

*National
Audit
Systems
Network*

AUDITING EFFECTIVENESS OF OFFICIAL CONTROL SYSTEMS

The network of national audit experts have produced this non-binding reference document based on agreed good practices to provide guidance on how auditors may approach auditing the effectiveness of official control systems.

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Version 1

The National Audit Systems (NAS) Network

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 882/2004¹. The networks meet regularly, under the chairmanship of, and facilitated by, the FVO 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 the FVO, consolidate agreed principles and good practices on specific topics into documents. These documents may be used as reference documents, however, they do not constitute an audit standard and are not legally binding.

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OBJECTIVE OF THIS DOCUMENT

The objective of this document is to guide and support audit bodies in verifying the effectiveness of the official controls, by proposing general principles.

The aim is to give the principles for the evaluation of the effectiveness of the official controls with a view of being applicable to audits of official control systems.

This document is intended to assist in the implementation of section 6.1 (Guiding Principles) of the Annex to Commission Decision 2006/677/EC, specifically focusing on Section 6.1.b..

SCOPE AND INTENDED AUDIENCE

This guidance applies to the evaluation of the effective implementation of official controls and competent authorities' control systems, and their suitability in achieving objectives, as required by Article 4(6) of Regulation (EC) 882/2004.

It is intended for use by audit bodies that carry out audits on official control (systems) according to the requirements of Article 4(6) of Regulation (EC) 882/2004.

It supports the development of good practice in the evaluation of effectiveness of the control systems.

Note: in performing audits on effectiveness of official controls (6.1.b), compliance with planned arrangements (6.1.a) should always be taken into account.

EFFECTIVENESS

This document should be read in conjunction with the definitions contained in Regulation (EC) No 882/2004 and Commission Decision 2006/677/EC² bearing in mind that the definitions from those documents apply.

Effectiveness: is the extent to which official controls produce an (intended) effect / achieve an objective³. In this particular context the objectives are those of Regulation (EC) No 882/2004.

¹ OJ L 191, 28.5.2004

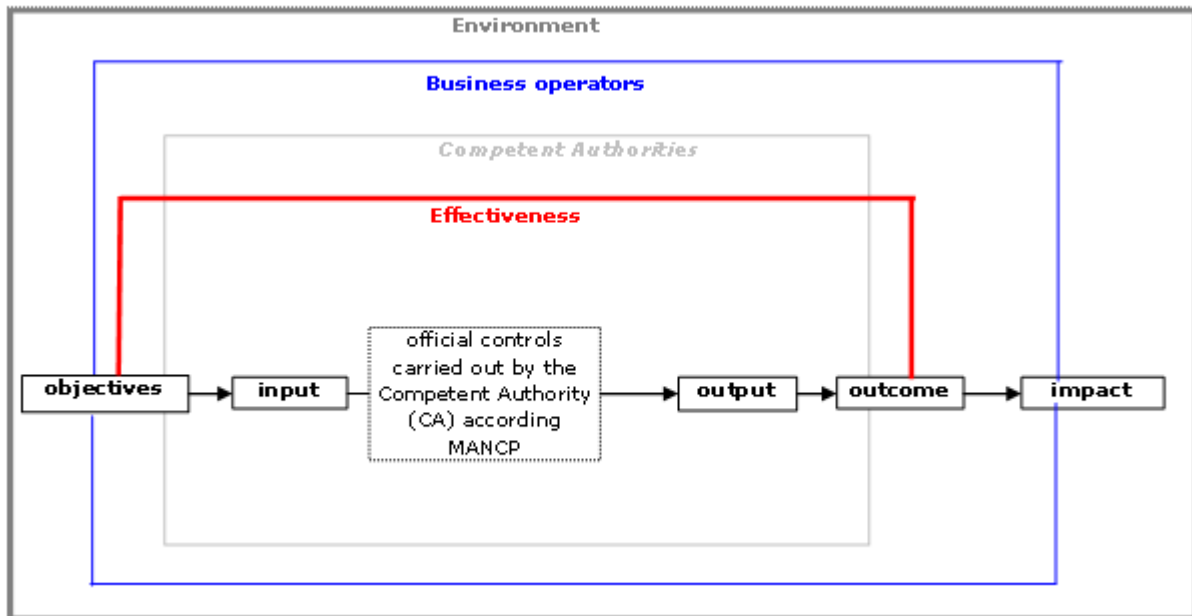
² OJ L 278, 10.10.2006

³ Objectives may be at a strategic or operational level.

