BTSF Initiative

Organisation and implementation of training activities on audit systems and internal auditing under the "Better Training for SaferFood" initiative

SYLLABUS

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BACKGROUND

Regulation (EU) No 2017/625 covers official controls performed in Member States of the EU to ensure the verification of compliance with feed and food law, plant health, animal health and animal welfare rules. This regulation provides for a management system for official controls, setting out the requirements that the various elements of this management system must meet in order to allow for the delivery of effective controls of consistently high quality and applied uniformly in the EU. The Regulation further requires, under Article 6, for national Competent Authorities to develop appropriate National Audit Systems (NAS) for the independent auditing of their official controls in the areas of food and feed, animal health and animal welfare. Effective implementation of Article 6 is an essential element in the management of the national official control systems in Member States. It checks that arrangements in place achieve the objectives of the control system (as outlined in the Member States Multi Annual National Control Plan (MANCP)) and also promotes continuous improvement.

The implementation of this requirement is guided by Commission Notice 2021/C66/02 which set out guidelines for conducting internal auditing of official controls as required under Regulation (EU) No 2017/625 and reflects international bodies' standards and recommendations regarding the organisation and operation of official services. This decision provides guidelines to assist Member States in the implementation of Article 6 of Regulation (EU) No 2017/625.

A well organised and effectively managed NAS within the EU control system will produce wide ranging benefits including:

- Enhancing confidence that a high level of food and feed safety and animal health is in place within the EU;
- Ensuring that official controls in the EU control system are performed in an effective and efficient manner across all relevant food, feed and animal sectors with best use of resources in that Member State;
- Assisting the EU Commission in the prioritisation process entailed in developing their annual risk based inspection programme.

Since 2015 the European Commission's Directorate-General for Health and Food Safety has audited 27 Member States to evaluate the systems which they have put in place to implement Article 4(6) of Regulation (EC) No 882/2004 (now repealed by Regulation (EU) No 2017/625). Overarching conclusions contained in the 2017 interim report (DG(SANTE) 2017-6256) and 2018 Overview report (2018-6810) on these audits demonstrated the strong link between effective implementation of Article 4(6) and the achievement of consistent and effective official controls: "those competent authorities with well-organised audit systems had effectively implemented audits of official controls and could demonstrate that their audit process contributed to ensuring the quality, and improving the consistency and effectiveness of official controls, provided that there was strong management commitment to the follow-up of audit recommendations".

In addition, it is recognised that the NAS of many Member States are in the development stage and the interim report concludes that "Member States are still experiencing some challenges in organising,

implementation and/ or following up audit of official controls". Optimisation of audit arrangements to enhance credibility and reliability of controls remains a challenge for some Member States as also ensuring independent scrutiny and effective follow-up of audit results. In particular, the 2017 interim report also highlights best practices which are in place in a number of Member States.

Based on the above, this training aims at:

- providing knowledge on the requirements of Article 6 of Regulation (EU) No 2017/625 and practical solutions for consistent and effective implementation;
- discussing in depth the current challenges experienced within the EU control systems in implementing Article 6 of Regulation (EU) No 2017/625 and solutions to overcoming these challenges;
- providing knowledge on how to ensure a minimum quality level for NAS;
- ensure that participants understand the difference between pure compliance audit and performance audit;
- sharing of best practices from Member States representatives' experiences.

KEY ISSUES

Key issues that have been taken in consideration for the preparation of the programme and training materials are:

- Current challenges of Member States in setting up and implementing NAS (DG SANTE report, 2017-6256-MR)
- Importance of the review of the audit programme for continuous improvement
- How the NAS link with MANCP
- Differentiate between compliance audit and audits focused on checking the effectiveness of official controls and the performance of the auditee
- Independence, independent scrutiny and transparency
- Root cause analysis
- The capacity of audit services to improve audit procedures both through the results of day-today activities and through the outcomes of independent scrutiny
- Auditor competence
- Measuring effectiveness of official controls

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CONTENTS OF THE TRAINING COURSE 2

Pre-recorded material in advance of training: Background, review of the legal framework and the audit process

1. Course Background and Objective

Participants are provided with an outline of this advance level course, the background to the course and objective to be achieved.

2. Recap on EU Legal Framework, NAS Reference Documents and International Standards

Participants are then provided with a recap of the legal framework, which governs the independent auditing of official controls of food, feed, animal health and animal welfare by competent authorities. This section covers why Member States are legally obliged to establish and implement a NAS. Participants are briefed on Regulation (EU) No 2017/625 with a particular focus on Article 6 on Audits. Participants are also reminded of the relevant Commission guidance which assists Member States in meeting the key requirements of Regulation (EU) No 2017/625 which applyto internal auditing.

