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 Belgium from 18 to 22 January 2016. 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.

Overall the report concludes that, with the exception of auditing of animal welfare controls, where no arrangements are in place and there is currently no certainty about what audit arrangements will be put in place:

- There is a mature, effective audit system in place, covering the official controls falling under the scope of Regulation (EC) No. 882/2004, which can achieve the objectives of article 4(6) of that Regulation. This includes a systematic, risk-based prioritisation process for establishing the audit programme, suitable arrangements, including documented procedures that ensure the effective implementation of the audit plan and the competence of the staff involved in audit activities. In addition, monitoring and review of the audit process and its results supports its continuous improvement as well the dissemination of good practice in the performance of the official controls;

- The guidelines laid down in Commission Decision 2006/677/EC have been taken into account and arrangements in place ensure independence of the audit process as well as independent scrutiny of the audit system. In addition, the extensive arrangements in place to ensure transparency of the audit process can provide assurance on its performance to both internal and external stakeholders;

- The audit system has the ability to identify areas for its own improvement and to take action to make such improvements, in order to ensure that the auditing arrangements continue to develop to better “add value” to the organisation;

- Auditing arrangements in place can provide credible, reliable results and systematic follow-up arrangements can demonstrate the effectiveness of actions taken in the light of those results.

The report makes a recommendation, addressed to the relevant competent authorities, aimed at rectifying the identified shortcoming and further enhancing the control measures in place.
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<tr>
<td>CA</td>
<td>Competent Authority/Authorities</td>
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<td>CCA</td>
<td>Central Competent Authority</td>
</tr>
<tr>
<td>CEO</td>
<td>Chief Executive Officer</td>
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<tr>
<td>DG</td>
<td>Directorate General</td>
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<tr>
<td>DG CONT</td>
<td>DG Control of the FASFC</td>
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<td>DG LAB</td>
<td>DG for Laboratories of the FASFC</td>
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<td>DG SANTE</td>
<td>European Commission Directorate General for Health and Food Safety</td>
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<tr>
<td>EMAS</td>
<td>The Eco-Management and Audit Scheme (A voluntary environmental management instrument, which was developed in 1993 by the European Commission)</td>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>FAC</td>
<td>The Audit Committee of the Federal Public Administration</td>
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<td>FASFC</td>
<td>Federal Agency for the Safety of the Food Chain <em>(Agence Fédérale pour la Sécurité de la Chaîne Alimentaire/Federaal Agentschap voor de veiligheid van de voedselketen)</em></td>
</tr>
<tr>
<td>FASFC-AC</td>
<td>FASFC’s Audit Committee</td>
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<td>FPS-HSFCE</td>
<td>Federal Public Service for Health, Safety of the Food Chain and Environment</td>
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<td>FVO</td>
<td>Food and Veterinary Office <em>(Directorate F – Health and Food Audits and Analysis - of DG SANTE, with effect from 1 February 2016)</em></td>
</tr>
<tr>
<td>IAQPMS</td>
<td>Internal Audit, Quality, Prevention and Mediation Service (of FASFC) <em>(Service Audit interne, Qualité, Prévention et Service de médiation Dienst Interne audit, Kwaliteit, Preventie en Ombudsdienst)</em></td>
</tr>
<tr>
<td>IAU</td>
<td>Internal Audit Unit (of the IAQPMS) <em>(Cellule Audit interne/ Cel Interne audit)</em></td>
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<td>IIA</td>
<td>Institute of Internal Auditors</td>
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<td>KPI</td>
<td>Key Performance Indicator</td>
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<td>NAS Network</td>
<td>The network of member states national experts on National Audit Systems, hosted by DG SANTE</td>
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<tr>
<td>PCU</td>
<td>Provincial Control Unit (of the FASFC) <em>(Unité provincial de contrôle/Provinciale Controle-Eenheid)</em></td>
</tr>
<tr>
<td>QMS</td>
<td>Quality Management System</td>
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| TBT          | *Tableau de board* (‘Dashboard’ – IT tool used in FASFC to monitor follow-up of corrective actions in response to audit recommendations)
1 INTRODUCTION

This audit took place in Belgium from 18 to 22 January 2016. The audit team comprised three auditors from the European Commission’s Directorate General for Health and Food Safety (DG SANTE).

The opening meeting was held on 18 January 2016 with FASFC. 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 by the Federal Agency for the Safety of the Food Chain (FASFC), the Competent Authority (CA) responsible for the majority of official controls falling under Regulation (EC) No 882/2004, to implement Article 4(6).

In addition, the DG SANTE audit team gathered some information on the state of advancement of planning to establish audit arrangements for animal welfare controls, for which competence had been devolved from the Federal level to the Regions.

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

\[
\text{Competent authorities shall carry out internal audits or may have external audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of this Regulation. These audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.}
\]

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\(^2\).

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(hereafter: Commission Decision 2006/677/EC). Where relevant, reference was made to 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 Belgian competent authorities can be found in the Country Profile for Belgium at:

http://ec.europa.eu/food/fvo/country_profiles/details.cfm?co_id=BE

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

http://ec.europa.eu/food/fvo/ir_search_en.cfm

While 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 Belgium 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 national competent authorities, responsible for the performance of audits of official control systems as provided for by Article 4(6) of Regulation (EC) No 882/2004. The Network meets regularly, under the chairmanship of, and facilitated by, DG SANTE to exchange experiences in implementing national audit systems on official control activities. During the course of these exchanges; discussions, workshops etc. good principles and practices are identified and agreed by the network.

To enable dissemination of information the Network, working in plenary session and through sub-groups, facilitated by DG SANTE, consolidate agreed principles and good practices on specific topics into Network Reference Documents.

In relation to NAS, at the time of this audit 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.

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 Belgian Multi-Annual National Control Plan and associated Annual Reports, the Country Profile of Belgium and sectoral audit reports;
- examination of certain documentation provided by the CA prior to the audit; and
meetings with the Internal Audit Unit (IAU) of the Internal Audit and Quality Management Services Department (IAPQMS), the unit 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 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 CA 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.”
Article 4(3) of the Regulation states that “When a Member State confers the competence to carry out official controls on an authority or authorities other than a central competent authority, in particular those at regional or local level, efficient and effective coordination shall be ensured between all the competent authorities involved, including where appropriate in the field of environmental and health protection.”