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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.

In the diagram below, evaluation of effectiveness by audit bodies is illustrated by the red line which refers to the comparison of outcome with objectives. This corresponds largely to point 6.1.b of the Annex of Commission Decision 2006/677/EC and to the obligation to audit effectiveness laid down in Article 4(6) of Regulation (EC) No 882/2004.



Legend to the diagram:

Objectives

- From the legislation, MANCP, other national plans and policies etc.

Inputs:

- Information – requirements, previous results, risk analysis etc.
- Resources – financial, material, human etc.

Processes (of controls implemented by the CA based on planned arrangements):

- Planning, sampling, analysis, sanitation, follow-up, review of the programme
- Verification of effectiveness, internal audits etc.

Outputs:

- Information on the control activities and results e.g. number of inspections, samples, enforcement actions, level of compliance etc.

Outcome:

- Effect of the controls on the level of compliance in FBO (in food safety)
- Reduction, elimination or control of risks to human, animal and plant health

Impact:

- Change in human cases of food-borne diseases, animal health status etc.

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- Consumer confidence in products and Competent Authorities
- Confidence of trading partners (internal market, EEA and Third Countries)

For more detailed and elaborated examples, please see Annex I.

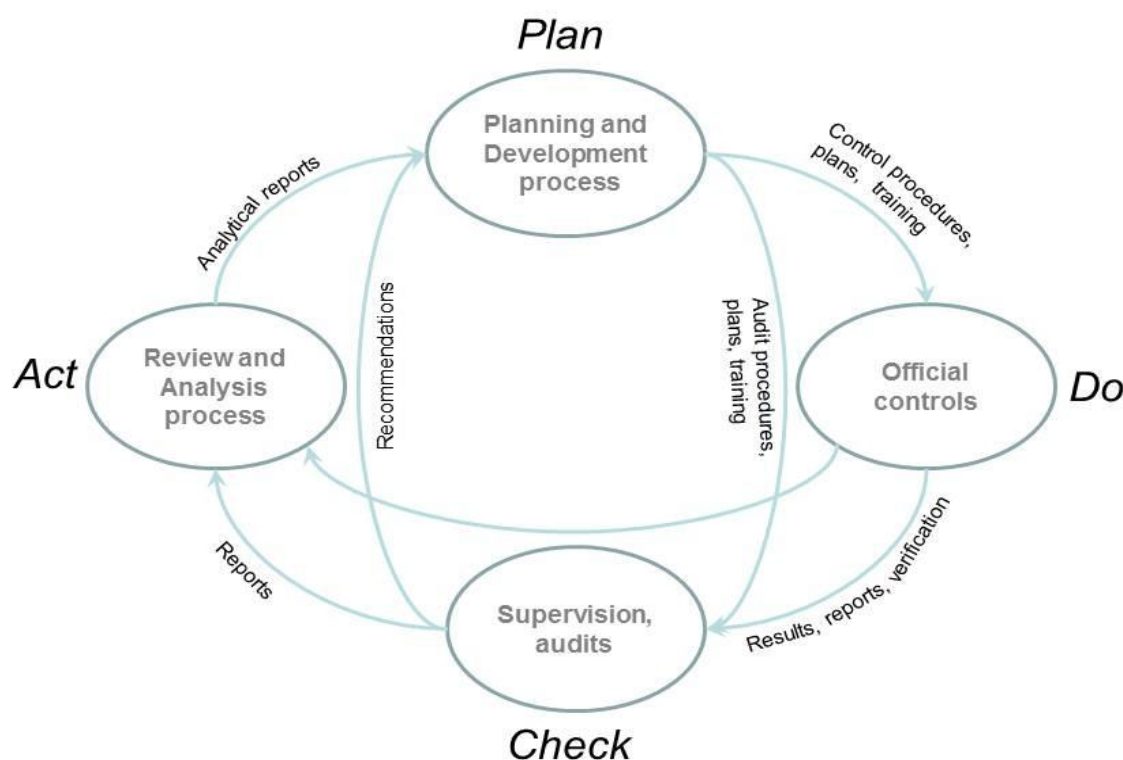
AUDIT CRITERIA FOR AUDITING EFFECTIVENESS