Participants are then briefed on the NAS reference documents produced by the National Audit Systems Network during the period 2014-2016. Many Member States have advised DG SANTE of the benefits of these reference documents in the setting up and implementation of their NAS, in particular:

- NAS reference document on Independence and Independent Scrutiny;
- NAS reference document on Risk based planning for audits of official control systems.

The various international auditing bodies and standards which are used widely in competent authorities are then presented e.g.:

- ISO 19011:2018—Guidelines for auditing management systems
- The Institute of Internal Auditors - guidance on internal auditing

During this topic questions are posed to the participants using the ARS to verify the level of understanding of the presented topics.

3. Recap on audit process and organisation of the audit system. Principles of risk based planning of audits, consideration of risks in individual audits, developing risk criteria

The principles of risk based planning of audits are then presented to the participants. This material covers the four main stages (establishing the audit universe, defining the risk universe, producing the audit programme and the review of the audit process) and covering other essential considerations such as the risks in individual audits, developing risk criteria, audit scheduling etc. This material prepares the participants for a number of questions on this topic at the end of the session.

Day 1. Risk Based Audit Programming, Risk Based Audit Programming

4a. Risk based audit programming

During this session, participants will be asked a number of questions on specific elements of risk based programming and asked to share their experiences and discuss practical solutions to challenges (e.g. achieving adequate coverage, justification of audit selection, identifying risk presented by nature of activities and commodities, review of audit programme, transparency in planning process).

Day 2. Risk Based Audit Programming, Independence and Effectiveness of Official Controls

4b. Group Work

During this session, participants divided in groups will engage in a simulation exercise to use the information just covered on risk-based audit programming to:

- Risk score a number of audit topics based on information provided by (i) considering and scoring the **probability** of failure of the control system and (ii) considering and scoring the **impact** of the failure of the control system. Each audit topic will then be categorized as high, medium or low risk.

Independence and Independent Scrutiny

5. Independence and Independent Scrutiny of the Audit Process

Participants are presented with presentation on Independence and Independent Scrutiny of the Audit Process.

During this session, participants engage in a discussion on practices adopted in their own countries to address independence and independent scrutiny of the audit process and share experiences and present practical solutions to particular challenges.

Verification of Effectiveness

6a. Verification of the Effectiveness and Suitability of Official Controls

Overall conclusions from the 2018 DG SANTE Overview report highlighted that some national audit services in Member States found it challenging to demonstrate that audit conclusions in relation to effective implementation and / or suitability of planned arrangements were arrived at in a systematic way". For this reason, this part of the course will focus on effective implementation.

Firstly, in Item 6a, participants will be presented with theory on the verification of the effectiveness and suitability of official controls. This includes what areas which the internal audit should focus on in order to assess the effectiveness and suitability of official controls being audited.

6b. Group Work: Measuring the effectiveness of official controls

Participants are asked to work in groups and discuss their experiences in relation to the assessment of the quality of official controls, the importance of data collection and analysis and the use of objectives and indicators.

Day 3. Audit Preparation, Evidence based findings Audit Process - Practical activity on Audit Preparation

7a. Group work on development of audit plan

Participants will work in groups to develop an audit plan in the area of food labelling.

7b. Group work on audit checklist development

Following the group work in 7a, participants will continue in work group to develop an audit checklist appropriate for a specific audit scope, criteria and objective provided.

Evidence based Findings - Audit Evidence

8a. Audit evidence and Sharing of experience on Audit evidence. Evidence based Findings and Forming Conclusion: Presentation.

The topic of audit evidence, audit findings and audit conclusions are covered in this session. Firstly, audit evidence is covered, in particular audit evidence definition, sources, techniques, and audit generation with some examples is presented. Following this the topic of audit findings is covered, particularly focusing on the generation of audit findings from audit evidence. Lastly, the formation of audit conclusions from audit findings is covered with examples for each of the above presented.

8b. Group work: Audit Evidence. Evidence based Findings and Forming Conclusion

The objective of this group work is to introduce participants to collect evidences and generating audit findings and conclusions. Participants are presented with information and asked to identify audit evidence, form audit findings and generate audit conclusions relating to the effectiveness of official controls, compliance with planned arrangements and suitability of official controls.

Day 4. Root Cause Analysis, Conclusions and Recommendations, Audit Reporting

Audit Findings - Root Cause Analysis

9a. Group Discussion

Participants will discuss their views and experience in relation to the methods, usefulness and applicability of root cause analysis during the internal auditing process.

9b. Group Work

Participants engage in a practical exercise to conduct a root cause analysis for findings from an audit evaluating official controls related to the food safety. Participants determine the possible underlying cause and suggest an appropriate system wide measure to address the cause of the problem.

