EC) No
The Croatian Ministry of Finance Internal Auditors' Manual, which is used by both audit bodies falling within the scope of this audit series, covers the essential elements of delivering a systematic internal audit activity to international standards. In particular, it describes ‘performance audits’ as assessing “the economy, efficiency and the effectiveness of processes or programmes” and provides a methodology for such audits.

The Food Safety Authority of Ireland has, in addition to its audits of Competent Authorities carrying out official controls, implemented targeted audits of sectors (e.g. cold stores). This practice is 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.

2.5.3. Audit reporting

All audit bodies 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, a number of problems in relation to NAS audit reports were identified. Some useful practices in relation to audit reporting were also identified.

Two of the audit bodies in France used report templates that included sections for audit findings highlighting strong points (both good performance and good practices) and areas for improvement, as well as non-compliance, which facilitates subsequent review of audit results as well as promoting continuous improvement going beyond simple compliance with procedures.

The audit report template used by the Internal Audit Unit of the Belgian Federal Agency for the Safety of the Food Chain also includes a section on main positive/strong points identified during the course of audits.

In Luxembourg the Organisation for the Safety and Quality of the Food Chain, with every audit report, produces a summary (‘synthèse’) providing a balanced and constructive conclusion which captures the main strengths and weaknesses of the control system audited, and serves as a useful tool for senior management.

2.5.4. Review of audit conclusions and dissemination of best practice

This audit series found that there was considerable variation in the degree to which audit bodies 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.

Most audit bodies provided audit results to senior management and made audit reports available on organisation intranets. Some additional useful practices were identified:
In Italy, for the official control areas falling under the responsibility of the Ministry of Health, Office III at central level aims to identify issues across all sectoral and regional audits to ensure that any horizontal issues are addressed. For this purpose, Office III maintains a "Register of negative findings and recommendations” of sectoral audits and obtains summary audit results from all regions for the Annual Report on the implementation of the MANCP. Auditors are required to highlight, in their reports, positive findings detected during audits, in addition to shortcomings. The sectoral Offices and Office III can thereby identify good practice which may then be included in guidance and other documents from co-ordination groups, discussed in working groups or reflected in training.

The Bulgarian Food Safety Agency has arrangements in place that allow the central level thematic Directorates to identify trends in the regions and to take corrective/preventive action where needed. Top management hold regular meetings with regional directors to discuss audit results.

The Irish Sea Fisheries Protection Agency requires its auditors to note best practice in their reports. The Technical Audit Review Group, which includes representatives from all ports and business units, reviews all audit results at their quarterly meetings, which enables the identification of possible system-wide weaknesses and strengths and, in the case of the former, these can be added to corrective action plans and the relevant managers are responsible for proposing appropriate measures to address such issues.

Within the French Directorate-General for Competition Policy, Consumer Affairs and Fraud Control, the ‘tool box’ available on the intranet includes examples of good practices, as well as practical guides and ‘how-to’ documents on performing various activities related to official controls, which allows dissemination of lessons learned from audits.

The Swedish National Food Agency considers the implications of audit findings in its annual review, which takes place as part of the preparation of an annual report. A statistician analyses data from the 60 to 70 audits which took place during the year in order to provide a stronger basis for overall conclusions. These conclusions are also included in the Annual Report on the operation of the MANCP.

### 2.5.5. Monitoring and review of the audit process

In general the audit bodies 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 bodies produced and annual report, in some cases this was predominantly an activity report and no review of the audit process, its strengths and weaknesses, was included. Nevertheless, some good examples were seen:

The Internal Audit Unit of the Belgian Federal Agency for the Safety of the Food Chain uses Key Performance Indicators (KPI) to monitor implementation of certain elements of the audit process, such as compliance with deadlines for issuing audit plans and drafting audit reports. In addition, they carried out a Satisfaction Survey of the auditees in 2015 which led to review and improvement of several aspects of the
audit process. Subsequently they decided to systematically request auditees to complete a satisfaction survey after each audit. **Systematic requests for auditee feedback** were also used by a number of other audit bodies met, including the Independent Internal Audit Service of the Croatian Ministry of Health, the audit body of the Hungarian National Food Chain Safety Office, and the Veterinary Internal Audit Unit of the Irish Department of Agriculture, Food and the Marine.

The Croatian Ministry of Finance Internal Auditors’ Manual requires all Croatian Independent Internal Audit Services to draw up an **annual report of internal audit activities**. The report should include a review of performed audits and of the programme actually implemented, key conclusions pertaining to the functioning of the control system and recommendations aimed at improving performance, activities aimed at implementing recommendations and information on recommendations not implemented and proposals for development of the internal audit. This report must be submitted to the head of the organisation and to the Ministry of Finance's Central Harmonisation Unit.

The Croatian Ministry of Finance Internal Auditors’ Manual also lays down requirements for **quality assurance and improvement programmes** for all Croatian Independent Internal Audit Services. A template is provided for such a programme. All Heads of these services must draw up a programme covering all aspects of the internal audit activity and its management, and including **periodic self-assessment** (the Internal Auditors’ Manual includes a questionnaire for use during periodic assessments), resulting in a report submitted to the Head of the service. This provides an opportunity for the audit service to review its own activity in depth at a regular interval.