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:



(See also a more detailed version in Annex II).

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).

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PRINCIPLES

The following principles are meant to provide a basis for carrying out audits on effectiveness. They are not to be taken as prescriptive requirements for audit bodies or competent authorities but merely to help in developing a structured approach to Article 4(6) audits.

A. Principles related to the audit body:

- In auditing effectiveness, objectives of the competent authorities' control system(s) and objectives of the EU legislation are the main audit criteria.
- The overall objective of auditing effectiveness is to evaluate to what degree the objectives of the competent authorities' control system are being met.
- Another overall objective is to compare competent authorities' objectives with those of EU legislation.
- In order to carry out a system effectiveness audit, the audit has to cover PDCA.

B. Principles related to the competent authorities:

- In order to be effective, there has to be an objective / intended effect (by definition).
- A cascade from strategic objectives down to operational goals is necessary.
- To monitor/ensure progress towards an objective, some indicator(s) are needed.
- In order to have a system, PDCA is needed.

AUDIT PROCESS

The following list outlines the main steps and issues to be taken into account while preparing and carrying out an audit with a focus on effectiveness. It is not intended to provide an exhaustive list of steps or a complete audit plan. Further details and examples can be found in Annex I.

- Take the objectives of Regulation (EC) No 882/2004 as described above, and use them as a starting point.
- Identify the objectives from the specific legislation within the scope of the audit. You may need to consult the preambles and explanatory memorandums if the body of the legal instrument does not specify clear objectives.
- MANCP may contain objectives to be used as audit criteria. Sometimes these objectives may be contained in policy papers, lower level plans or procedures.
- Specify the objectives (audit criteria) derived from the different sources and make sure you have an agreement on these with your audit client, as appropriate. Prior agreement on the criteria may or may not be necessary for a successful audit.
- Determine your audit objectives – keep it short and simple but make sure that objectives mention effectiveness and system level.
- How to make the final evaluation of effectiveness?

Annex I

Example – Salmonella control programme in broilers

Objectives

Objectives for official controls

Regulation (EC) No 178/2002:

- *Article 17(2): "Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution."*
- *For that purpose...*
- *In other words, the purpose is: to monitor and verify that the relevant requirements of food law are fulfilled by FBO at all stages of production, processing and distribution.*

Regulation (EC) No 882/2004:

- *Preamble (1): "Feed and food should be **safe and wholesome**. Community legislation comprises a set of rules to ensure that this objective is attained."*
- *Preamble (6): "The Member States should **enforce** feed and food law, animal health and animal welfare rules and **monitor and verify** that the relevant requirements thereof are fulfilled by business operators at all stages of production, processing and distribution. Official controls should be organised for that purpose."*
- *Preamble (11): "The Competent Authorities for performing official controls should meet a number of operational criteria so as to ensure their **impartiality and effectiveness**."*
- *Preamble (12): "...Training is also required in order to ensure that the competent authorities take **decision in a uniform way**, in particular..."*
- *Preamble (14): "Official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out **uniformly** and of a **consistently high quality**."*

Objectives of National Salmonella Control Programmes (broilers)

Regulation (EC) No 2160/2003:

- *Preamble (18): "However, for certain zoonoses and zoonotic agents it is necessary to lay down specific requirements for controls."*
- *Preamble (19): "Those specific requirements should be based on targets for the reduction of the prevalence of zoonoses and zoonotic agents."*
- *Preamble (21): "To ensure the achievement of the targets in good time, Member States should set up specific control programmes, which the Community should approve."*
- *Preamble (28): "... As regards poultry meat, the aim is to place on the market poultry meat with reasonable assurance that it is free from relevant salmonella."...*
- *Article 1(1): The purpose of this Regulation is to ensure that proper and effective measures are taken to detect and to control salmonella and other zoonotic agents at*

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all relevant stages of production, processing and distribution, particularly at the level of primary production, including feed, in order to reduce their prevalence and the risk they pose to public health."