Recommendations and Action Plans

10. Group Work

Participants engage in a practical exercise to form suitable recommendations and action plans based on information provided.

Audit Reporting & Dissemination

11a. Presentation and Group Discussion

The objective of this presentation is to give participants an insight into the requirements regarding audit reporting and dissemination. It will engage the participants in discussing:

- The preparation of the audit report
- The approval and distribution of the audit report (nationally, regionally), and
- How the audit report fits into the internal audit process.

The presentation will then focus on the audit report, namely:

- Requirements/purpose of an audit report
- Appropriate section of Regulation (EU) No 2017/625 to report on
- Audit conclusions and audit recommendations and how to address them
- Structure/focus of an audit report.
- Top Management involvement in audit report sign off (significant-how final reports are perceived by auditees)
- How to deal with auditee's dissatisfaction with the draft report
- How to disseminate the audit report / Availability of audit reports to the public

Participants will have the opportunity to discuss the top management involvement with the audit report and how to manage differences of opinion (e.g. if the auditee is dissatisfied with the draft report). Finally, the dissemination of the audit report will be discussed.

11b. Group Work

In Session 11b, a practical exercise on audit reporting (based on informationprovided) will be outlined to participants. Participants can complete this after the training as an additional exercise.

Day 5. Audit Management and Review, Wrap-up, Conclusions

Audit Management and Review

12a: Measuring the effectiveness of official controls

To prepare for this topic, participants will have listened to a pre-recording outlining findings from a DG Sante audits on the 'effectiveness of official controls' in Ireland and in particular the procedures and best practices in place within the National Food Control System in Ireland which demonstrates effectiveness of official controls.

For this session participant will be encouraged to share the experiences from their own member states in this topic and provide **examples of structures such as coordination mechanisms, supervisory checks, data** use etc. to ensure effectiveness of official controls.

12b. Group Work. Audit Management and Review.

Participants are briefed on audit management and review and the PDCA cycle. Following this, participants will engage in a practical exercise to review an audit process based on information provided and make suggestions for improvements.

Dissemination

The final activity of Course 1 is a session on Dissemination. There will be a presentation on the important topics of Course 1 which the participants should focus on to present to their colleagues in their own organization. Following the presentation there will be a brainstorming session on how and when the dissemination can take place.

FAQ

Q1: How many times do you have to do an audit in an organization?

A1: Commission Notice 2021/C66/02 sets out a guideline that the audit programme should ensures adequate coverage of all relevant areas of activity and all relevant competent authorities within the sectors at an appropriate risk-based frequency **over a period not exceeding five years.** In some cases some very low risk areas are not included for an audit in the five year audit programme, however these very low risk areas must always be discussed within the audit programming process as they form part of the audit universe.

Q2: Is Commission Notice 2021/C66/02 a guideline?

A2: Yes, Commission Notice 2021/C66/02 is a guideline (and therefore not legally binding). As the internal audit structures for member states are vastly different this document acts as a guidance document for assisting MS on how to set up and implement their internal audits functions under Article 6 of Regulation (EU) No 2017/625.
This guideline is currently under review and will be replaced with a new guideline document following the recent introduction of Regulation (EU) 2017/625 which recently replaced Regulation (EC) No 882/2004. The title of this new guideline will no refer to Commission Decision which currently is confusing for the reader with regard to the legal status of the document.

Q3: Are ISO standards legally binding?

A3: ISO standards and Commission Notice 2021/C66/02 are not legally binding but does serve to provide useful guidance to the Member States in the implementation of Regulation (EU) No 2017/625. However, it can be obligatory if a legislative act requires application of a specific standard or guideline.

Q4: Should there be a documented procedure of how to review an audit system?

A4: Yes, the entire audit process should be have documented instructions on how to conduct the specific step. Documented procedures are important for consistency in the auditing process. The review procedure should include elements of the audit process which must be reviewed, who is responsible and frequency of the review process. Specifically, Commission Notice 2021/C66/02 outlines that the audit process should 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.

Q5: What's the difference between recommendation and non-compliance?

A5: A non-compliance detected during an audit refers to the non-fulfilment of a specific requirements from the audit criteria (e.g. legislation requirement, documented procedure, microbiological or chemical criteria). Recommendation refer to the actions which is proposed in order

to address this non-compliance and which should result in the non-compliance not happening in the future.

Q6: Should most of the findings be discussed with relevant people prior to the closing meeting?

A6: It is important that there are no surprises at the closing meeting. To avoid this, it is important that findings are brought to the attention of the relevant person as the audit progresses.

Q7: How do you feel about 'declaration of problems' at the opening meeting?

A7: This sounds very formal and requesting this at the opening meeting may make the auditee nervous. It may be better just to ask at the opening meeting if there are any issues of concern that the auditee would like to make the audit team aware of.