In section 5.1 of the Annex of Decision 2006/677/EC further guidance is provided to Member States on the ‘Systematic’ and, in particular, it states that “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.”

In section 5.3 of the Annex of Decision 2006/677/EC further guidance is provided to Member States on the ‘Independence’:

“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.

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. Auditees should not be in a position to impede the audit programme, findings or conclusions. They should be consulted on the draft report and their comments should be considered by the audit body. Where appropriate, those comments should be taken into account in a transparent manner.

The following points may help ensure that the audit process safeguards the independence of both the audit body and the audit team:

— a clear, documented mandate affording adequate power to conduct the audits should be provided,

— neither the audit body nor the audit team should be involved in managing or supervising the control systems being audited,

— for external audits, the audit body and audit team should be external to, and independent of, the organisational hierarchy of the auditee,
— for internal audits, the following general principles should apply to ensure the process is independent and transparent:

— the audit body and audit team should be appointed by top management,

— the audit body and/or the audit team should report to top management,

— a check should be carried out to ensure no conflict of interest exists for either the audit body or the audit team.

Independent audit bodies should be external to or separate from the management of audited activities. Internal audit bodies should report to the most senior management within the organisational structure.

Where technical expertise required for the audit is available only within a competent authority, measures should be taken to ensure the audit team remains independent. Where control activities are organised on a regional basis, technical specialists could be exchanged in order to ensure they are independent.”

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 Belgium at:

   http://ec.europa.eu/food/fvo/country_profiles/details.cfm?co_id=BE

2. FASFC and the Federal Public Service for Health, Safety of the Food Chain and Environment (FPS–HSFCE) are the main competent authorities in the areas of food and feed safety, animal health and plant health. The FPS–HSFCE is responsible for the preparation of policy, relevant legislation and the preparation of standards. However, responsibility for animal welfare controls was devolved from FPS-HSFCE to the Regions in 2014 (see finding 5).

3. The FASFC, under the Minister competent for food safety, verifies that all legislation and standards are respected by all actors within the food chain. It is also responsible for the preparation of process standards. The FASFC Directorate-General "Control Policy" is responsible for policy on control measures and programmes. The Directorate-General "Control" (hereafter DG CONT) has central services responsible for co-ordinating and integrating control activities while the controls themselves are carried out by the 11 Provincial Control Units (PCU) of this Directorate. The central services of the Directorate-General "Laboratories" (DG LAB) co-ordinate all analysis activities carried out by the five federal FASFC laboratories under their direction and the external laboratories used.
4. FASFC has implemented a Quality Management System (QMS) with FASFC services certified to the ISO 9001 standard, FASFC inspections accredited according to ISO 17020, and official laboratories according to ISO 17025.

5. In 2014, responsibility for animal welfare was transferred from federal level to the three Belgian Regions (Flanders, Wallonia and Brussels Capital). At the time of the DG SANTE audit, protocols had been signed between FASFC and each of the Regions under which FASFC will perform animal welfare controls at slaughterhouses and on farms. Regions remain directly responsible for follow-up of non-compliance and any necessary enforcement action arising from the results of the controls carried out by FASFC. The management contracts defining the modalities of the controls were in the course of being finalised and signed. The IAU informed the DG SANTE audit team that the contracts include a provision for the Regions to audit, or have audits carried out on, the animal welfare controls performed by FASFC on their behalf.

5.1.2.2 Responsibility for audits of official controls

6. The audit system comprises several structural layers:
   - Audit Committee of the Federal Public Administration (FAC);
   - FASFC Audit Committee (FASFC–AC);
   - FASFC-IAQPMS;
   - The FASFC pool of auditors.

7. See section 5.2.2 regarding the roles of FAC and FASFC-AC.

8. The Internal Audit Unit (IAU) is a service of the Internal Audit, Quality, Prevention and Mediation Service (IAQPMS) of FASFC. The IAU has been operational since July 2007 and ISO 9001 certified since October 2008. It comprises 3.8 full time equivalents (FTE) auditors. The audit resource is split along linguistic lines, with the francophone resource (2 FTE) auditing activities in Wallonia and the Dutch-speaking resource (1.8 FTE) auditing in the Flemish Region. The Director of the IAQPMS acts as the Chief Audit Executive (CAE), responsible for the overall functioning of the unit, but does not act as an auditor.

9. Up to the end of 2015, DG LAB had a pool of about 30 part time auditors among the laboratory staff that carried out internal audits of laboratories against the ISO 17025 standard. IAU will be taking over auditing laboratories with effect from 2016, but at the time of the DG SANTE audit, this activity had not yet started (although IAU had already audited other aspects of laboratory performance in the past). IAU can call upon the DG LAB pool of auditors as technical experts, as required.

10. A pool of technical experts from the central services, the PCUs and the laboratory quality team can be called upon to assist the audit service. The range of expertise is wide (technical, quality teams, laboratory experts, externs for specialised tasks such as...
IT and finances). Many controllers/inspectors in the PCUs were trained as auditors for self checking systems (SCS) (a certified training was held in 2007).

11. The technical experts work under the supervision of the lead auditor (who is always one of the full time auditors of the IAU) and the CAE for the duration of an audit.

12. The CAE informed the DG SANTE audit team that a proposal has been made to amalgamate all internal audit services of the Federal Ministries and Agencies under a single Federal Internal Audit Service. Discussions were on-going as to the effect this will have on IAU’s audit functions (whether some or all should be transferred to this new single Service). At the time of the current audit, it was not clear what the final outcome of these discussions would be and what effect this may have on the auditing carried out to meet the requirements of Article 4(6) of regulation (EC) No. 882/2004.

13. The DG SANTE audit team met with representatives from the Regions, responsible for controls on animal welfare. A representative of the regional internal audit service of the Flanders Region was also present. In the case of Flanders, the internal audit representative confirmed that his service was aware of the need to plan audits in relation to animal welfare controls to meet the requirements of Article 4(6) of Regulation (EC) No. 882/2004 and that while the planning for 2016 did not include its topic, audits were expected to take place in 2018. The modalities of these audits had not been confirmed. At the time of the DG SANTE audit, the representatives of the Walloon and Brussels Capital Regions could not confirm what audit arrangements would be put in place.