Regulation (EC) No 646/2007:

- *Preamble (6): "In order to verify progress on the achievement of the Community target, it is necessary to provide for repeated sampling of flocks of broilers, in this Decision."*
- *Article 1(1): "The Community target, as referred to... shall be a reduction of the maximum percentage of flocks of broilers remaining positive of Salmonella enteritidis and Salmonella typhimurium to 1% or less by 31 December 2011."*

Regulation (EC) No 200/2010:

- *Preamble (8): "In order to ascertain progress in the achievement of the Union target, it is necessary to provide for repeated sampling of breeding flocks of Gallus gallus."*
- *Article 1(1): "From January 2010, the Union target ... shall be a reduction to 1% or less of the maximum percentage..."*

National Control Programme:

- *"Must state the aim of the programme taking into consideration the importance of the zoonosis or zoonotic agent concerned." (Annex II, A(a) of Regulation (EC) No 2160/2003)*

Inputs:

- The requirements of Annexes to Regulations (EC) Nos 646/2007 and 200/2010 provide the input for planning the control programme as well as the general requirements in Annex I.A. of Regulation (EC) No 2160/2003.
- Results (trends, sources, exceptional cases) of previous monitoring – as laid down in section 4 of Annex to Regulation (EC) No 200/2010 provide information on the current state of play in relation to the target and will indicate whether any amendments are needed or not. (feed-back from outputs below)
- Results of audits and verification of effectiveness (feed-back from outputs below)
- Information necessary to provide for a risk based sampling as laid down in section 1(b), second indent of Annex to Regulation (EC) No 646/2007: *"Sampling by the competent authority shall include each year at least one flock of broilers on 10% of the holdings with more than 5000 birds. It shall be done on a risk basis each time the competent authority considers it necessary."*
- Control staff and laboratory capacity, as laid down in Article 4(2)(c) of Regulation (EC) No 882/2004: *"The competent authority shall ensure that they have..."*
- Financial resources as laid down in Article 26 of Regulation (EC) No 882/2004: *"Member States shall ensure that adequate financial resources are available to provide the necessary staff and other resources for official controls by whatever means considered appropriate..."*

Processes (of controls implemented by the CA based on planned arrangements):

- Sampling, analysis, decisions, sanitation, follow-up etc.

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- Documented procedures, training, supervision, planning and review of the programme.
- Verification of effectiveness, internal audits etc.
- N.B. All of these processes are covered by the PDCA diagram.

Outputs:

- The total number of flocks of broilers sampled by the competent authority or by the food business operator;
 - The total number of infected flocks of broilers;
 - All serotypes of Salmonella isolated;
 - Explanations of the results, in particular concerning exceptional cases;
- (all of the above are specified in Annexes to Regulations (EC) Nos 646/2007 and 200/2010)
- Results of internal/external audits; and
 - Results of verification of effectiveness.

Outcome:

- Reduction (or increase) in flocks infected by Salmonella; and
- Change in the prevalence of infected broilers on the shelf.

Outcomes as regards quality of the control programme:

- Improvements to control procedures as a result of verification procedures; and
- Improvements to control programme as a result of internal audits.

Impact:

- Change in human cases of salmonellosis attributable to poultry (relevant serotypes);
- Consumer confidence in poultry products and Competent Authorities controls; and
- Confidence of trading partners (internal market, EEA and Third Countries).

Annex II

Auditing effectiveness of official control systems

