EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2017-6020

FINAL REPORT OF AN AUDIT
CARRIED OUT IN
HUNGARY
FROM 03 APRIL 2017 TO 07 APRIL 2017
IN ORDER TO
EVALUATE THE SYSTEM PUT IN PLACE TO IMPLEMENT ARTICLE 4(6) OF REGULATION (EC) NO 882/2004 (NATIONAL AUDIT SYSTEM)

Executive Summary

This report describes the outcome of an audit in Hungary carried out from 3 to 7 April 2017. 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 the arrangements in place achieve the objectives of Article 4(6) of Regulation (EC) 882/2004. Internal audits in Hungary provide assurances to (a) the hierarchy on management of risks, (b) stakeholders on the quality of controls and (c) the European Commission on the operation of internal audits.

Auditing arrangements in place provide credible and reliable results in the areas within the scope of Regulation (EC) 882/2004. The audit process is systematic and goes beyond simply verifying compliance with planned arrangements by verifying their effective implementation and suitability to achieve the objectives of legislation. The audit system could better add value and improve the achievement of the objectives of Article 4(6) of Regulation (EC) 882/2004 by better disseminating best practices and other audit results.

The audit body aims to continuously improve its audit system, although independent scrutiny by ISO 9001 certification does not take into account the specific objectives of Article 4(6) or the more general objectives of Regulation (EC) 882/2004.

The report contains one recommendation to the competent authority of Hungary to address the shortcomings identified.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
CA	Competent Authority
DG SANTE	The European Commission's Directorate-General for Health and Food Safety
EU	European Union
MANCP	Multi-annual National Control Plan
NAS Network	The network of member states national experts on National Audit Systems, hosted by DG Health and Food Safety
NFCSO	National Food Chain Safety Office
QMS	Quality Management System (for official controls)

1 INTRODUCTION

This audit took place in Hungary from 3 to 7 April 2017 as part of the published Directorate-General for Health and Food Safety (DG SANTE) audit programme. The audit team comprised two auditors from DG SANTE, one national expert from another Member State, one observer from European free trade association surveillance authority and one observer from Australia.

The opening meeting was held on 3 April 2017 with the National Food Chain Safety Office (NFCSO), in particular with the Supervision Unit of the Directorate for System Management and Supervision which is in charge of the internal audits required by Article 4(6) of Regulation (EC) No 882/2004 in Budapest. 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, SCOPE AND AUDIT CRITERIA

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[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 NFCSO.

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 Network Reference Documents produced by the Network of Member States National Experts

[1] Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, Official Journal L 165, 30.4.2004, pages 1 to 141, corrected and re-published in OJ L 191, 28.5.2004, pages 1 to 52.

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

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 European Union (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 AUDITS

Detailed information on the structure and organisation of the Hungarian Competent Authorities (CA), including a follow-up status valid as of January 2017, can be found in the Country Profile for Hungary at:

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

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

http://ec.europa.eu/food/audits-analysis/audit_reports/index.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 sectorial audits carried out since 2006 as well as the general audit carried out in 2008-2009 (reference number DG(SANCO)/2009-8346).

At the time of writing, there were no open recommendations to Hungary 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 CA, responsible for the performance of audits of official control systems as provided for by Article 4(6) of Regulation (EC) No 882/2004. The Network meets regularly, under the chairmanship of, and facilitated by, DG SANTE to exchange experiences in implementing national audit systems on official control activities. 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, 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
- Root cause analysis, November 2016 – version 1

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

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

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

To verify:

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

- *Compliance of official controls with planned arrangements at a national level, which may include:*
    - *Control plans of any kind (MANCP, business-, operational-, control-, monitoring-plan etc.) with the purpose of giving effect to legal requirements.*
    - *Policies, strategies, procedures, guidelines.*

To evaluate:

- *Suitability of the planned arrangements in achieving the objectives of Regulation (EC) No 882/2004.*
- *Effectiveness and consistency of the implementation of planned arrangements i.e. the capability to deliver the planned outcomes.*
- *Whether enforcement measures are effective, proportionate and dissuasive.*