Other audit bodies 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. In some cases, such as in France and Belgium, this took place in the context of **management reviews** held regularly as part of the **quality management system**. In addition, preparation of annual reports on internal audit activity for audit committees, senior management and/or for the Annual Report of the implementation of the MANCP provided many audit bodies with an opportunity to reflect on their own performance and identify areas and measures for improvement.

The Internal Audit Body of the Cypriot Department of Agriculture has procedures in place for continuous improvement as required by ISO 9001:2008, and in particular performs, under derogation by the certification body, **internal audits on their own audit arrangements**, which provides for a critical review of the audit process.

### 3. Follow-up of audit recommendations

Ultimately, the impact of the NAS audit arrangements is determined by the effectiveness and appropriateness of the corrective actions implemented in response to audit findings/recommendations. A number of useful practices in relation to follow-up of audit recommendations were noted:
Many audit bodies had procedures in place to **increase pressure on auditees to address audit recommendations**, where necessary. These procedures usually involved drawing the attention of senior management to the outstanding issues. Examples were seen, in serious cases, in Bulgaria where such measures led to disciplinary proceedings and in Sweden, where legal proceedings were taken against a small number of municipalities.

In Latvia, the Food and Veterinary Service developed a **procedure to be used to resolve disagreement between auditors and auditees** in relation to corrective action plans: in such cases a third party opinion from experts at the organisation's central level provides the final judgement.

Some audit bodies, including the Internal Audit Unit of the Belgian Federal Agency for the Safety of the Food Chain, the Independent Internal Audit Service of the Croatian Ministry of Agriculture and the Inspectorate-General of Services in Directorate-General for Competition Policy, Consumer Affairs and Fraud Control in France, carried out **specific audits targeted at checking progress with implementing corrective action plans**. In addition, most audit bodies had the possibility to carry out sector-specific follow-up audits where this was judged necessary.

In cases where organisations operated accredited **quality management systems**, follow-up of audit recommendations was often integrated into subsequent quality audits and other quality management activities.

A number of Competent Authorities used **root cause analysis** in the context of development of corrective action plans, 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. To help address this challenge:

- 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; and

- The Internal Audit Unit of the Belgian Federal Agency for the Safety of the Food Chain had a **specific procedure when serious non-compliance was found**: the auditor and relevant audited services met prior to the closing meeting and completed the root cause analysis together and agreed the necessary corrective actions.

- Within the Danish Veterinary and Food Administration, **root-cause analysis and identification of the most appropriate corrective action is assigned to a team** of officials who come from different parts of the department, thus providing various perspectives on the problem and ensuring that corrective action has a sustainable effect. This interdisciplinary team approach was found to lead to strong ownership and commitment of the auditees and sustainable improvements in the control systems.

- Similarly, 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.

4. Transparency

It was noted that in almost all cases good transparency was achieved between the audit bodies and the services audited ('internal transparency'). 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. The degree to which audit bodies 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.

A number of useful practices in relation to transparency were noted:

Regarding internal transparency:

- A number of audit bodies reported that they provided training on the internal audit process to officials within their organisations, in order to promote better understanding of, and co-operation with the internal audit body.

- In addition to providing such training, the Portuguese Directorate-General for Food and Veterinary Matters also provided the audited services with a “Good auditing practices manual for auditees”.

Regarding external transparency:

Many MS publish their MANCP and the Annual reports on the implementation of those plans. These documents are required to contain information on audit arrangements, although the level of detail varied considerably. The material published in Annual Reports by Italy and Hungary was notably detailed and informative.

Some audit bodies publish annual reports on audits and results:

- In Belgium, the FASFC Audit Committee publishes an Annual Report on the FASFC website. This report gives details of mission and objectives of the internal audit body, the actors in the audit process, the organisation and functioning of the Internal Audit Unit, the activities during the year, the follow-up of audit results and the programme of audits undertaken in the year.

- In Portugal, the Directorate-General for Food and Veterinary Matters and the
General Inspection for Agriculture, Sea, Environment and Spatial Planning Ministry make publicly available audit-related information (audit procedures, audit programme, summaries of audit reports) through their webpages and in addition the former publishes a bi-annual review of audit reports.

- The Bulgarian Food Safety Agency publishes on its website its multi-annual audit programme, its risk methodology, its audit procedure including annexes, and its annual reporting on audit activities in the context of the annual report on the implementation of the MANCP.

- In Luxembourg, the Organisation for the Safety and Quality of the Food Chain publishes a summary of audit activities in its activity report which is published on the websites of the Ministry of Health and the Ministry of Agriculture, Viticulture and Consumer Protection.

- In Cyprus, the Internal Audit Body of the Department of Agriculture's summary of the annual report is published on the department's website and the Internal Audit Service of the Public Health Service prepares an annual activity report including a review of the audit findings and conclusions. The report is published on their website and is publicly available.

The Danish Veterinary and Food Administration, in addition to publishing their audit charter and audit programme on the internet and information on internal audits in the MANCP, annually presents their audit programme and results to the strategic stakeholder committee established to ensure close dialogue with stakeholders and provide a forum for discussing topics of strategic importance. The charter for the strategic stakeholder committee specifically mentions that results of internal and external audits will be submitted to the committee for discussion.

The Audit and Investigations Division of the Food Safety Authority of Ireland publishes its audit reports on its own website. Similarly the Ministry of Health in Italy publishes all systems audit reports and executive summaries of sectoral audit reports.
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