Conclusions

14. Responsibility for auditing of official controls has also been clearly allocated, with the exception of controls on animal welfare falling under the scope of Regulation (EC) No. 882/2004, for which auditing arrangements have not yet been defined.

15. The possible effect of the Federal-level centralisation of the internal audit functions of the Federal Ministries and Agencies on the future conduct of audits required under Article 4(6) of regulation (EC) No. 882/2004 was not known at the time of this audit.

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:

“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

16. Article 3 of the Royal Decree of 20 December 2007 which establishes the FASFC requires that, inter alia, the services contained within IAQPMS (internal audit, quality management, prevention and mediation) report directly to the Delegated Administrator (i.e. the Chief Executive Officer (CEO) of the FASFC).

17. Article 10(2) of the same Royal Decree makes explicit reference to the direct reporting line between the IAU and the FASFC-AC for tasks related to controls. In addition, it requires all services and individual staff members of the Agency to cooperate with the IAU. The placement of the IAU, in the FASFC-IAQMS, under the hierarchical supervision of the CEO of the Agency and the functional supervision of the FASFC-AC, ensures that the audit function is clearly separated from the processes it audits.

18. Both FASFC-AC and the Federal Audit Committee include ensuring the independence of the internal audit function among their responsibilities (see section 5.2.2.2 for further information on these committees).

19. The mission and mandate of the IAU is defined in the Audit Charter, which was drawn up based on:

- The ISO 19011 standard: guidelines for auditing management systems;
- Commission Decision 2006/677/EC;
- The standard of the Institute of Internal Auditors (IIA); and
- The guidance documents of the NAS Network.

20. The reporting lines described in findings 16 and 17 above are confirmed in the Charter. In addition, the independence of the audit service is highlighted as essential for
effectiveness of the internal audit function and the need for independence of ‘ad hoc auditors’ is also recognised.

21. The four internal auditors of the IAU are dedicated to the internal audit task, with the exception of 1 auditor who spends a small proportion of time on some environmental management tasks (FASFC was EMAS accredited until 2015 but, following a management decision this accreditation was not maintained, even if certain environmental management objectives were retained).

22. The IAU is not responsible for, or involved in the delivery or management of the official controls which it audits, or the development or approval of the associated procedures.

23. The Code of Ethics for internal auditors (based on the Code produced by the Institute of Internal Auditors – IIA) sets out rules of ethical conduct under the headings of integrity, objectivity, confidentiality and competence, and obliges auditors to reveal any information which could risk compromising their objectivity during an audit. The Code is also applicable to any technical experts/ad hoc auditors joining the IAU audits. All such ad hoc auditors must sign a statement declaring that they will respect the requirements the Audit Charter and Code of Ethics and will report any potential conflicts of interest to the CAE. IAU maintains a register of conflicts of interest.

24. At a functional level, despite budget cuts in recent years, the CAE stated that the IAU has sufficient resource to deliver its audit programme as foreseen, and access to sufficient numbers of technical experts, including external expertise where necessary, to ensure planned audits can be performed.

25. IAU auditors have access to all relevant procedures, documentation and databases for the activities which the audit. For those documents and databases to which direct access is not possible (for legal or other reasons, such as protecting confidentiality of personal data) IAU can request relevant extracts.

26. When asked by the DG SANTE audit team, the IAU auditors could provide examples of infrequent situations where potential threats to independence arose (mainly in connection with the use of technical experts) and of the actions taken to address these situations, such as exclusion of a technical expert from those parts of the audit where a self-review risk (i.e. a risk of auditing work for which the technical expert was responsible) arose.

27. IAU uses a ‘two-year rule’ for internal auditors, i.e. an internal auditor may not audit the service where they work previously for at least two years after leaving it.

28. Ultimately where threats to independence are identified, the CAE is responsible for the final decision regarding mitigating measures.
Conclusions

29. The IAU demonstrated good awareness of potential threats to independence and appropriate mitigating measures. Effective arrangements have been put in place that ensure the independence of the audit process at an organisational, functional, process and individual auditor level, thereby contributing to 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

30. The FASFC Audit Committee (FASFC–AC) is responsible for both ensuring the independence of the IAU and for independent scrutiny of the audit process.

31. FASFC–AC was established by the Royal Decree of 27 December 2007 and Ministerial Decree of 22 September 2009. It comprises 5 representatives and 3 alternate members: the chairperson, who is an external expert in internal audit and quality systems, one member of the Executive Committee of the FASFC, two stakeholders - representatives of industry and consumer organisations - and 2 alternates, one representative of the Minister in charge.

32. Its mission is to assist the Managing Director and the Executive Committee of the Agency in monitoring the operation of the FASFC. Their task is to evaluate the annual audit programme and interim audit requests, and its implementation; to develop an overview on all internal and external audits, evaluate all audits carried out, and present

33. The charter and the rules of procedure are approved by the Minister. According to the Charter, the duties of the chairperson are externalised since 2012. All members of the Committee have to sign a declaration of confidentiality. The charter describes the rights, obligations and the incompatibilities of members, and the rules for the organisation of meetings. The Committee meets usually 4 times per year.

34. The Federal Audit Committee (FAC), established by the Royal Decree of 17 August 2007, provides an additional layer of independent scrutiny. Its members were appointed by the Council of Ministers on 12 February 2010. The Royal Decree gives wide powers to this Committee concerning internal audit. Its duties and responsibilities are to:

- evaluate the operation of the Federal government (evaluating their internal control system):
  - implementation of orderly, ethical, economical, efficient and effective operations;
  - compliance with the obligation to be accountable and the reliability of financial and management information;
  - compliance with applicable laws and regulations;
  - the protection of resources against loss, misuse and damage;
- review internal audit activities carried out within the services (approved audit programs and assessing audit results);
- alarm function in cases of severe dysfunction;
- guaranteeing the independence of the internal audit activities and monitors the effectiveness and quality.

35. The head of IAQPMS attends monthly co-ordination meetings organized by the FAC.

36. In addition, the Audit Charter requires the IAU to have an external audit every five years. In 2011, the external audit was carried out by the Federal Public Service of the Interior. The scope of the audit encompassed the requirements of "Standards for the Professional Practice of Internal Auditing" and ISO 19011. 14 recommendations were made. The actions proposed in the action plan drawn up in response to that audit had been totally implemented just prior to the DG SANTE audit.