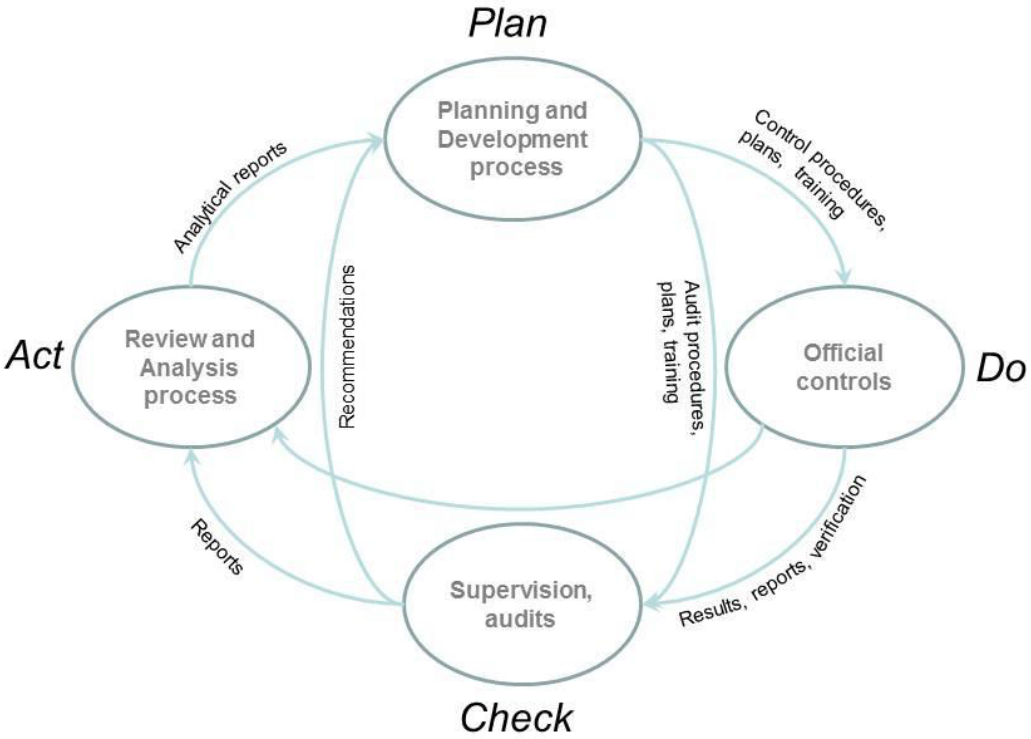
To identify:

- *Areas for improvement in the CA control and management systems.*
- *Audits may also play a supportive role in risk identification and analysis."*

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

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

"To ensure high quality of official controls…" (from preamble 14)
"…*in verifying compliance with legal requirements" (from preamble 6, Article 1)*
Ensuring implies application of the PDCA cycle:



Quality consists of:

- *Uniformity of controls and decisions (from preambles 12 and 14).*
- *Consistency of controls (from preamble 14).*
- *Effective risk-based targeting of controls (Article 3.1).*
- *Reliable detection of non-compliance.*
- *Turning non-compliance into compliance, when detected (Articles 54, 55)."*

4.3 METHODOLOGY

The evaluation process consisted of:

- an initial desk study phase in which the relevant information already available in DG SANTE was collated and analysed. This included the Hungarian Multi-Annual National Control Plan and associated Annual Reports, the Country Profile of Hungary and sectoral audit reports;
- examination of certain documentation provided by the NFCSO prior to the audit; and
- meetings with the NFCSO in Budapest. During these meetings, the audit team evaluated arrangements in place and verified their application through examination of a variety of evidence, including documentation of the programme development and for a number of audits.

Observing the performance of individual auditors was not included in the scope of this audit as the audit team considered that the effectiveness of an individual audit can be better judged in the context of relevant DG SANTE 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 NFCSO 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."*

5.1.2 Findings

5.1.2.1 Responsibility for official controls

1. The Ministry of Agriculture is responsible for all official controls under the scope of Regulation (EC) No 882/2004. Within the Ministry, the NFCSO is in charge of coordinating and managing the controls, which are carried out by County and District Government Offices.

2. The country profile of Hungary describes the structure of the CA and the organisation of official controls. It is accessible at: http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=HU

5.1.2.2 Responsibility for and coordination of audits of official controls

3. Within the NFCSO, the Supervision Unit of the Directorate for System Management and Supervision is in charge of internal audits.

Conclusions

4. Responsibilities for carrying out audits on official controls have been clearly allocated.
5. As there is only one audit body, there is no need for coordination of audit programmes.

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':

"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."

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

6. The objectives, mandate, powers and responsibilities of the audit body is are provided and documented in the organisational and operational rules (ministerial decision 1/2013), quality management handbook, audit procedure, job description for auditors and credentials for the auditors.

7. Organisational independence is provided by placing the audit function (Technical Supervision Department) in the System Management and Supervision Directorate, which reports directly to the president of NFCSO.