Q8: Should we ask for audit evidence in advance of the audit?

A8: Yes, the auditor can ask for documentation/information etc in advance of the audit. However, it is sometimes important not to give a direct indication of the exact files which you intend to audit e.g. inspections reports, establishment records etc.

Q9: Are there any rules on what is 'sufficient evidence'?

A9: Logic needs to dictate what is sufficient evidence in an audit. There is a need to strike a balance with time needed to gather further evidence and the resource constraints (time available to complete the audit). The important thing is that the auditor feels comfortable with the amount of evidence obtained in order to present an audit finding based on this evidence.

Q10: How should non-tangible evidence be recorded? If there is only non-tangible evidence available should the auditor give up on this issue?

A10: Take notes of interviews i.e. names, location, dates and details of the comments made by the auditee. If all parties agree to recording the discussions, then this method is acceptable. Always get permission before taking photos.

Q11: How is a difference of opinion (between auditor and auditee) treated in the final report?

Generally, differences of opinion should be discussed during the audit and attempts should be made to resolve these differences before the closing meeting. However, if there is a difference of opinion and it cannot be resolved prior to the final report being issued then the report should acknowledge the difference of opinion.

Q12: At the closing meeting when trying to agree what are the required corrective actions to be implemented, what happens of the auditee needs to do a root cause analysis in order to agree the corrective action?

A12: The lead auditor should understand where this is necessary and agree with the auditee a specified date for the auditee to complete this and subsequently agree the corrective actions.

Q13: How should we agree on the timeframes for close out of corrective actions?

A13: Use your experience to evaluate if the auditee is not being reasonable. Sometimes close out of corrective actions can take a long time as the close out may relate to resource issues e.g. extra staff need to be recruited which can take a lot of time.

Q14: Does the audit universe include all audits of food businesses that the competent authorities will carry out.

A14: The audit universe relates to all audits carried out by the audit body, under Regulation (EU) No 2017/625. It does not relate to the food business audits.

Q15: During management review does the top manager e.g. CEO actually carry out the review?

A15: Generally, this task will be delegated by the CEO to a senior management group and will then be signed off by the CEO.

Q16: An issue with the a particular control sector is discovered and this sector is not included in the audit schedule for the current year. At what stage should the audit programme be amended?

A16: The decision to amend the audit programme to include this new sector should be based on risk. If there is a risk to human health, then it is recommended that the audit programme is changed immediately and that this sector is audited as soon as possible. Otherwise the audit programme should be amended soon as is feasible (this may be at the audit review stage).

Q17: Does adequate coverage in the DG Sante Interim report on NAS refer to thematic coverage or geographical coverage?

A17: Adequate coverage refers to the coverage of all the themes within the audit universe. An audit programme must ensures adequate coverage of all relevant areas of activity and all relevant competent authorities within the sectors covered by Regulation (EU) No 2017/625 at an appropriate risk-based frequency over a period not exceeding five years. These sectors should be risk categorised and the appropriate frequencies of audits determined from this. The geographical locations of the competent authorities and activities should not be a factor in the risk categorisation.

Q18: Independence:

- **How can the audit team maintain independence when the internal audits units are very small and auditors may audit the same unit which they have oversight of?**
- **Is it correct to audit in the area in which you are expertise, and in which you have some management responsibilities?**
- **Are there solutions for small countries which struggle with independence?**

A18: The area of maintaining independence is challenging for very small member states (e.g. Malta) and small organisations. In many cases, particularly in small organisations, independence can be demonstrated by the freedom from responsibility for the activity being audited or freedom from bias and conflict of interest." (ISO 19011:2011 – definition of audit, note 1). Wherever practicable, auditors should be independent of the activities audited and should in all cases act in a manner that is free from bias and conflict of interest. Internal auditors should be independent from the operating managers of the function being audited.(ISO 19011:2011 Clause 4 (e)).

An example of a solution from a small CA in Ireland: A system of peer-to-peer auditing has been developed and progressively implemented in one small competent authority in Ireland since 2010. In this case there are approximately 28 small competent authorities with one veterinary inspector in each CA. To address challenges with internal audit requirements and the need for independence, each of these CA is audited by another of the 28 CAs.

Q19: What is the difference between the following a (i) first party audit (ii) second party audit and (iii) third party audit?

i. First part audit: Conducted by organization itself by management review; confirms the effectiveness of QMS, obtains information for improvement, etc. Example: internal audit.

ii. Second party audit: Conducted by parties having an interest in the organization, such as a customer's auditing a supplier, etc.

iii. Third party audit: Conducted by independent auditing organizations, such as regulators or certification bodies (e.g. DG Sane Audit of Member States competent authority).