37. The next internal audit should be carried out in 2016, but in view of the pending decisions in relation to the possible re-organisation of the internal audit function (see finding 12) no arrangement had been put in place at the time of the DG SANTE audit.

38. In addition to the above sources of independent scrutiny, the audit system achieved ISO 9001 certification in 2008 and accreditation ISO 17020 in 2010 (by BELAC) and is subject to quality audits every 5 years.
39. In 2015 IAU carried out a satisfaction survey of FASFC management in which feedback on all aspects of the audit process was solicited. This provided additional information on the performance of the audit function and possible areas for improvement. With effect from the beginning of 2016, feedback will be systematically requested from auditees on the performance of each audit.

40. IAU could demonstrate to the DG SANTE audit team specific examples of feedback and/or recommendations from all of the above-mentioned sources which led to improvements to the internal audit function. Examples include, but are not limited to:

- Introduction of the ‘A – B –S’ classification system for audit recommendations (see finding 89);
- The introduction of the satisfaction surveys (see finding 39);
- Changes to the FASFC-AC (chairman to be an external member);
- Improvements in the definition of audit scopes;
- The development of a working instruction on the use of technical experts;
- Changing the location of closing meetings to the central level, which increased the participation of central level staff in such meetings, bringing them together with provincial level staff thereby improving the root cause analysis of problems identified.

Conclusions

41. Extensive arrangements have been put in place to ensure independent scrutiny of the audit process and this independent scrutiny has clearly contributed to the continuous improvement of the audit process.

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

42. IAU has a work instruction dealing with training and evaluation of internal auditors, which includes a ‘training matrix’ identifying all relevant skills required and a standard evaluation form for use to determine if an internal auditor is ready to act as a lead auditor.

43. The training process includes:

- Development of knowledge of relevant standards, such as EU legislation, ISO standards, COSO (internal control) standards, the FASFC audit charter and code of conduct for internal auditors;
- Following internal audits conducted by the qualified IAU auditors, initially as an observer and later taking part in some activities under supervision;
- Performing two internal audits (from preparation through to evaluation of the action plan) under the supervision of a qualified IAU auditor, who evaluates the trainee’s performance;
- Evaluation of the trainee by the CAE, which may lead to additional training if the need to further develop either technical or personal skills is identified;
- Final decision by the CAE that the trainee is accepted as a qualified internal auditor and can act as a lead auditor.

44. The CAE also carries out an annual evaluation of each internal auditor, using a standard evaluation form. This evaluation is based on the CAE’s knowledge of the work of the auditors, arising from supervision of all reports and attendance at as many audit closing meetings as possible as well as periodic attendance at other audit activities.

45. The annual evaluation is done according to defined criteria including:

- Personal behaviour and characteristics;
- General knowledge (procedures, standards) and skills;
- Specific knowledge and skills for auditing management systems;
• General knowledge and skills as a lead auditor (leadership and organisational skills).

46. During the annual evaluation meetings held between the CAE and each auditor, positive points and points for improvement are discussed and training needs identified for the following year.

47. The four IAU auditors are highly qualified and benefit from regular further training and other opportunities for continuous professional development (e.g. participating in the Benchmarking activity of the Heads of Agencies group, performance of periodic audits with external bodies, exchanges with audit bodies in other Member States, etc.). The objective of at least 5 days training per internal auditor has been set, but in practice this is usually exceeded (the average in recent years has been closer to 10 days per auditor). At the time of the DG SANTE audit, two of the internal auditors had completed Masters’ degrees in internal or forensic auditing. In addition, each internal auditor has the objective of participating in an audit in an external body once every 3 years, in order to broaden their experience.

48. The IAU makes effective use of the further training undertaken by its auditors. For example, the risk-based prioritisation methodology in use since 2014 (see section 5.2.4) was developed by one auditor in the context of a project in his Master’s degree.

49. The current IAU team is multi-disciplinary, including backgrounds in veterinary medicine, law and criminology, agronomy and industrial engineering.

50. The recruitment of new internal auditors is not a frequent activity, due to the small size and relative stability of the team of internal auditors. In the past it has been possible to recruit new team members from within the Agency. The CAE explained that previous audit experience is not necessarily a prerequisite, the appropriate personal characteristics and ‘soft’ skills can be sufficient. Nevertheless, due to previous audit training with the FASFC many potential applicants have relevant training and experience.

51. IAU has a work instruction dealing with training and evaluation of technical experts aimed at ensuring that they understand their role and responsibilities, prior to participation in audit activities. Each technical expert must sign a document stating their agreement to respect the provisions of the code of conduct and Audit Charter, and undertaking to inform the CAE if any conflict of interest should arise during the course of the audit.

52. Training for technical experts is run at the start of the year for all technical experts that will be used in the audit programme for that year. Technical experts are trained on the relevant internal audit procedures and their role in the audit team.

53. At the start of the audit preparation phase, each lead auditor must brief the technical expert on their role in, and expected contribution to, the audit.
54. After each audit, the lead auditor evaluates the performance of the technical expert using the standard evaluation form, which covers, *inter alia*, compliance with the code of conduct, technical skills, motivation and participation. These evaluation forms can be used by the CAE for subsequent selections of technical experts.

### Conclusions

55. Appropriate procedures have been put in place to ensure that auditors have sufficient competence to perform their duties and that they can maintain and further develop their auditing competence. Additional technical expertise can be used in an appropriate manner when needed.

#### 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*.”

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

56. The IAUs procedure on developing and managing an audit programme defines the steps to be followed in preparation and approval of the audit programme. While the main steps described therein are followed, the process for one step in particular, the risk assessment, has changed since this procedure was approved. This procedure is programmed to be completed in March 2016, but has been delayed pending the outcome of discussions on a possible reorganisation of Federal internal audit services (see finding 12).

57. Broadly, the process consists of the following steps:

- synthesis of inputs/proposals from FASFC management;
- risk assessment (reviewed each year);
- selection of processes/sectors to be audited, based on the output of the risk prioritisation methodology (see findings 59 to 69);
- submission of the proposed program for opinion of the Management Committee (discussion);
- validation by the FAFSC-AC;
- presentation to Management Committee;
- communication by email to each concerned director and publication on intranet;
- receipt of the advice (a posteriori) of the FAC.