8. General objectives for internal audits are described in the quality management handbook. The handbook emphasises the need for up-to-date information on the operation of official controls, risk-based targeting of audits and the importance of continuous improvement.

9. Functional independence is ensured by providing qualified and competent staff (see paragraphs 17-21), sufficient funding and continuous professional development and access to independent technical experts as well as procedures for managing conflict of interest.

10. The audit body develops its audit programme as well as audit scope and objectives of individual audits. Audit procedure ensures that auditees do not have undue influence on audit reports and that the overall independence of the audit process is maintained. The audit team reports directly to the senior management of the auditee; any differences of opinion between auditors and auditee should be resolved before the final report is issued. If a consensus is not reached, and in order to resolve any difference of opinion without compromising the independence of the audit process, the auditee has the right to attach his/her opinion to the final report.

11. The recruitment and rotation mechanisms are suitable to maintain a pool of auditors with an independent mind-set. The auditors interviewed during this audit showed a clear understanding of what is meant by objectivity.

12. The auditors are also involved in audit activities outside the scope of Article 4(6) of Regulation (EC) No 882/2004 or in routine and annual audits of organic certification bodies.

Conclusions

13. Mechanisms are in place to ensure independence of the audit process, thereby contributing to the objectivity and credibility of audit results. These mechanisms are sufficient to provide assurances on organisational, functional, audit process and auditor independence and subsequently, confidence in the objectivity 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."

The network document on independent scrutiny further explains the objectives by way of spelling out the expected output and outcome of this process:

- *Output: an opinion on effectiveness of the audit process, independence of the audit body/auditors and a report identifying best practices and areas for improvement; and*
- *Outcome: confidence for the audit body, CA management and other stakeholders that the internal audit through the audit process is meeting the objectives of Article 4(6) of Regulation (EC) No 882/2004.*

5.2.2.2 Findings

14. Independent scrutiny of the audit process is provided by a certification body, which certifies that the audit body complies with the standards ISO 9001:2008 and ISO 19011:2011. This arrangement provides assurances that internal audits are systematic, consistent, carried out according to the planned arrangements (including ISO 19011 guideline) and that audit process is subject to continuous improvement. However, they do not meet one of the objectives, which is to systematically (and explicitly) evaluate the audit process' effectiveness i.e. capability to provide assurances on official controls' achievement of the objectives of Regulation (EC) No 882/2004.
15. While the audit team could confirm that this independent scrutiny is professional, detailed and provides assurances on the generic elements of a quality management system of an audit body, this scrutiny evaluates the performance against the quality policy statement as described in the quality manual. Neither the audit report nor the certificate provide statements that would ascertain the effectiveness of the audit process in achieving the objectives of Article 4(6) of Regulation (EC) No 882/2004.

Conclusions

16. Although the current independent scrutiny arrangements can provide assurance in relation to many aspects of the implementation of Article 4(6) of Regulation (EC) No 882/2004, the confidence provided to the management and stakeholders only extends to compliance with the relevant ISO standards and achievement of the audit body's own quality policy statement.

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

17. Auditor recruitment starts with a call for interest, which normally results in a relatively large number of applicants. This ensures that the audit body can choose new recruits from a pool of sufficiently qualified candidates.

18. The qualifications for auditors are defined in the quality management handbook:

- personal characteristics – in line with ISO19011 requirements;
- higher level education (university degree);
- qualifications related to their activities as auditor; and,
- at least three years years of work experience in public administration.

19. The audit body provided evidence of basic and continuous professional training of the auditors, and documented evidence that all of the competences listed in section 6.6 of the Annex to Commission Decision 2006/677 are well maintained. Training is based on individual needs and covering all aspects of the audit process – including "soft skills" expected from an auditor.

20. All auditors have also participated in Better Training for Safer Food training for auditors and further disseminated the knowledge obtained from these courses.

Conclusions

21. Adequate procedures are in place to ensure that auditors have sufficient competence to perform their duties and that they can maintain and further develop their auditor

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."

The network document "risk-based planning of audits on official controls" explains the audit experts' common understanding of the objectives of risk-based planning:

The main objective of risk-based planning of audit programmes is to contribute to consumer safety, animal health and welfare, plant health and increase stakeholder confidence in effective and efficient use of resources. This is achieved by ensuring that:

- *Audit universe(s) do not overlook any relevant areas;*
- *Planning processes are able to identify and categorise main risks appropriately;*
- *The whole process is subject to regular review; and*
- *Audit bodies (in case there are several) coordinate their planning processes.*

5.2.4.2 Findings

22. The NFCSO uses an audit universe as defined in the network document on risk-based planning of audits:

> *"An inventory of all audit areas relevant to responsibilities of CAs that is compiled and maintained to identify possible areas for audit during the audit planning process. The list should include all official control and key food, feed, plant health, animal health and animal welfare systems that could be audited as part of the overall cycle of planned work (including delegated bodies). The audit universe serves as the source from which the risk assessment for the five-year audit planning and the annual audit planning are performed."*

The audit universe consists of 8 horizontal topics (e.g. laboratories, IT systems, training) and 44 sectoral areas covering e.g. plant health, food safety, feed, animal health and welfare, organic production and residues of veterinary medicines and plant protection products. It also includes topics, which are not within the scope of Regulation (EC) No 882/2004.

