In response to information provided by the competent authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.
Executive Summary

This report describes the outcome of an audit carried out by the European Commission’s Directorate General for Health and Food Safety in the Czech Republic from 15 to 19 May 2017. The objective of the audit was to evaluate the system 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.

The scope of the audit covered the procedures put in place to implement Article 4(6) by the State Veterinary Administration (SVA), Czech Agriculture and Food Inspection Authority (CAFIA) and Central Institute for Supervising and Testing in Agriculture (CISTA), the central competent authorities (CCAs) responsible for the majority of the official controls falling under the scope of Regulation (EC) No 882/2004.

Overall, the report concludes that all CCAs covered by the scope of the audit have put audit arrangements in place aimed at addressing the requirements of International Standards Organisation (ISO) standards on quality management systems and also at taking into account Article 4(6) of Regulation (EC) No 882/2004. The continuous improvement approach is embedded in the audit activities which form part of the key informational/measurement tool of the quality management systems.

The organisational structures of all CCAs ensure independence of the audit process. All CCAs demonstrated that audit related staff is competent and kept up to date for their audit-related duties.

Adequate arrangements have been put in place to ensure that compliance with planned arrangements is audited in a systematic manner. Suitability of arrangements is regularly addressed in the audits carried out by all CCAs. The effective implementation of planned arrangements is addressed to a lesser extent, in a rather sporadic manner, by all CCAs. The impact of the audit activities is evident in all CCAs, specifically in the case of CAFIA and to a lesser extent as regards SVA and CISTA, due to the limited number of non-compliances identified in recent years.

All CCAs have put in place arrangements to ensure internal transparency and some limited arrangements for external transparency.

The audit results contribute to the improvement of the official controls systems but their impact is reduced by:

- Lack of risk-based audit programmes (contrary to the objectives of the Regulation (EC) No 882/2004). The relevant process is not well documented/transparent, and it lacks clear risk-based prioritisation. Therefore, it results in audit programmes that do not achieve an appropriate risk-based coverage of relevant official control activities. Moreover lack of coordination of different authorities’ audit programmes is also a factor that influences the adequacy of coverage of the relevant areas in which more than one of the CCAs are competent.
- Inadequate arrangements for independent scrutiny of the audit process (contrary to Article
Concerning audit reporting:

- audit objectives / criteria, the activities actually assessed and the outcome of that assessment are not always described in a clear manner,
- the basis and methodology for certain findings/conclusions in relation to assessment of compliance, effectiveness of official controls, and the suitability of planned arrangements are not explicitly stated.

There are arrangements in place to ensure that audit results are reviewed to identify potentially system-wide issues and opportunities for improvement of official control systems (and this is one of the strong points of the audit systems). As regards identification and dissemination of good practices in the official controls this is done on an ad hoc basis, which means that there is no formalised process for doing this systematically. Follow-up arrangements are sufficiently effective for the deficiencies that require actions.

The report contains recommendations to the CCAs to address the shortcomings identified.
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<td>Better Training for Safer Food</td>
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<td>CA</td>
<td>Competent authority/authorities</td>
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<td>ISCVBM</td>
<td>Institute for State Control of Veterinary Biologicals and Medicines</td>
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<td>International Organisation for Standardisation</td>
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<td>Multi-Annual National Control Plan</td>
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<td>NAS Network</td>
<td>Network of Member States National Experts on National Audit Systems</td>
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<td>PPP</td>
<td>Plant protection products</td>
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<td>RASFF</td>
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1 INTRODUCTION

This audit took place in the Czech Republic from 15 to 19 May 2017. The audit team comprised two auditors from the European Commission’s Directorate General for Health and Food Safety (DG SANTE) and one national expert from another Member State.

The opening meeting was held on 15 May with the central competent authorities (CCAs) covered by the scope of the audit: Ministry of Agriculture (MA), Ministry of Health (MH), State Veterinary Administration (SVA), Czech Agriculture and Food Inspection Authority (CAFIA), Central Institute for Supervising and Testing in Agriculture (CISTA), Institute for State Control of Veterinary Biologicals and Medicines (ISCVBM) and the Czech Breeding Inspectorate (CBI). At this meeting the audit team confirmed the objectives of, and itinerary for, the audit, and obtained additional information required for its satisfactory completion.

2 OBJECTIVES AND SCOPE

The objective of the audit was to evaluate the system(s) 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\(^1\) (hereafter: Regulation (EC) No 882/2004).

The scope of the audit was limited to the procedures put in place to implement Article 4(6) by the CCAs responsible for the majority of the official controls falling under the Regulation (EC) No 882/2004, i.e. SVA, CAFIA and CISTA.

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

> 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 audit team took into account Commission Decision 2006/677/EC setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 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\(^2\) (hereafter: Commission Decision 2006/677/EC). Where relevant, reference was made to

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Network Reference Documents produced by the 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.

3 LEGAL BASIS

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

Full EU legal references are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the latest amended version.

4 BACKGROUND

4.1 PREVIOUS DG SANTE AUDITS

Detailed information on the structure and organisation of the Czech competent authorities can be found in the country profile for Czech Republic at:

http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=CZ

DG SANTE has carried out numerous inspections and audits in the Czech Republic, the reports of which can be found at:

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

Whilst the topic of the current audit has not been the specific objective of any previous audit, the subject has been considered within the scope of numerous sectoral audits carried out since 2006. At the time of writing, there were no open recommendations to the Czech Republic in relation to the application of Article 4(6).

4.2 CONTEXT: ARTICLE 4(6) OF REGULATION (EC) NO 882/2004

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.

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 compliance with planned arrangements, effective implementation of arrangements and their suitability to achieve objectives are provided. Guidance is also provided in relation to audit reporting, follow-up of the audit outcome, audit review and dissemination of best practice, resources 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”.

The NAS Network is a network of officials (auditors) from Member States’ CAs, 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 this audit in the Czech Republic 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;

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 (Multi-Annual National Control Plan (MANCP), business-, operational-, control-, monitoring-plan etc.) with the purpose of giving effect to legal requirements.
- Policies, strategies, procedures, guidelines.

To evaluate:

- 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).”

4.3 METHODOLOGY

The evaluation process of the current DG SANTE audit consisted of:

- an initial desk study phase in which the relevant information already available in DG SANTE was collated and analysed. This included the Czech MANCP and associated Annual Reports, the country profile for Czech Republic and sectoral audit reports;
- examination of certain documentation provided by SVA, CAFIA and CISTA prior to the audit; and
- meetings with the service responsible for carrying out audits under Article 4(6).

The DG SANTE audit team 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 team 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 audit team 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; and
• How and to what extent transparency is ensured.

In addition, the audit team gathered information on particular challenges faced by the CAs when implementing Article 4(6).

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

5.1.1 Legal requirements

Article 4(6) of Regulation (EC) No 882/2004 states, that “Competent authorities shall carry out internal audits or may have external audits carried out…….”

Article 2(6) of the same Regulation defines “audit” as “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.”

5.1.2 Findings

5.1.2.1 Responsibility for performance of official controls

1. For full details of the division of all relevant competences between all involved competent authorities, see the country profile for Czech Republic at http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=CZ

2. MA and MH are the CCAs for co-ordination of the functions of the authorities related to food safety. MA plays the main role in the implementation of official controls in the agriculture sector as regards food and feed safety, animal health and welfare and plant health and adopts veterinary and phytosanitary legislation and legislation associated with the production and labelling of foodstuffs.

3. MH is the CCA responsible for the policy and adopting other legislation for food. These include food for special dietary use, pesticide residues and food contact materials.

4. This audit covered the CCAs responsible for the majority of the official controls falling under the Regulation (EC) No 882/2004, i.e. SVA, CAFIA and CISTA:

   a. SVA is the CCA responsible for implementing official controls related to animal health, foodstuffs of animal origin, import controls of live animals and products of animal origin, transmissible spongiform encephalopathies (TSE), animal by-products (ABP), residues of veterinary medicines, and animal welfare.

   b. CAFIA is the CCA responsible for implementing official controls; on foodstuffs of plant origin. In addition it carries out controls on foodstuffs of animal origin in the catering and retail sectors with the exception of retail sections in premises
where raw materials of animal origin are treated (e.g. meat, milk, fish, poultry or eggs) which is under the responsibility of SVA. Since 2015 it also controls with the MH, operators working in the public catering sector.

c. CISTA is the CCA responsible for implementing official controls; along the entire feed chain and also the marketing and the use of plant protection products (PPP). In addition it carries out official controls related to import and movement of plant and plant products.

5.1.2.2 Responsibility for audits of official controls

5. SVA, CAFIA and CISTA have put in place arrangements for implementation of auditing in line with Article 4(6) of Regulation (EC) No 882/2004 within their organisations. Those arrangements include audits on the set up of the systems for official controls and the performance of the official controls in the context of Regulation (EC) No 882/2004. In addition, as all three CCAs have ISO 9001 certified quality management systems and under the certification scheme are carrying out audits of their quality management system.

6. There are no arrangements in place for the co-ordination to ensure a seamless audit process across the relevant competent authorities. The audit team noted two cases related to the lack of co-ordination:

a. CAFIA, as national contact point for Rapid Alert System for Food and Feed (RASFF) planned an audit on RASFF related activities. The CCAs did not consider the relevance of such an audit for SVA, although the scope of the official controls falling within SVA’s responsibility entail significant RASFF related activities.

b. Whilst both MH and CAFIA are CCAs responsible for official controls at the public catering sector, there is no co-ordination of audit programmes covering this area of control.

Conclusions

7. The CCAs have established audit systems which are intended to achieve the objectives of Article 4(6) of Regulation (EC) No 882/2004. Responsibilities for carrying out audits on official controls have been clearly allocated, ensuring the proper functioning of the audit systems but the lack of co-ordination of audit programmes negatively influences the adequate coverage of the relevant areas in which more than one of the CCAs are competent.
5.2 AUDIT ARRANGEMENTS

5.2.1 Independence

5.2.1.1 Legal requirements

Article 2(6) of Regulation (EC) No 882/2004 defines “audit” as “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 5.3 of the Annex of Decision 2006/677/EC further guidance is provided to Member States on ‘independence’, including:

“All 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 provides additional guidance to Member States on threats to independence and mitigating measures.

5.2.1.2 Findings

8. The audit instructions of all CCAs provide the basis for and a clear reference to the independence of the audit function and of the auditors. For all three CCAs the organisational structure and the positioning of their audit function, directly appointed by and reporting to top management, ensure the independence of the audit processes.

9. The audit team noted that the CCAs have not put in place sufficiently formalised arrangements to cover all threats to independence of audit personnel including the technical experts should a need to use them in an audit arises. There are no clearly set criteria and mitigating measures to ensure that all threats to the independence of the audit process/auditors are considered (e.g. familiarity risk, self-interest, lack of competence)3.

10. The CCAs commented that although there are no detailed references on this matter in the audit procedures, they pay particular attention when they select auditors/experts for

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3 In their response to the draft report SVA indicated the actions planned/implemented to address this deficiency. In the context of updating the SVA audit guideline there is an update of the internal auditor and technical expert code of ethics as well as the declaration of the absence of conflict of interest.
an audit in order to ensure that those selected have a certain degree of independence from the audited authority. In addition, as a rule experts are used in audits from other regions/areas of activities to the ones they are working in.

**Conclusions**

11. In general, the arrangements put in place by the CCAs ensure the independence of the audit function and process and to a certain degree that of individual auditors, to safeguard the credibility and reliability of audit results.

5.2.2 Independent scrutiny

5.2.2.1 Legal requirements

Article 4(6) of Regulation (EC) No 882/2004 requires that the audits “shall be subject to independent scrutiny”.

In section 5.4 of the Annex of 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.”

5.2.2.2 Findings

12. The CCAs described the cases of external assessments (annual surveillance audits) performed by the ISO certification bodies in the context of the certification schemes for ISO 9001:2015 standard. The audit team noted that those assessments cover the internal audit functions within the context of the relevant requirements of the ISO standard.

13. There is no particular focus (in the external assessment done to date) 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 (e.g. no assessment of the risk-based planning and of the independence of the audit process and auditors, no opinion on effectiveness of the audit process etc). The audit team considered that the CCAs have inadequate arrangements in place to fulfil the requirement of Article 4(6) of Regulation (EC) No 882/2004 as regards the independent scrutiny of the audit process.
Conclusions

14. All CCAs have arrangements in place to ensure independent scrutiny of their quality management systems through the ISO certification external audits that they receive. However, those arrangements do not sufficiently cover the audit processes contrary to the requirements of Article 4(6) of Regulation (EC) No 882/2004.

5.2.3 Auditor competence

5.2.3.1 Legal requirements

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.”

5.2.3.2 Findings

15. Within the SVA, Department of Internal Audit and Control, there are currently four auditors. These are full time officials in the department of internal audit and control and they dedicate approximately 50% of their time to internal audit activities on official
controls in the context of Regulation (EC) No 882/2004. The CCA stated that two veterinarians were recently recruited in order to increase the number of auditors and to bring the essential veterinary expertise to the audit function as in the previous years no veterinarians were included in this department. The audit team examined audit reports from the year 2016 and observed that, in audits related to official controls on animal health, there was no veterinary expertise for the coverage of technical matters. Those audits did not identify non-compliances.

16. In SVA the new recruits attend training on internal auditing and quality management. This training is a two day session provided by an ISO certification body. The new auditors attend audits as second auditors for a minimum period of 12 months after which they are assessed (by the audit unit manager) in a specialised exam for audit skills and also by interview in which their soft skills are verified. SVA stated that all staff including the auditors are assessed once per year to verify their competence and that they are kept up to date for their areas of working by attending appropriate training. This includes attendance of Better Training for Safer Food (BTSF) sessions on auditing provided by the European Commission.

17. CAFIA carries out internal audits using its own staff (25 internal auditors on a part time basis) trained on auditing by a certification body. CAFIA chooses officials that become auditors from different organisational levels, to guarantee the necessary expertise and required independence. According to the internal audit procedure an officials may be recruited as internal auditors if they have worked at least one year in the organisation and have a positive staff assessment record. The auditors need to possess certain personal attributes (e.g. integrity, responsiveness), general knowledge and skills, audit knowledge and skills, technical knowledge (processes and products for a given area) and sufficient work experience that demonstrates the achievement of good results at work. CAFIA prepares an annual training plan (courses on audit techniques, communication skills for auditors etc) to keep auditors up to date and to maintain their competences in internal auditing. Auditors also attend BTSF sessions on auditing as well as other topics.

18. The CISTA audit unit has five full time auditors. The essential requirements for recruitment as an auditor are to be a public servant and have an academic background at higher education level (preferably focused on science, economics, agriculture and forestry). In addition the official should possess a driving licence and is required to have good communication and time management skills. To keep the audit staff up to date on the required areas of expertise CISTA provides a training scheme for newcomers as well as experienced staff. The newcomers attend an adaptation programme (formalised by internal CISTA procedures): on legal acts relevant for CISTA activities, internal CISTA acts and procedures, a mentoring programme not formalised but kept in practice – it takes approximately 6 – 8 months and finishes with newcomer leading an audit under the senior auditor supervision. As regards the continuous training for auditors, this includes BTSF trainings (Hazard analysis and critical control points, Auditing), E-learning modules provided by the European Commission, trainings and conferences.
organised either by CISTA, other institutions or a private sector’s organisations (certification bodies’ training on ISO 19011 standard).

19. The audit team noted that the internal auditors met during the audit demonstrated a sufficient level of audit expertise as regards knowledge of audit principles and techniques.

20. The audit team noted that whilst there is a set of activities ensuring the systematic learning within the audit units, there is no dissemination of the information (guidance documents etc) that is produced at the NAS network. This means that the CCAs that do not receive the relevant documentation miss the opportunity to receive technical guidance on audit related aspects to shape their audit strategy and methodology with the one agreed among the EU Member States.

21. Audit instructions of all three CCAs describe the possibility of using additional technical expertise when it is needed. SVA has made limited use of technical expertise (4 audits out of 23 in 2016) due to difficulties in sourcing staff as most officials are too busy to be involved in audits. CAFIA has used experts in their audit activities and CISTA officials stated that they have used experts on a sporadic basis.

Conclusions

22. All three CCAs have put in place effective arrangements to ensure that auditors have sufficient competence to perform their duties and that they can maintain and further develop their auditing competence.

23. Additional technical expertise can be used in an appropriate manner when needed. The limited sourcing of external expertise (in the case of SVA) reduces the ability of the audit function to identify and properly assess technical matters and underlying causes for existing deficiencies in the performance of the official controls, especially in particularly technical areas of official controls.

5.2.4 Development of the programme of audits

5.2.4.1 Legal requirements

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”.

In their response to the draft report SVA noted that they have updated the list of technical experts for the performance of audits on the systems of official controls to increase the frequency of the use of technical experts. The inclusion of technical experts in the list is voluntary; with their consent to be included in the list of veterinarians – technical experts, they have expressed their consent and willingness to participate in the performance of the audits.
The definition laid down in Article 2(6) specifies, *inter alia*, that audits should be 'systematic'.

In section 5.1 of the Annex of 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.”

5.2.4.2 Findings

24. SVA has an audit programme that covers a five year period which is broken down into annual audit programmes. In general, each regional administrative unit is audited once every three years. SVA carries out audits in line with the audit plan which is divided into basic fields of activities as follows:
   a. animal health and welfare,
   b. hygiene and safety of food of animal origin,
   c. imports and exports of animals and products of animal origin and
   d. veterinary drugs.

The main areas are split into sub-areas; for example animal health and welfare area consists of animal health, identification and movement, TSE and animal welfare. A similar approach applies to the other main areas which are split from between two to four subareas. The 5-year audit programme (2017-2021) aims at covering all sub-areas at a specified frequency (at least once) and in different regional units (predetermined). In addition to professional areas, audits also address horizontal processes (e.g. organisation and management, human resources management, information transfer processes). Audit activities include on annual basis the assessment of the quality management system requirements as per ISO 9001 standard.

25. SVA sets audit priorities based on management proposals, legal requirements, results of analyses and risk assessments in the area of official controls and the findings and results
of previous audits. Each audit programme may be modified in the course of operational management authority on the basis of emerging needs.

26. The audit team noted that, when developing the audit programme, SVA has not properly defined all relevant audit areas (the audit areas are not sufficiently detailed e.g. animal health is determined as an audit area although this could be further broken down to different animal species, activities, diseases etc.) and the audit programme development process is not well-documented as regards risk-based prioritisation (it is not evident whether all relevant areas were considered and on which basis decision on selection of audit topics was made).

27. In 2017, SVA initiated a tool for the definition of the audit areas, their risk grading and subsequently the selection of audits based on risk prioritisation. This is under development in order to produce a map of all the relevant activities of official controls and a decision making tool for the appropriate targeting of audits and the effective coverage of all relevant areas within a reasonable period of time.

28. CAFIA management approves the programme of internal audits for a given period (normally from September of current year to June of next year). The programme is drafted after the review of the quality management system by management. Internal audits are carried out throughout the year at all CAFIA inspectorates. The vast majority of internal audits are focused on processes of official controls and audits of the quality management system according to the requirements of the ISO 9001 standard. The main audited areas are: foodstuffs of plant origin (production to marketing and imports), foodstuffs of animal origin (retail sale of packed food) and RASFF related activities. The areas covered are food safety, food hygiene, food adulteration, E-commerce and advertisement. Apart from the technical areas, the audits address horizontal processes (e.g. organization and management, human resources management, consistency in the performance of official controls).

29. The audit areas in CAFIA audit system are expanded since 2011, and the annual audit programme indicates an addition of new audit topics. The topics include microbiological sampling, traceability, genetically modified organisms in food, risk-based planning of official controls etc. The audit team noted that there is no evidence on how new topics are determined and there is no overview of the areas that need to be considered in the audit programme. In addition, there is no evidence that the development of the audit programme has considered all relevant areas, and it is not evident how this results in risk based prioritisation and effective coverage of all areas in a reasonable timeframe.

30. According to the audit directive of CISTA the audit programme is prepared based on: risk analysis and evaluation in audited areas, proposals by the Director of the Institute, section directors, findings and measures of internal and external audits carried out, organizational changes, the current state of professional control activity. The Director of the Institute may, if necessary, decide to include an audit that was not included in the audit programme.
31. The main audited processes in CISTA are: official controls of feed, fertilizers and PPP (check of administrative procedures, process of official controls at regions), monitoring of soil, controls of crop protection, monitoring harmful organisms, variety and seed testing, areas of plant health care, methodology, quality management system, economical procedures. Audit teams carry out about 15 internal audits per year, with between two and four audits focused on official controls on feed.

32. The audit team noted that CISTA has not adequately defined the areas that need to be covered by the audit activities. In addition although the planned arrangements refer to risk based planning of audit programmes, CISTA could not demonstrate that audit programmes resulted from a risk-based prioritisation.

33. The audit team noted that, in all three CCAs, the audit arrangements cover the audited services at central level by either including them in the audit plan or by addressing deficiencies to them which are identified during the audits that mostly relate to planned arrangements and organisations of official controls, normally the responsibility of the CCA.

**Conclusions**

34. All three CCAs have developed and implemented processes for establishing annual and multiannual audit programmes. These processes are not adequately documented thus the CCAs cannot demonstrate that all relevant areas have been considered, an adequate coverage in a reasonable timeframe has been achieved and that audit programmes result from a risk-based prioritisation.

35. The audit programmes cover all relevant levels of competent authorities’ hierarchies (including central level) and this means that the audit systems can ensure that the objectives of Regulation (EC) No 882/2004 are met in this respect.

5.2.5 **Implementation of the audit process**

5.2.5.1 **Legal requirements**

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 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."

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.”
5.2.5.2 Findings

5.2.5.2.1 Documented Procedures

36. All three CCAs have implemented a Quality Management System which is certified to the ISO 9001:2015 standard. The scope of the certification includes the organisation and delivery of the official controls. Audit activities are organised in the context of the ISO standard requirements for internal auditing but have also embedded the requirements of Regulation (EC) No 882/2004. The documented systems include a set of instructions, checklists and forms (e.g. report templates, corrective action forms etc).

37. The audit team noted that only SVA audit arrangements formally refer to Decision 2006/677/EC but all CCAs include in their procedures part of the concepts developed in the Decision and this is also evident in the scope of their audit activities. The audit team noted that the audit systems are undergoing development as regards the consideration of the Decision and the relevant Network Reference Documents.

38. The audit team noted that the quality management systems of all CCAs form the basis of standardised and integrated activities across each organisation. This leads to audit functions that cover a wider scope of activities i.e official controls, ISO requirements, financial matters etc. in an efficient manner. All CCAs follow a process-based approach in auditing and this provides the basis for thorough assessments of the performance of the audited services against the set objectives for each process.

39. SVA audit directive lays down a comprehensive set of audit objectives that go beyond compliance with legislation and procedures. The objectives include the:
   a. The verification of compliance with EU and national legislation and planned arrangements of SVA,
   b. assessment of the effectiveness and suitability/appropriateness of arrangements and official controls (to be effective and functional),
   c. identification of opportunities for improvements and preventive measures.

40. CAFIA internal audit procedure lays down the objectives of the audit activities which are to monitor the processes in order to verify:
   a. their compliance with legislative requirements and planned arrangements,
   b. their effective implementation.

In addition audits should aim to identify opportunities for improvement and preventive measures that could enhance the performance of the processes.
41. CISTA audit objectives are described in the audit directive which refers to verification of:
   a. compliance with law, regulations and internal rules,
   b. suitability of official controls and specialized processes,
   c. effectiveness, efficiency and relevance of the set system,
   d. information for the improvement of the systems, and preventive measures.

42. According to their audit procedures, the CCAs are applying various techniques to auditing. This includes the use of pre-audit questionnaire, verification of the documented procedures and official control records, interviews, on site visits (at food business operators, retail etc.) and shadow inspections.

43. The audit team noted that whilst all CCAs refer to the assessment of suitability of planned arrangements and the verification of effective implementation of official controls no methodology is described in the audit procedures on how to address suitability/effectiveness concepts. None of the authorities had considered the guidance document on auditing effectiveness of the official control system adopted by the NAS Network in the development of their audit instructions. In addition there is no explicit description of the threats to independence and the respective mitigating measures (finding 9).

5.2.5.2.2 Compliance with planned arrangements

44. The audit team checked a sample of audit reports and confirmed that these mostly deal with compliance issues.

45. The audit team observed that the risk-based approach is built into audits. This means that the auditors aim at selecting areas/activities/elements of the official controls that may present significant risk and in addition in most audits there is a verification of the risk based nature of the official controls. The audit team noted that the risk-based approach in auditing is adequately applied in the audit activities despite not being described in detail in the audit procedures.

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

46. The CCAs regularly evaluate the suitability of arrangements for official controls. In some examples discussed, the assessment during the internal audit went beyond compliance and aimed at evaluating the appropriateness of the documented procedures. The audit team noted that, in the cases examined, the CCAs have adequately assessed significant matters related to the suitability of arrangements.

47. The audit team found that in several cases there are findings and recommendations related to the suitability of procedures and in general planned arrangements. In those cases the recommendations are not binding but are presented as suggestions for improvement and this allows the audited service the flexibility to assess the issue and decide whether an action plan needs to be prepared and provided to the audit unit.
48. The audit team assessed the audit procedures and a number of audit reports from all CCAs and found that verification of the effective implementation of the controls was occasionally included in the audit activities and there was insufficient information on the methodology used and on the results relating to the evaluation of effective implementation of the official controls. The CCAs commented on the difficulties of developing and applying a methodology to verify the effectiveness of the official controls.

49. CAFIA implements audits on food business operators to assess compliance of their systems with the legal requirements. Those audits address recommendations to the audited companies and do not examine official controls at those operators which means that the CCA misses the opportunity to verify the effective implementation of the official controls and enhance their performance.

5.2.5.2.4 Audit reporting

50. The CCAs have documented procedures for audit reporting including report templates. The report approval procedure includes a provision for the auditees’ management to comment on the findings. There are also instructions for the subsequent distribution of the report.

51. The audit team noted that based on the files assessed, the planned reporting arrangements are adequately followed and support the effective implementation of the audit process.

52. The audit team highlighted some cases of audit reports (of all CCAs)\(^5\) with deficiencies in coherence, consistency, and clarity:

a. listed audit criteria that were not assessed against,

b. stated audit objectives that were not concluded upon,

c. conclusions made without solid audit evidence (e.g. “the system complies with internal rules/ Regulation (EC) No 882/2004”, instead of making explicit reference to the sections assessed among a wide range of legal requirements,

d. findings that do not always cite specific evidence to demonstrate that certain activities were assessed even though a reference is made to them. This point related to the assessment of compliance but mostly to the suitability of the planned arrangements and the effectiveness of the official controls.

The audit team noted that a particular risk arises where some of the listed audit criteria are not actually addressed by the findings of the audit report but, nevertheless, the conclusions provide a judgement on compliance with the audit criteria.

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\(^5\) In their response to the draft report SVA noted that in order to improve the coherence, consistency and clarity of audit reports they have updated the audit report form in the context of the update of the audit guideline.
5.2.5.2.5 Review of audit conclusions and dissemination of best practice

53. The audit team noted that the CCAs have put in place arrangements to review the audit results to identify potentially system-wide issues and opportunities for improvement of official control systems. These arrangements do not systematically cover the identification and dissemination of good practices in the performance of the official controls.

Conclusions

54. In general, audit arrangements and their implementation are well documented and ensure that all necessary activities are carried out in a consistent and transparent manner.

55. Adequate arrangements have been put in place to ensure that compliance with planned arrangements is audited in a systematic manner. Suitability of planned arrangements is regularly addressed in the audits carried out by all CCAs. The effective implementation of planned arrangements is addressed to a lesser extent, in a rather sporadic manner, by all CCAs.

56. Audit reporting procedures aim at ensuring consistent reporting of relevant audit results, even if there is, in certain cases, some scope for improvement in clarity in relation to the activities actually assessed and the outcome of that assessment, and/or the basis for certain findings/conclusions in relation to effectiveness of official controls.

57. Arrangements have been put in place to ensure that audit results are reviewed to identify potential system-wide issues and opportunities for improvement but these do not include adequate arrangements to ensure that good practices are identified and disseminated.

5.2.6 Follow-up of audit recommendations

5.2.6.1 Legal requirements

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 Decision 2006/677/EC further guidance is provided to Member States on ‘Independence’, in relation to 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 provides guidance on follow-up of audit outcome:
“Where appropriate, an action plan should be drawn up and delivered by the auditee. It should propose time-bound corrective and preventive 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”

5.2.6.2 Findings

58. The audit team noted the following:

a. SVA arrangements require that the audited services take action on major non-compliances identified during the audits and may take action or not as regards minor non-compliances and recommendations for improvement.

b. CAFIA arrangements require that the audited services take action on non-compliances and comments (deficiencies of minor significance) and may take action or not as regards recommendations for improvement.

c. CISTA arrangements require that the audited services take action on non-compliances and findings (minor non-compliances) and may take action or not as regards recommendations for improvement.

59. The audit team noted that the deficiencies in the reporting style (finding 52) combined with the audit arrangements (method of categorising audit outcomes to determine follow-up - finding 58) makes it possible that an identified non-compliance may lead to a recommendation for improvement. The possibility that such a deficiency can end up not being addressed by the audited service is reduced by the fact that management has a thorough view of audit activities and reviews the results of all audits in the context of management meetings and the management review process (finding 61).

60. The CCAs have put in place adequate arrangements for the follow-up of implementation of corrective actions taken in response to audit findings and recommendations.
61. All CCAs have arrangements in place to bring the results of audits to the attention of top management and this provides an additional means of ensuring the improvement of the audited systems at national level. In the context of the management review of the quality management system results of all audits are systematically brought to the attention of management. This practice supports the continuous improvement approach of the management systems and, in several cases, has ensured the initiation of corrective/preventive actions on matters that according to the arrangements (finding 59) there was no obligation for the audited services to act upon.

62. The audit arrangements include formal close-out procedures that are described in the audit procedures.

63. If deemed necessary, follow-up audit and verification of effectiveness of corrective actions are performed and in addition all CCAs have in place periodic reviews to assess progress in the achievement of quality objectives and to assess the performance of the quality management system (which includes regular input of audit results).

64. The audit team noted that with the exception of one case of a minor non-compliance that was not resolved after an SVA audit, in all cases in the last three years all non-compliances have been addressed in SVA and CAFIA. In addition, several recommendations made for improvement were addressed either via the follow-up process or via the decision of management in all three CCAs. The impact of the audit activities in CAFIA was significant as numerous deficiencies were dealt with in a satisfactory manner. The impact of CISTA and SVA audit functions was limited as in the last three years CISTA audits had not identified non-compliances (in an average of two to four audits per year) and SVA audits had identified three minor non-compliances (in an average of 20 audits per year).

Conclusions

65. All CCAs had put in place appropriate procedures to ensure that corrective actions were taken in response to audit findings, thereby ensuring that audit results were acted upon and had an impact on ensuring the quality of official controls.

66. The use of clearly defined procedures to inform top management about the audit results helped to ensure that the audit results are enhancing improvement in the performance of official controls.

67. The impact of the audit activities is evident in all CCAs, particularly in the case of CAFIA but to a lesser extent as regards SVA and CISTA, due to the limited number of non-compliances identified in recent years.
5.2.7 Transparency

5.2.7.1 Legal requirements

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

Section 5.2 of the Annex of Commission decision 2006/677 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.”

5.2.7.2 Findings

68. All audit systems have arrangements in place to ensure transparency of the audit process within the CCAs. All staff of each CCA, involved in the official controls, have access through their respective intranets, to the audit instructions, the audit programme, the plan for each audit and the final reports including the action plan where applicable.

69. In all CCAs, the audited services have active involvement in the preparation of the audit programme and the opportunity to comment on the draft audit report.

70. All CCAs make available audit related information (e.g. audit reports) at the request of the external stakeholders, including the public. The authorities publish some information related to their audit activities in the annual report in the context of the MANCP in their web pages. These reports include some information on the audit activities (mainly description of the areas covered and their results in a rather general form (descriptive statistics). No other systematic arrangement to provide assurance to the external stakeholders is in place.
Conclusions

71. Appropriate, arrangements are in place to achieve transparency of audit procedures, results and follow-up within each of the CCAs, thereby ensuring the auditees can have a clear understanding of the audit process and its outputs and that knowledge of audit activities and results can be used throughout the organisations.

72. The limited transparency regarding audit activity to relevant stakeholders means there is a missed opportunity to provide assurance to all external stakeholders about the effectiveness of the audit functions in ensuring the quality of official controls.

5.3 Challenges reported by the Competent Authorities

73. When asked about the particular challenges faced when implementing Article 4(6), the CCAs highlighted the following issues:

   a. SVA commented on the limited availability of human resources (number of auditors) combined with the wide range of tasks that are assigned to the audit function (e.g. active involvement on anti-corruption scheme). In addition they discussed the difficulties in sourcing technical experts and keeping auditors up to date in order to have adequate level of competence in the audit activities.

   b. CAFIA commented on the time restraints posed for auditors (requirement to maintain comprehensive set of audit-related documentation, obligation to deal with often numerous comments made by the auditees on the draft report, difficulties in scheduling audits at suitable dates) as they are involved in audit activities on a part time basis (all auditors are official assigned in various posts within CAFIA as inspectors, etc.).

   c. CISTA commented on the difficulties in the preparation and delivery of the audit programme because of different topics falling within the responsibility of the audit function apart from audits on official controls (e.g. financial audits). In addition they commented on the time restraints related to auditing (time length of audit cycle), the difficulties in keeping auditors up to date on technical matters and on cases in which the auditees do not appreciate the value-adding role of the audit activities.

6 Overall Conclusions

All CCAs covered by the scope of the audit have put audit arrangements in place aimed at addressing the requirements of International Standards Organisation (ISO) standards on quality management systems and also at taking into account Article 4(6) of Regulation (EC) No 882/2004. The continuous improvement approach is embedded in the audit activities which form part of the key informational/measurement tool of the quality management
The organisational structures of all CCAs ensure independence of the audit process. All CCAs demonstrated that audit related staff is competent and kept up to date for their audit-related duties.

Adequate arrangements have been put in place to ensure that compliance with planned arrangements is audited in a systematic manner. Suitability of arrangements is regularly addressed in the audits carried out by all CCAs. The effective implementation of planned arrangements is addressed to a lesser extent, in a rather sporadic manner, by all CCAs. The impact of the audit activities is evident in all CCAs, specifically in the case of CAFIA and to a lesser extent as regards SVA and CISTA, due to the limited number of non-compliances identified in recent years.

All CCAs have put in place arrangements to ensure internal transparency and some limited arrangements for external transparency.

The audit results contribute to the improvement of the official controls systems but their impact is reduced by:

Lack of risk-based audit programmes (contrary to the objectives of the Regulation (EC) No 882/2004). The relevant process is not well documented/transparent, and it lacks clear risk-based prioritisation. Therefore, it results in audit programmes that do not achieve an appropriate risk-based coverage of relevant official control activities. Moreover lack of coordination of different authorities’ audit programmes is also a factor that influences the adequacy of coverage of the relevant areas in which more than one of the CCAs are competent.

Inadequate arrangements for independent scrutiny of the audit process (contrary to Article 4(6) of Regulation (EC) No 882/2004).

Concerning audit reporting:

audit objectives / criteria, the activities actually assessed and the outcome of that assessment are not always described in a clear manner,

the basis and methodology for certain findings/conclusions in relation to assessment of compliance, effectiveness of official controls, and the suitability of planned arrangements are not explicitly stated.

There are arrangements in place to ensure that audit results are reviewed to identify potentially system-wide issues and opportunities for improvement of official control systems (and this is one of the strong points of the audit systems). As regards identification and dissemination of good practices in the official controls this is done on an ad hoc basis, which means that there is no formalised process for doing this systematically. Follow-up arrangements are sufficiently effective for the deficiencies that require actions.
7 CLOSING MEETING

A closing meeting was held with the CCAs on 19 May 2017. At this meeting the DG SANTE audit team presented their preliminary conclusions and confirmed the time limits for production of the report and the CCAs’ response.

The CCAs’ representatives generally accepted the conclusions presented by the audit team.

8 RECOMMENDATIONS

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<tr>
<td>1.</td>
<td>To strengthen the risk-based approach in the development of the audit programme and to ensure that the internal audits meet the objectives of Regulation (EC) No 882/2004 and cover all relevant areas of activity. &lt;br&gt;Recommendation based on conclusion: 34. &lt;br&gt;Associated findings: 26, 29 and 32.</td>
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<td>2.</td>
<td>To ensure that the arrangements for independent scrutiny fulfil the requirement of Article 4(6) and the objectives of Regulation (EC) No 882/2004. &lt;br&gt;Recommendation based on conclusion 14. &lt;br&gt;Associated findings: 12 and 13.</td>
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The competent authority's response to the recommendations can be found at:
## ANNEX 1 – LEGAL REFERENCES

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<th>Legal Reference</th>
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