58. Input to the programme planning process is requested from all DGs, the FASFC-AC and the IAU auditors. Recommendations made by internal and all external auditors (DG SANTE, ISO, FAC and the 2011 audit done by the Federal Public Service of the Interior) are also taken into account.

59. IAU defines its audit universe in terms of 47 processes covering all FASFC work (covering not just the official controls falling under the scope of the requirements of Article 4(6) of Regulation 882/2004, but also plant health and other activities such as budgeting, personnel, translation etc.), closely linked to the QMS process mapping, and 40 sectors, covering all relevant operators. Audits included in the programme may cover part or all of one or more processes and/or sectors.

60. The underlying principle of the risk prioritisation system is that auditing each year each process and sector in detail each year, so the prioritisation process aims to ensure that audit resources are directed towards the right scopes. A methodology has been developed to apply risk weightings based on defined criteria to each process and sector, with a view to achieve a transparent, risk-based, systematic prioritisation.

61. Eight risk criteria have been defined for the 47 Processes:

- Is the process included in the core business of FASFC (control, sample analysis, regulation) or related to the realization of strategic objectives? Yes: 10 (certainly), + / - : 5, No : 1 (certainly not);
- Does the processes that support overall the QMS (10, 5, 1);
• Is the process dispersed geographically or between several external entities (20, 1);
• Could non-conformity in this process cause a potential risk for human health? (30, 15, 1);
• Could non-conformity in this process causes potential financial impact for FASFC? (10, 5, 1);
• Could non-conformity in this process causes potential financial impact for FBOs? (10, 5, 1);
• Did the topic/theme submitted by Management or the FASFC-A, identify a specific risk? (30, 1);
• Date of the last internal audit? (10, if more than 4 years; 5: between 3 to 4 years; 1: less than 3 years).

62. Additional criteria allow for subjective choices/prioritisation by internal audit service (audit takes place earlier or later), based on their knowledge or experience. All such choices must be documented.

63. Five risk criteria have been defined for the 40 sectors:
   • Date of the last internal audit (10, 5, 1 – as for the processes);
   • Did the topic/theme submitted by Management or the FASFC-AC, identify a specific risk? (30, 1);
   • Date of the last evaluation mission inside the Control administration (10, 5, 1);
   • Date of the last DG SANTE mission (10, 5, 1)
   • Public awareness concerning this sector/any press releases in the last year? (10, 1).

64. The additional criterion considered is the need to respect the 5-year period for coverage of all official control areas (if necessary at the end of the cycle).

65. The risk weighting for each process and sector is calculated based on the above criteria and weightings (an EXCEL table is used to document this). The method is in effect semi-quantitative as the extra criteria referred to above can be used to adjust the ranking. The criteria were selected based on the principle that protection of public health is the core business of FASFC.

66. PCUs to be included within the scope of an audit are chosen at time of programming. Usually one PCU is included in each audit (where relevant activities take place at PCU level). On average PCUs will receive at least one audit per year.

67. In 2015, the programme consisted of 21 audits:
   • 2 follow-up audits (each administration every two years)
   • 6 sector audits
     o combined each time with the process "planning and setting up of controls from control plan"
• 13 processes audits
  o 2 combined with FBO sectors (food carrier control/import control)
  o 2 on FAFSC control program (inspection program/sampling program)
  o 1 on audits of FBO’s auto-control system
  o 2 in FAFSC laboratories
  o 1 in external laboratory

68. In 2016, the programme consisted of 22 audits:
• 2 follow-up audits
• 6 sector audits
• 14 processes audits:
  o 2 on controls outside control plan (e.g. RASFF, export certification)
  o 2 on sanctions (removal of registration and approval / administrative fines)
  o in FAFSC laboratories
  o 2 in an external authorities:
    ▪ controls delegate to regions (potato plants)
    ▪ in agreement with Ministry of Economy (e.g. fraud and labelling)

69. The method currently in use was developed during 2013 and applied for the first time in the 2014 programme. It is now planned to continue to refine it to:
• compare (and align if necessary) the universe of 47 processes used with the new (2015) mapping of processes in FAFSC,
• better define the request for proposals (inputs) to ensure better risk identification;
• reassess the structure of the Universes (to consider aggregating or subdividing certain sectors or processes)
• reassess the weights and, in particular, align the weight of the first criteria with the new strategic objectives (Business Plan 2015-2017);
• strengthen the weight of criteria “date of the last internal audit” (10, 5, 1 adapted to 20, 10, 1);
• consider possible new criteria (e.g. results of last audit).

70. The audit program contains all internal audits for the year (the annual programme) but involves an approach based on a period of 3 years (reviewed annually) to meet the requirements of the QMS/ISO 9001 certification. In addition, coverage of sectors is reviewed to ensure all sectors are covered over a 5 year period, in line with the guidance laid down in Commission Decision 2006/677/EC. If any sector is not completed by the end of the 5-year cycle, it is prioritised in the next cycle. The cycles to date have run from 2007 to 2001, and from 2012 to 2016.

71. The final annual programme contains all the audit scopes (themes) and the concerned services (auditees), the auditors’ names and the estimated time of the audit (month). Audit objectives and the detailed scope are specified in the pre-announcement sent 3
weeks before the beginning of the audit (see section 5.2.5.2.1). Additional processes may be added to an audit at the brainstorming phase during the preparation of the preannouncement.

72. The development of the audit programme was fully documented and the implementation of the steps could be demonstrated to the DG SANTE audit team. In addition, based on the audit programmes actually implemented in 2014 and 2015, it could be seen that in general the planned programmes could be delivered in practice.

Conclusions

73. The IAU has developed and implemented a procedure for establishing annual and multiannual audit programmes using a transparent, systematic risk-based prioritisation process.

74. The programmes so established could be implemented by the IAU largely as planned and generally achieved a coverage of activities, sectors and services within FASFC sufficient to provide assurance regarding the quality of the official controls audited.

75. The IAU continues to improve their methodology.

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 provides guidance on implementation of the Audit Process:

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

(a) Verification of compliance with planned arrangements in order to provide assurances that official controls are carried out as intended and that any instructions or guidelines given to staff carrying out the controls are followed. This may largely be addressed by document review, but will also require on-site verification. The audit team will require good generic audit knowledge and skills to address this audit objective.