23. The annual audit programme is based on a multi-annual programme, which currently covers the years 2016-2020. The annual programme (as well as the audit universe) is reviewed each year before starting the approval process. The annual planning process starts in November each year and spans a period of 1- 1.5 months.

24. The 52 topics in the audit universe are ranked according to their risk as follows:

    - The likelihood of three risk factors (shortcomings in official controls, incomplete regulation and lack of information) are scored on a scale of 1-5 for each topic.

- The potential impact of these risk factors on consumer health, plant health, environment, economic interest and reputation/trust is then scored similarly on a scale of 1-5.
- Impacts are then multiplied by the likelihoods – this provides a risk-score from 1 to 25 for each potential impact.

The risk-scores are then added up, giving a total score on a scale from 1 to 400 for each of the 52 topics in the audit universe.

25. The audit universe is divided into five categories according to the total risk score. A total of 35 topics fall into categories 1-2 (scores 1-160), 17 topics into categories 3-4 (scores 161-320) and none into category 5 (scores 321-400).

26. The process is capable of producing a programme of audits covering the scope of Regulation (EC) No 882/2004 within a 5-year cycle.

27. The planning process is continually improved and contributes towards the objectives outlined in the network document on "risk-based planning for audits of official control systems". According to the information provided to the audit team, this year it was decided not to change the topics covered. Individual areas will however be reviewed at the end of this year, in line with the new structure and development of the plan.

Conclusions

28. The risk-based planning of audits achieves the objectives and follows the principles laid down in the network document on risk-based planning of audits of official control systems. This contributes to confidence that the planning process is able to identify and categorise main risks appropriately and that the audit process does not overlook any relevant areas.

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. It defines the concept of effectiveness as follows:

Effectiveness*: is the extent to which official controls produce an (intended) effect / achieve an objective. In this particular context the objectives are those of Regulation (EC) No 882/2004. Effectiveness is not to be confused with efficiency, which is normally used when we want to refer to input-output ratio i.e. cost and/or resources required to produce an output.*

For further details on the objectives of Regulation (EC) No 882/2004 and in particular, objectives of Article 4(6), see section 4.2 above.

5.2.5.2 Findings

5.2.5.2.1 Documented Procedures

29. Audit process, including audit planning, execution and reporting were well documented and the audit team could review documentation of all stages of the process from the internal document management system.

30. The audit team found evidence of effective implementation of the documented procedures and followed through several sample audits to verify this.

5.2.5.2.2 Compliance with planned arrangements

31. The audit body successfully included the verification of compliance with planned arrangements in their audits. This was evident from both planning documents for individual audits as well as from the audit reports.

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

32. Audit records provided evidence that verification of effective implementation and suitability to achieve objectives are built into the design of audits consistently and according to the guidance provided by the relevant network document.

5.2.5.2.4 Audit reporting

33. Suitable documented procedures – including report templates – were in place for reporting the findings and conclusions of audits. There are procedures for report drafting and approval, including provision for auditees to comment on draft reports and the subsequent distribution of the reports.

34. The audit team found evidence that these procedures were implemented in practice – all audit records studied by the audit team indicated that the procedures are followed consistently.

35. In some cases, audit reports were "balanced" – providing positive feedback as well as areas for improvement and recommendations. In other cases, only non-compliances and deficiencies were reported.

36. In general, audit reports are considered strictly confidential i.e. between the auditor/audit body and the management of the auditee.

5.2.5.2.5 Review of audit conclusions and dissemination of best practice

37. Individual audit engagements are systematically reviewed and quality of the reports monitored. However, there are no explicit, systematic mechanisms for disseminating positive findings (good/best practice).

5.2.5.2.6 Monitoring and review of the audit process

38. The audit team found evidence of management review resulting in corrective action and improvements to the audit process.

39. Feed-back from auditees is also used for reviewing the audit process. The audit body has found a feed-back mechanism useful in monitoring auditors' performance and has taken corrective actions based on the results.

