RISK-BASED PLANNING OF AUDITS OF OFFICIAL CONTROL SYSTEMS

The network of national audit experts has produced this non-binding reference document based on agreed good practices to provide guidance on risk-based planning of audits of official control systems

National Audit Systems Network

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The National Audit Systems (NAS) Network

The NAS network is a network of officials from Member States, responsible for the performance of audits of official control systems as provided for by Article 6 of Regulation (EU) 2017/625 (¹). The network meets regularly, under the chairmanship of, and facilitated by, the Health and Food Audits and Analysis office, to exchange experiences in implementing national audit systems on official controls and other official activities.

The network, working in plenary session and through sub-groups, exchanges experiences and consolidates agreed principles and good practices on specific topics into documents to enable dissemination of information. These documents may be used as reference documents; however, they do not constitute an audit standard and are not legally binding (²).

NAS Network Reference Document on risk-based planning of audits of official control systems

LEGAL BACKGROUND

Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (hereafter: "the Regulation").

Commission Notice (2021-C 66-02) (³) on a guidance document on the implementation of the provisions for the conduct of audits under Article 6 of Regulation (EU) 2017/625 (hereafter: "the Commission Notice").

SCOPE

This reference document applies to planning of audits as required by Article 6 of the Regulation. It is intended for use by audit bodies that carry out audits on official controls and other official activities.

This document does not attempt to cover internal risks of the audit body, such as those mentioned in section 8 of the Commission Notice, for example lack of auditors' competences or resources within the audit body.

OBJECTIVES

The objective of this document is to provide guidance and support to audit bodies by proposing general principles for the development and implementation of risk-based audit programmes in the areas of official controls specified in Article 1(2) and 1(3) of the Regulation.

(¹) OJ L 95, 7.4.2017.
(²) The term "should" in this reference document means good practice, not a binding requirement.
(³) OJ C 66, 26.2.2021.

This document also aims to identify good practices in performing risk-based planning of audits and assist audit bodies in finding a balance between full coverage of the audit universe during a 5-year period and appropriate risk prioritisation.

This document is intended to complement the guidance on risk-based planning of audits as described in Section 5.1 (Systematic Approach) of the Commission Notice.

DEFINITIONS

This document should be read in conjunction with the definitions contained in the Regulation and moreover in section 3 of the Commission Notice, especially those for "*Audit body*", "*Audit system*", "*Audit universe*" and "*Audit programme*".

Risk universe: This is the audit universe (an inventory of audit areas that is compiled and maintained by the audit body to identify areas for audit during the audit planning process) with a risk categorisation applied to each audit area. Therefore, the risk universe is the result of the identification and assessment of the probability of a risk materialising in each audit area identified in the audit universe and its consequences should it arise.

N.B.: The terms audit universe and risk universe in this document are used in the context of a multi-annual risk-based planning process. However, analogous concepts exist for annual planning as well as planning for an individual audit.

Horizontal audits ([4])***:*** These are audits where the audit criteria are taken from general requirements (not sector specific) in the Regulation, or strategic objectives of the MANCP ([5]). Horizontal audits can be carried out across control systems.

***Vertical audits*:** These are audits where the audit criteria are taken primarily from sector specific ([6]) requirements. Vertical audits are carried out within a control system.

Risk-based planning of audit programmes

OBJECTIVES

The objectives of risk-based planning of audit programmes are to ensure that:

- The audit universe(s) does not overlook any relevant areas and competent authorities.
- Planning processes can identify and categorise main audit risk areas appropriately.
- The whole process is transparent and subject to regular review.
- Audit bodies (in case there are several) coordinate their planning processes.
- Resources available to the audit body are used effectively and efficiently.

([4]) The separation of the concepts of horizontal and vertical audits is somewhat artificial as they are quite commonly used in combination, i.e., an audit may contain a horizontal and vertical component.
([5]) The MANCP Network reference document on Developing Objectives and Indicators provides relevant guidance on objectives.
([6]) Sectors as specified and classified in Article 1(2) and 1(3) of the Regulation.

PRINCIPLES

1. **Risk-based planning can be viewed as four separate processes, with clearly specified inputs and outputs for each.**

These processes are: 1) establishing the audit universe, 2) defining the risk universe, 3) producing the audit programme and 4) designing the review process. These are outlined in the Annex below.

2. **Audit bodies should define their own Audit universe and use it for audit planning.**

It is up to the audit body to determine the detail in the audit universe. To minimise the potential for gaps and overlaps between competent authorities, it is good practice that the audit universe be determined as a coordinated process between audit bodies within the Member State. When an audit body is defining the audit universe, it is important to ensure that:

- all the requirements of the Regulation are included and considered.

- the audit universe includes all areas of the MANCP relevant to the responsibilities of the relevant competent authority; and

- the audit areas are defined and presented in a way that facilitates risk assessment and audit planning.

3. **The audit areas within the audit universe should be categorised according to risk to produce a risk universe.**

The risk assessment of audit areas should consider the probability of a failure in a control area and the consequences of such a failure (also referred to as likelihood vs impact). It is up to the audit body to select a method for risk assessment, but the procedure used should be documented and demonstrate clear methodology. The risk assessment process should result in the creation of a risk universe where audit areas are prioritised depending on the risk assigned to each.

4. **Adequate coverage during a 5-year cycle can be achieved by using a combination of horizontal and vertical audits combined with a periodic review of negligible risk areas.**

Based on the output of the risk-based planning process, the areas identified as high-risk should be covered using both horizontal and vertical audits, while low-risk areas can be covered by a lower frequency of horizontal audits. Negligible risk audit areas can be considered as being covered, even if not audited, when they have been included in the audit universe, considered in the planning process and are periodically reviewed.

5. **All elements of the risk-based planning process should be subject to a periodic review.**

The review is a checkpoint which serves the purpose of validating/verifying the existing audit universe, risk universe and audit programme prioritisation methods to ensure that they are still fit for purpose and are updated as necessary. It does not imply that the whole process depicted in Diagram 1 (below) should be repeated at every review.

6. **All elements of the planning process should be clearly documented.**

"All elements" means that the main steps in the process should be described as well as records kept on the planning and review process. The level of detail depends on the circumstances, but the general principle is that the planning process should be auditable.

ANNEX I

Process flow diagram for risk based planning
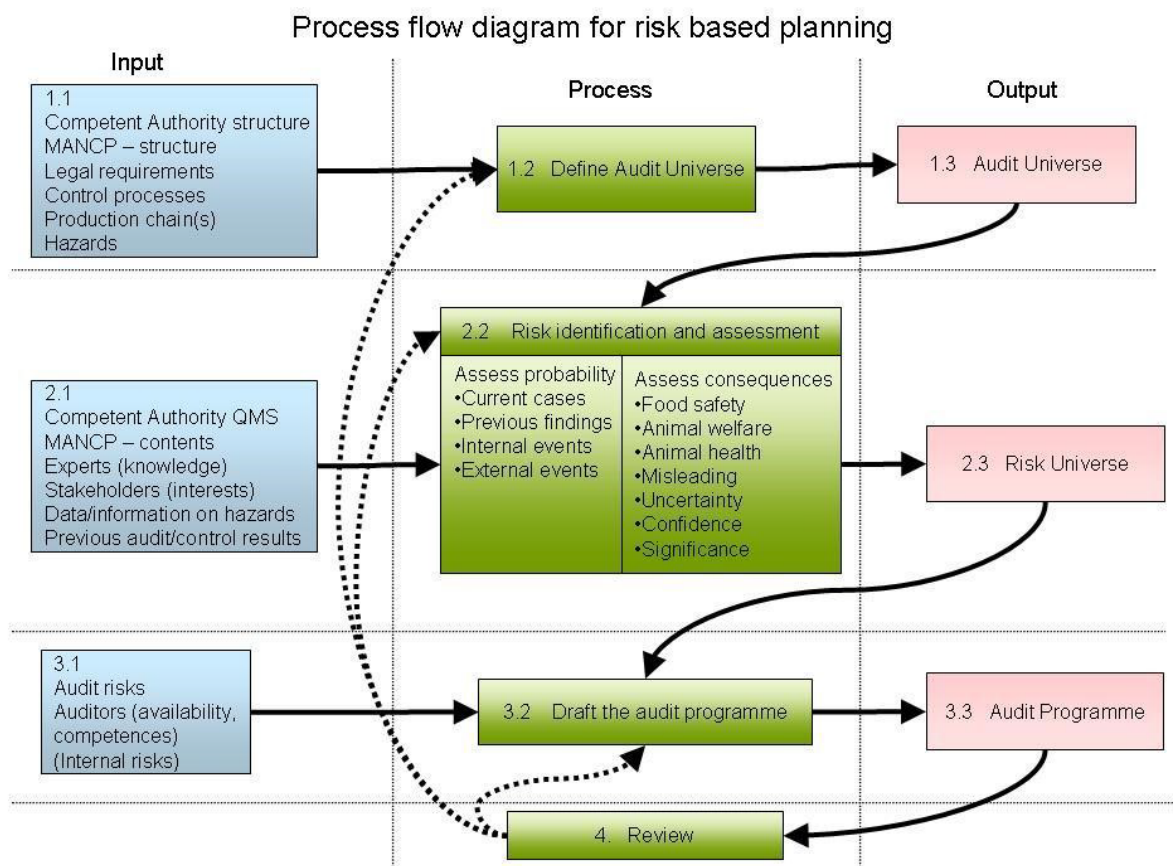
The Process – explanations to the diagram

1. Define Audit Universe

    1.1. The entries in box 1.1 are not an exhaustive list of inputs. Whichever combination of these or other inputs is being used, sufficient and suitable information about official controls and competent authorities should be available to define the actual audit universe.

    1.2. The purpose of defining the audit universe is to ensure that all areas to be covered by the audit planning process are considered and represented in a format that is useful/helpful in achieving that. It is important to take into account planning resources in order to have a realistic number of audit areas which can be assessed with the resources available.

    1.3. The output is a comprehensive list of areas (if needed subdivided in main areas and sub areas) covered by the Regulation which could be subject to audit. It serves as an input for stage 2. An example of an audit universe can be found in Annex II.

2. Define Risk Universe.

    2.1. The entries in box 2.1 are not an exhaustive list of inputs. Whatever information is being used, it should be documented to provide transparency. At this stage it may be useful to make a distinction between inherent risks and for example, prior knowledge about competent authorities' management systems (i.e., accreditation/certification to an international standard). Evidence on robust management systems, for example a comprehensive MANCP, detailed planning of control activities, annual reporting and an established review process may change the residual risk associated with a particular competent authority.

    2.2. The purpose of this process is to identify and assess risks to different audit areas within the audit universe to define audit priorities by using the additional inputs from box 2.1. A documented process/procedure (method) should be in place to prioritise the audit areas in the audit universe according to the probability and consequence of an undesirable event or failure.

    2.3. The output (risk universe) from this step serves as an input for stage 3.

3. Draft the Audit Programme

    3.1. Input to the planning process may also include "interfering" factors like emerging issues, management requests, changes in available resources etc.

    3.2. The purpose of this process is to consider the risk universe, management requests, audit risks, resources, and any other factors to produce an audit programme.

    3.3. The programme should include justification for the selection of audit areas; related planning documentation should be retained for verification/validation purposes.


4. Review

    The competent authority/audit body should review its planning process periodically. The purpose of the evaluation/review is to ensure that audit priorities continue to reflect all relevant information (e.g., findings from preceding audits) and where possible, to improve the planning process.

ANNEX II

Example of the audit universe used by DG SANTE F as part of the process of risk-based planning of audits within the DG SANTE F audit programme.

Audit universes will vary depending on the areas of control for each competent authority, for example in the audit universe below there are areas not included within the Regulation but under the responsibility of DG SANTE (i.e., Health section).
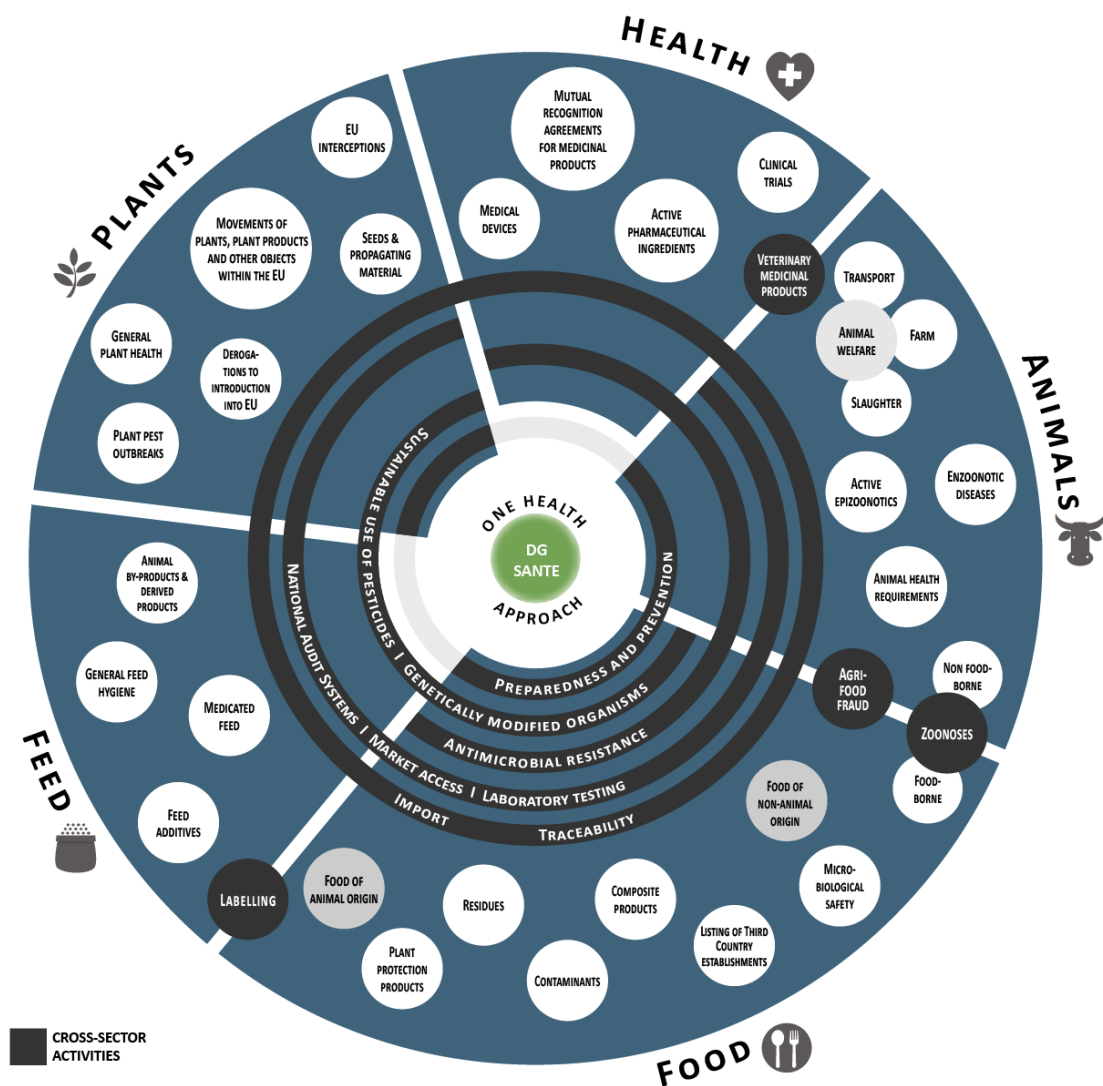
This audit universe is the basis for the drafting of the work programme:

https://food.ec.europa.eu/horizontal-topics/official-controls-and-enforcement/health-and-food-audits-and-analysis/work-programmes_en