(b) Verification of the effective implementation of planned arrangements. In order to assess effectiveness, that is the extent to which planned results are achieved, on-site operational implementation must be included. This should include an assessment of the quality and consistency of the controls and should involve on-site audit activities. The audit team will require the relevant technical expertise in order to address this audit objective.

(c) The audit system should also seek to assess whether the planned arrangements are suitable to achieve the objectives of Regulation (EC) No 882/2004, and in particular the single integrated multi-annual national control plan. This should include assessing the suitability of official controls, with regard, for example, to their frequency and the methods applied, having regard to the structure of the production chain(s) and to production practices and volume. The audit team should have substantial knowledge and understanding of system auditing, together with relevant technical input to address this audit objective.

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

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

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

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

5.2.5.2 Findings

5.2.5.2.1 Documented Procedures

76. The IAU has developed procedures for:
• Execution of an internal audit;
• Setting-up the audit program;
• Request of an audit outside the audit program.

77. The above procedures are currently under review and are scheduled to be updated by March 2016.

78. The IAU has the following working instructions for internal use:

• Satisfaction survey;
• Evaluation of technical experts;
• Conducting internal audit;
• Training and evaluation of auditors.

79. The working instruction on conducting an internal audit covers all steps from the development of the audit programme, through planning individual audits, developing the audit scope and the audit questionnaire, communicating the scope and methodology to the auditee, agreeing the timetable, meetings and site visits, how the opening and closing meetings and other audit activities should be conducted, how audit results should be reported, including how auditees comments on the draft report should be reflected in final audit reports, how reports should be distributed and published, how action plans should be accessed and how follow-up should be conducted.

80. Templates are available, inter alia, for announcement of audits, communication of the audit plan, audit questionnaires (including a list of domains to be audited), conduct of opening and closing meetings, reports and action plans. In addition, checklists are available for all audit tasks and for ISO Standards, to assist auditors in ensuring that all necessary aspects are considered.

5.2.5.2.2 Compliance with planned arrangements

81. Adequate arrangements have been put in place by IAU to ensure that auditors can adequately assess compliance with planned arrangements. Procedures and the related work instruction address this aspect of the audit process and the IAU has access to sufficient competent auditors and technical experts (see section 5.2.3.2) to perform such evaluations. Technical experts are involved during the audit preparation stage and in the development of the audit questionnaire to ensure that compliance with technical requirements is adequately assessed.

82. Documentation seen by the DG SANTE audit team, including audit plans, audit reports and audit questionnaires, demonstrated that above-mentioned arrangements are effectively implemented.
5.2.5.2.3 Verification of the effective implementation of planned arrangements and their suitability to achieve objectives

83. The mission and objectives laid down for IAU in its Audit Charter reflect not only the need to evaluate compliance with legal requirements and the QMS, but also verifying whether the objectives of the organisation have been achieved, with a view to adding value and contributing to the continuous improvement of the organisation.

84. In the context of individual audits, from the sample seen by the DG SANTE audit team, it was clear that some referred explicitly to the need to verify the effectiveness of arrangements in place and some contained recommendations that clearly addressed the suitability of arrangements. However, the DG SANTE audit team noted that the description of the audit scope (which included the audit objectives) varied considerably between reports and was not always consistent with the type of recommendations made. For example, in one case the scope was described as evaluating compliance with various requirements while one of the recommendations clearly addressed the suitability and effective implementation of those arrangements. In response to this observation, the IAU audit team demonstrated the results of some further work recently undertaken to harmonise the way in which scopes are drafted which should address the inconsistency noted by the DG SANTE audit team.

85. IAU could demonstrate that many audit recommendations related to adjustment of procedures or arrangements to ensure they could be effectively implement and were suitable to achieve objectives. They considered that the practice of identifying 3-5 major risks associated with the sector/process at the start of the audit questionnaire ensured that the auditor was conscious of the objectives to be achieved by the audited activities.

86. The IAU highlighted that, as a process-based approach is taken in the internal audit programme, it may be necessary to evaluate the outcome of a number of audits to determine if a control objective is being achieved.

5.2.5.2.4 Audit reporting

87. IAU has put in place documented procedures for reporting the findings, conclusions and recommendations of audits, including report templates, and for report approval, including provision for auditees to comment on draft reports and the subsequent distribution of the reports.

88. The audit report template also includes a section on main positive/strong points identified during the course of audits.

89. In response to requests from the FASFC-AC and FASFC management, since 2013 audit recommendations are classified as follows (see section 5.2.6.2 for details of the effect of classification of subsequent follow-up):
• A: immediate and severe danger and/or immediate and severe impact on Public health, animal health, plant health; Image of the FASFC; Internal functioning or financing of the FASFC; Goals or management system of the FASFC; Application of regulations.
• B: danger and/or impact over time on Public health, animal health, plant health; Image of the FASFC; Internal functioning or financing of the FASFC; Goals or management system of the FASFC; Application of regulations.
• S: Suggestion or point of attention: includes possibilities to improve the (quality) system and/or to increase the efficiency of the (quality) system.

90. The CAE supervises draft reports to ensure the relevance of the findings and the consistency of the recommendations with those findings. In the case of final reports, the CAE ensures that the auditees’ comments have been treated appropriately, in line with the criteria laid down in the relevant working instruction.

91. The DG SANTE audit team examined audit reports covering a variety of different processes/sectors and in both working languages and found that the prescribed templates had been used and in general reports were clear and consistent. While some inconsistencies were noted, particularly in relation to scope, action had already been taken to address this (see finding 84).

5.2.5.2.5 Review of audit conclusions and dissemination of best practice

92. The availability of all audit reports, action plans and IAU evaluations of those plans available on the FASFC intranet ensures that all staff can access audit conclusions/recommendations as well as information of the strong points identified.

93. IAU’s practice of sending all audit reports to all Directors ensures that the whole management team have access to information on deficiencies and strong points identified.

94. The DG SANTE audit team met with staff responsible for quality coordination in DG CONT, who explained that audit results were reviewed with a view to identifying potential system-wide issues or opportunities for improvement and that these results were discussed at quality meetings.

95. In addition, at the meetings of Regional Directors, the results of internal audits in PCUs is a standard point on the agenda, which means that relevant audit conclusions and findings regarding good practices can be discussed in this forum.

96. In relation to dissemination of best practice, the CAE highlighted the participation of IAU auditors in external activities as a way of identifying and sharing best auditing practices. In particular:

• IAU auditors are expected to participate in an audit in an external service at least once every 3 years;
• IAU auditors can attend external training and conferences, such as conferences of the Institute of Internal Auditors (IIA) and ‘Better Training for Safer Food’ events organised by the European Commission. In the case of the latter, IAU staff will participate also as trainers;
• IAQPMS staff has participated in the Bench-Marking exercise carried out under the auspices of the Heads of Services and Agencies group of the EU Member States.

5.2.5.2.6 Monitoring and review of the audit process

97. The implementation of the audit process is monitored by the CAE and the necessary IT tools to support this process are available.

98. Key Performance Indicators (KPI) have been set to monitor implementation of certain elements of the audit process:
  • Realisation of the audit programme (target in 2014: 80% by 31 December);
  • Deadline for closing meeting (target in 2014: 100% to be held within 5 working days);
  • Delivery of draft audit report to the auditee (targets in 2014: 90% within 30 calendar days, 100% within 50 calendar days);
  • Delivery of the final report to the auditee (targets in 2014: 80% within 10 working days, 100% within 20 workings days).

99. Actual achievement of KPI is reported in the annual report of the FASFC-AC. Data from 2012, 2013 and 2014 showed that the KPI for realisation of the audit programme was exceeded (realisation between 92 and 100%), that for timing of the closing meeting was achieved in 100% of cases in 2014 and 2012 and 95% in 2013, while the ‘30 day’ target for delivery of the draft reports was not achieved, although an improving trend could be seen between 2013 and 2014. The achievement of targets for delivery of final reports was better than for drafts, even if not all targets were met between 2012 and 2014.

100. The internal audit process in FASFC is part of the QMS and, as such, is included in the annual management review of the system.

101. In addition, the IAU highlighted other activities that they consider contribute to review and continuous improvement of the audit process:
  • The input from the FASFC-AC and FAC contribute to the review of the audit process (see section 5.2.2.2). In particular, the preparation of the FASFC-AC annual report provides an opportunity to review the audit process each year;
  • In recent years a number of IAU procedures have been reviewed and new work instructions drafted, which provided opportunities to review elements of the audit process;
• The Satisfaction Survey of the auditees carried out in 2015 led to review of several aspects of the audit process in response to the auditee feedback, including clearer definition of audit scope/objectives and holding of closing meetings at the central level to increase participation of the central services, as well as practical steps to ensure the optimum timing for audits and the participation of only the necessary auditee staff at each stage of the audit;

• With effect from 2016 IAU will systematically request auditees to complete a satisfaction survey after each audit;

• The IAU team of auditors periodically discuss issues related to harmonisation of findings, recommendations and reporting (see finding 84).

Conclusions

102. Audit arrangements and their implementation are documented sufficiently to ensure that all necessary activities are carried out in a consistent and transparent manner, even if updating of some procedures is still in progress.

103. Adequate arrangements have been put in place to ensure that compliance with planned arrangements is audited effectively and in a systematic manner. Effective implementation and suitability of arrangements were also addressed in audit findings and recommendations.

104. Audit reporting procedures are sufficient to ensure clear reporting of relevant audit results. Actions have been taken to improve the clarity of reports where scope for improvement was identified.

105. Adequate arrangements have been put in place to ensure that the audit process is monitored and reviewed and that continuous improvement is thereby achieved.

106. FASFC has put in place arrangements that ensure that audit results are reviewed to identify potentially system-wide issues and opportunities for improvement.

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

107. Clearly defined procedures are in place both in IAU and in the other FASFC for follow-up of audit recommendations.

108. The relevant auditee is responsible for preparing an action plan in response to audit recommendations. This is usually done after receipt of the final report, except in the case of recommendations categorised as ‘A’ (relation to an immediate and severe danger and/or immediate and severe impact – see finding 89) where an accelerated procedure is followed. ‘A’ recommendations are relatively uncommon.

109. A standard template is used for action plans. For recommendations categorised as ‘B’, the auditee should complete the template with a root cause analysis of the problem and proposed corrective actions, identifying the timetable for implementation of those actions and the person responsible. This should be done within 15 working days of receipt of the e-mail request from IAU, which is issued after transmission of the final report. In the case of ‘A’ recommendations, the same template is used, but the auditor and relevant audited services meet prior to the closing meeting and complete the root cause analysis together and agree the necessary corrective actions.
110. In the case of ‘S’ suggestions, no action plan is required and there is no formal follow-up by IAU, although previous suggestions may be taken into consideration when a subsequent audit is carried out.

111. The IAU auditor is responsible for validating the action plan, to ensure that the root cause analysis has been performed and appears adequate and that the proposed corrective actions are likely to address the problems identified and the deadlines proposed for completion of those actions are reasonable. Where the IAU auditor is not satisfied with the action plan, contact is first taken with the quality co-ordinator to try to resolve outstanding issues. If it is not possible to resolve issues at this level, IAU auditor records their disagreement in the ‘comments’ field of the action plan. In such cases the CAE can pursue the issue through meetings with management. At present there is no specific procedure defined for dealing with such cases (this has been done on an ad hoc basis to date), but this is being considered.

112. After IAU validation of the action plan, subsequent monitoring of the implementation is the responsibility of the quality coordinator of the relevant service. EXCEL tables with a common format (‘Dashboard’ or ‘Tableau de board’ – hereafter TBT) are used by all services for this purpose, so that the tables can be up-dated and combined regularly to give management an overview of progress.

113. The quality coordinators liaise with the persons responsible for implementing corrective actions in the services and up-date their TBT to record progress. When it is considered that an action is completed, they are also asked to record the documentary proof of the completion of the action and to carry out a check on the effectiveness of the correct action and record this in the table.

114. In addition to the follow-up activity carried out by the auditees, the IAU carries out a specific follow-up audit dealing with the progress on implementing corrective action plans in each DG every 2 years. In the case of the PCUs, open recommendations are usually followed up at the next audit which includes that PCU in its scope.

115. The IAU follow-up audit seeks evidence that planned actions have been completed and effective. This can include site visits and on-the-spot checks if necessary. Following the audit, recommendations can be classified as closed, in progress or still open (if no action is being taken to address them). In addition, where recommendations have become outdated, they may be reformulated. Where necessary new recommendations may also be issued. IAU may disagree with the quality coordinator’s assessment that a recommendation has been addressed.

116. Progress with follow-up of recommendations is published in the annual report of the FASFC-AC. The last published results (from 2014) show that for the 4 DG and 3 PCU receiving follow-up audits, 81% of recommendations were closed, 14% in progress, 3% still open and 2% reformulated. Three new recommendations were issued. Figures presented by IAU during the current DG SANTE audit, covering 3DGs and 7 PCU
showed the equivalent results for 2015 were 95.4% closed, 25.9% in progress, 2.3% open, 7.5% reformulated and 1 new recommendation.

### Conclusions

117. Clear, systematic and comprehensive arrangements are in place in FASFC to ensure that underlying causes of deficiencies are identified, appropriate corrective actions proposed and implemented and that these actions have been effective at ensuring deficiencies are addressed.

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

118. The following arrangements have been put in place to ensure that auditees and the management team are aware of the audit activities and outputs:

- The audit charter, auditor’s code of conduct, audit procedures are available to all FASFC staff via the Agency’s intranet and a link to their location is systematically included in the pre-audit announcement sent to all auditees as well as being referred to by the lead auditor at each audit opening meeting;
• The annual audit programme is also published on the intranet and sent to the FASFC Audit Committee, the Federal Audit Committee, as well as to all Directors concerned;
• The report of the external audit of IAU, and the associated action plan, were published on the intranet;
• The pre-audit announcement letter communicates each audit scope and objectives, the working procedures and methodology, the audit team and the proposed agenda for the audit. Further details are provided in the audit plan (which confirms the schedule) and at the opening meeting. Templates are available for all of these communications so that all of these points are covered;
• The same information is reiterated at each debriefing meeting held with audited services during the course of the audit;
• The closing meeting includes a summary of findings and conclusions;
• The auditees have an opportunity to comment on draft reports and these comments feature in the final report, along with an explanation of how they were reflected in the final report, or why they were not accepted, as applicable;
• All final reports and associated action plans, as well as the IAU’s evaluation of the action plan, are published on the intranet;
• Final audit reports are also sent to every Director General in the FASFC and to the Federal Audit Committee;
• After follow-up audits, IAU prepares a detailed report on progress with addressing recommendations and this too is published on the intranet;
• A list of final reports is presented to each meeting of the FASFC Audit Committee and the results are presented for any audit that the committee requests;
• Audit activities are reported in the FASFC annual management review;
• The CAE makes an annual presentation to the DG CONT management on audit results and developments;
• Similar presentations are made to other relevant meetings on request or when there are new developments which would be relevant for management;

119. The following arrangements have been put in place to ensure that external stakeholders aware of the audit activities and outputs:

• Since 2014, the FASFC Audit Committee publishes an Annual Report on the FASFC website. This report gives details of mission and objectives of the internal audit function, the actors I the audit process, the organisation and functioning of the IAU, the activities during the year, the follow-up of audit results and the programme of audits undertaken in the year. A copy of this report is also sent to the federal Audit Committee;
• The CAE also presents audit activity and results to the FASFC Advisory Committee, which includes representatives of stakeholders.
120. The IAU team demonstrated a strong commitment to transparency and a good awareness of its importance in ensuring the confidence of both auditees and external stakeholders in the audit process.

**Conclusions**

121. Extensive arrangements are in place to achieve transparency of audit procedures, results and follow-up within the FASFC.

122. Appropriate arrangements are in place to ensure transparency of audit activity and results to external stakeholders.

**5.3 CHALLENGES REPORTED BY THE COMPETENT AUTHORITY**

123. When asked about the particular challenges faced when implementing Article 4(6), the IAU highlighted the following:

- At present in Belgium consideration is being given to amalgamating all internal audit services of Federal Institutions into a single Federal internal audit service. It is not yet clear what effect this may have on the future of audits done in accordance with Article 4(6) of Regulation (EC) No. 882/2004;

- As the audit activity develops from mainly auditing compliance with planned arrangements towards evaluating the effectiveness and suitability of those planned arrangements, it can become more difficult to get acceptance by management of recommendations. This can be because the judgement of effectiveness and suitability may appear more subjective than that of compliance and/or because corrective actions to address issues of effectiveness and suitability may be more demanding than those necessary to address compliance issues.

**6 OVERALL CONCLUSIONS**

With the exception of auditing of animal welfare controls, where no arrangements are in place and there is currently no certainty about what audit arrangements will be put in place:

- There is a mature, effective audit system in place, covering the official controls falling under the scope of Regulation (EC) No. 882/2004, which can achieve the objectives of article 4(6) of that Regulation. This includes a systematic, risk-based prioritisation process for establishing the audit programme, suitable arrangements, including documented procedures that ensure the effective implementation of the audit plan and the competence of the staff involved in audit activities. In addition, monitoring and review of the audit process and its results supports its continuous improvement as well the
dissemination of good practice in the performance of the official controls;

- The guidelines laid down in Commission Decision 2006/677/EC have been taken into account and arrangements in place ensure independence of the audit process as well as independent scrutiny of the audit system. In addition, the extensive arrangements in place to ensure transparency of the audit process can provide assurance on its performance to both internal and external stakeholders;

- The audit system has the ability to identify areas for its own improvement and to take action to make such improvements, in order to ensure that the auditing arrangements continue to develop to better “add value” to the organisation;

- Auditing arrangements in place can provide credible, reliable results and systematic follow-up arrangements can demonstrate the effectiveness of actions taken in the light of those results.

7 CLOSING MEETING

A closing meeting was held on 22 January 2016 with the CCA. At this meeting the DG SANTE audit team presented their preliminary conclusions and confirmed the time limits for production of the report and the CA response.

The representatives of the CCA accepted the conclusions presented by the audit team.

8 RECOMMENDATIONS

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| 1.  | The competent authorities responsible for controls on animal welfare should ensure that adequate audit arrangements are put in place to achieve the objectives of Article 4(6) of regulation (EC) No. 882/2004 and that appropriate measures are taken in the light of the results of those audits.  

*The recommendation is based on conclusion No. 14.*  

*Associated findings No. 5 and 13.* |

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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