40. The following mechanisms for review (and feedback) are also in place:

- following audits and observing performance;
- monitoring of quality management system (QMS) process indicators; and,
- management review may also consider suggestions and/or complaints from the field.

Conclusions

41. Overall, the audit process is systematic and has been implemented effectively, in line with Commission Decision 2006/677/EC and relevant network documents. The audit process is in general capable of achieving credible and reliable audit results.

42. The audit body has procedures in place to ensure that audits verify compliance with planned arrangements effectively and in a systematic manner. Similarly, the audit process verifies systematically effective implementation and suitability of planned arrangements in achieving objectives.

43. Audit reporting procedures ensure clear reporting of relevant audit results. Dissemination of audit findings is limited to the auditee and to the top management of the NFCSO. The opportunity for others (than auditees) to learn from both positive and negative audit findings is not systematically availed of. This limits to some extent the impact that audits can have on continuous system improvements and it is a missed opportunity to have impact also beyond the auditee.

44. Review of the audit process takes place both at individual audit engagement level and at the annual audit programme level. This contributes to the credibility and improvement

of the audit process.

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

45. Audit reports identify non-compliances and generally try to classify them into critical and non-critical. Recommendations are implicit – when a non-compliance is identified, the auditee is expected to address it.

46. The auditee is responsible for proposing the most appropriate corrective action and identifying the root-cause for non-compliance, as appropriate.

47. The audit team found evidence that the follow-up procedures are applied in practice, and could confirm that generally, corrective action takes place. In the cases when it does not take place, management review is able to capture this and take follow-up measures.

Conclusions

48. Arrangements are in place to ensure that the auditee takes appropriate action in the light of audit findings. This contributes towards achieving one of the main objectives of Article 4(6): continuous improvement. It also adds to the credibility of the audit process and consequently contributes to stakeholder confidence.

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

49. All relevant documentation related to audits is available to the auditee: audit procedure, audit schedule, annual audit plan and the audit report, which is normally drafted on the spot and presented to the auditee at the end of the audit day. Audit reports remain with the auditee and are not distributed any further.

50. An annual audit report is prepared every year, and a summary of it is part of the Chief Veterinary Office report as well as of the annual MANCP report available at: http://portal.nebih.gov.hu/web/guest/-/legfrissebb-jelentes-itnet-jelentes.

Conclusions

51. Appropriate arrangements are in place to ensure sufficient transparency with the auditees to promote confidence in and collaboration with the audit process. This facilitates the internal audits in achieving their audit objectives and contributes to the objectives of Article 4(6).

52. Arrangements are in place for providing external stakeholders an overview on audit activities and their results.

5.3 CHALLENGES REPORTED BY THE COMPETENT AUTHORITY

53. The NFCSO did not report any particular difficulties in implementing the audit system.

6 OVERALL CONCLUSIONS

Overall, the report concludes that the arrangements in place achieve the objectives of Article 4(6) of Regulation (EC) 882/2004. Internal audits in Hungary provide assurances to (a) the hierarchy on management of risks, (b) stakeholders on the quality of controls and (c) the European Commission on the operation of internal audits.

Auditing arrangements in place provide credible and reliable results in the areas within the scope of Regulation (EC) 882/2004. The audit process is systematic and goes beyond simply verifying compliance with planned arrangements by verifying their effective implementation and suitability to achieve the objectives of legislation. The audit system could better add value and improve the achievement of the objectives of Article 4(6) of Regulation (EC) 882/2004 by better disseminating best practices and other audit results.

The audit body aims to continuously improving its audit system, although independent scrutiny by ISO 9001 certification does not take into account the specific objectives of Article 4(6) or the more general objectives of Regulation (EC) 882/2004.

7 CLOSING MEETING

A closing meeting was held on 7 April 2016 with the CA. At this meeting, the audit team presented their main findings and preliminary conclusions.

The representatives of the CA did not express any disagreement to the main findings and preliminary conclusions as presented by the audit team.

8 RECOMMENDATIONS

No.	Recommendation
1.	To ensure that independent scrutiny achieves the objectives of Article 4(6) of Regulation (EC) No 882/2004. In particular, to ensure that the body providing independent scrutiny provides assurances that the audit body is capable of

No.	Recommendation
	evaluating whether official controls achieve the objectives of Regulation (EC) No 882/2004. *Based on conclusion (16), and associated findings (14) and (15).*

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2017-6020

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004 - Article 45 (MS)	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Dec. 2006/677/EC	OJ L 278, 10.10.2006, p. 15-23	2006/677/EC: Commission Decision of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules