

*MANCP
Network*

VERIFICATION OF EFFECTIVENESS

The network of MANCP national experts have produced this non-binding reference document to provide guidance on how to verify effectiveness of official controls and to contribute to the effective implementation of the provisions of Regulation (EC) No 882/2004.

October
2016
Version 1

The Multi Annual National Control Plan (MANCP) Network

The MANCP network is a network of officials from national competent authorities, who have a coordinating role in the preparation and reporting on the MANCP, provided for by articles 41 to 44 of Regulation (EC) No 882/2004¹. The network meets regularly, under the chairmanship of, and facilitated by, DG Health and Food Safety's Directorate F – Health and Food audits and analysis to exchange experiences on preparation, implementing and reporting on MANCPs. During the course of these exchanges; discussions, workshops etc. good principles and practices are identified and agreed by the network.

To enable dissemination of information the network, working in plenary session and through sub-groups, facilitated by DG SANTE, consolidates 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.

Verification of Effectiveness of Official Control Systems

INTRODUCTION AND BACKGROUND

Regulation (EC) No 882/2004 lays down general rules for the performance of official controls to verify compliance with feed and food law, animal health and animal welfare rules. These rules include fundamental operational criteria for the performance of controls which highlight the need for ensuring the effectiveness, appropriateness, impartiality, quality and consistency of official controls. It is not sufficient for competent authorities (CAs) to simply perform official controls; they are explicitly required to verify that the controls in place are effective and to take corrective action to ensure they are effective if and when required.

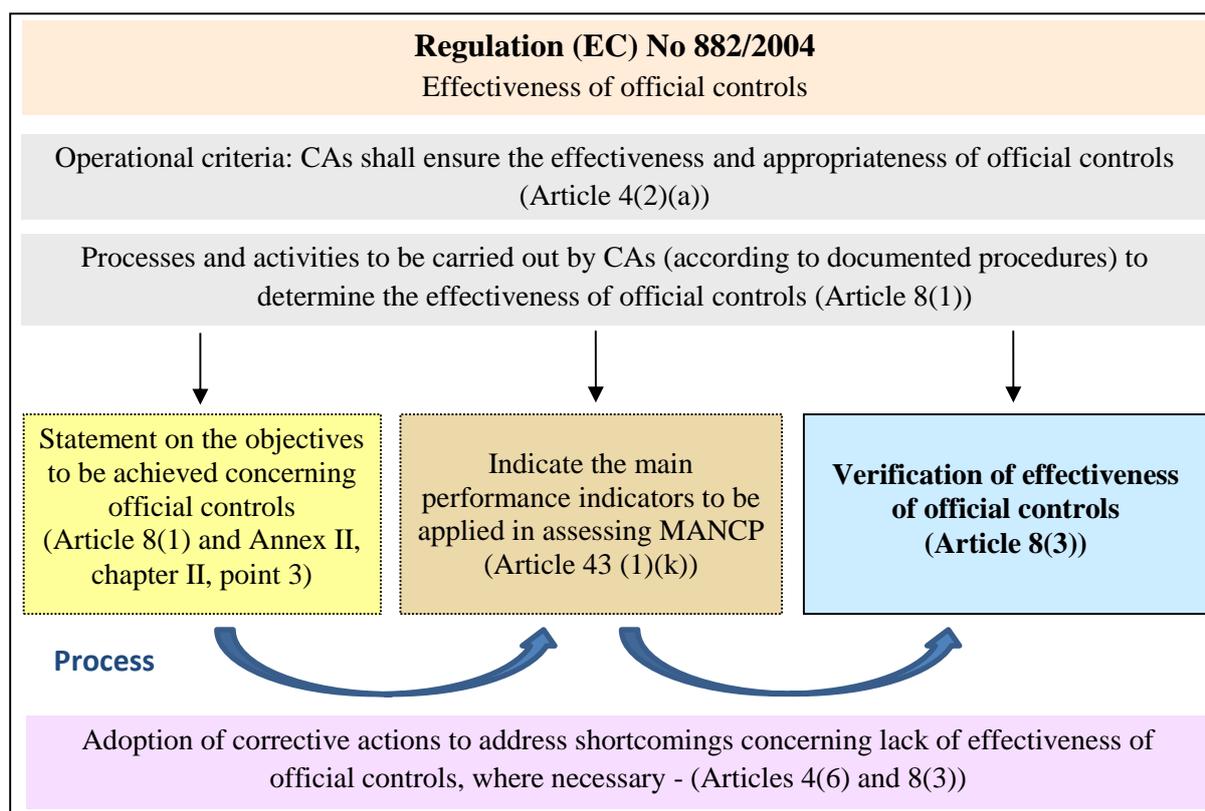
Official control systems operate in a dynamic environment; known risks may recede and new ones emerge, food business operators behaviour may change in response to official control activities and, or, to changes in the economic and social environment in which they operate. Control methods and techniques which were effective when introduced need to remain under review to ensure the methods and techniques used remain appropriate to the changing environment.

Regulation (EC) No 882/2004 does not prescribe how the effectiveness of official control systems should be verified, that is a matter for the CAs to decide. CAs are not obliged to create a dedicated function, similar to the internal audit function, for the verification of effectiveness. Verification of effectiveness in most instances is an integral part of the management of the official control systems as ensuring the effectiveness, appropriateness, impartiality, quality and consistency of official controls is closely linked to good governance. CAs (or the relevant CA level) responsible for the management of control systems could address this issue by having control verification procedures in place; that is arrangements and actions to be performed for the purpose of ensuring that official controls and other control activities are consistent and effective.

¹ OJ L 191, 28.5.2004

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An illustration of these regulatory obligations is presented below:



In the context of a Plan-Do-Check-Act cycle of official controls, the diagram in Annex I illustrates those elements of the official control system that are part of the verification of effectiveness process.

DG Health and Food Safety carried out a series of fact-finding missions and audits in 2012 and 2013 in order to evaluate the systems put in place to give effect to Article 8(3) of Regulation (EC) No 882/2004. CAs already have in place certain measures which could give an indication of effectiveness of official controls (and demonstrate that they could take corrective actions, when issues undermining the effectiveness of official controls were identified). However, these measures are not always identified as such or considered by CAs as actions intended to implement Article 8(3) but are often embedded in other activities.

CAs have found that identifying and measuring effectiveness of official controls poses a significant challenge. This reference document takes on board the key findings from the Overview Report².

International organisations such as the Food and Agriculture Organisation and Codex Alimentarius are also addressing the need for guidelines in this area and are developing performance measures in the food safety domain from which CAs can draw examples for their own purposes.

² http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=69

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OBJECTIVES AND SCOPE

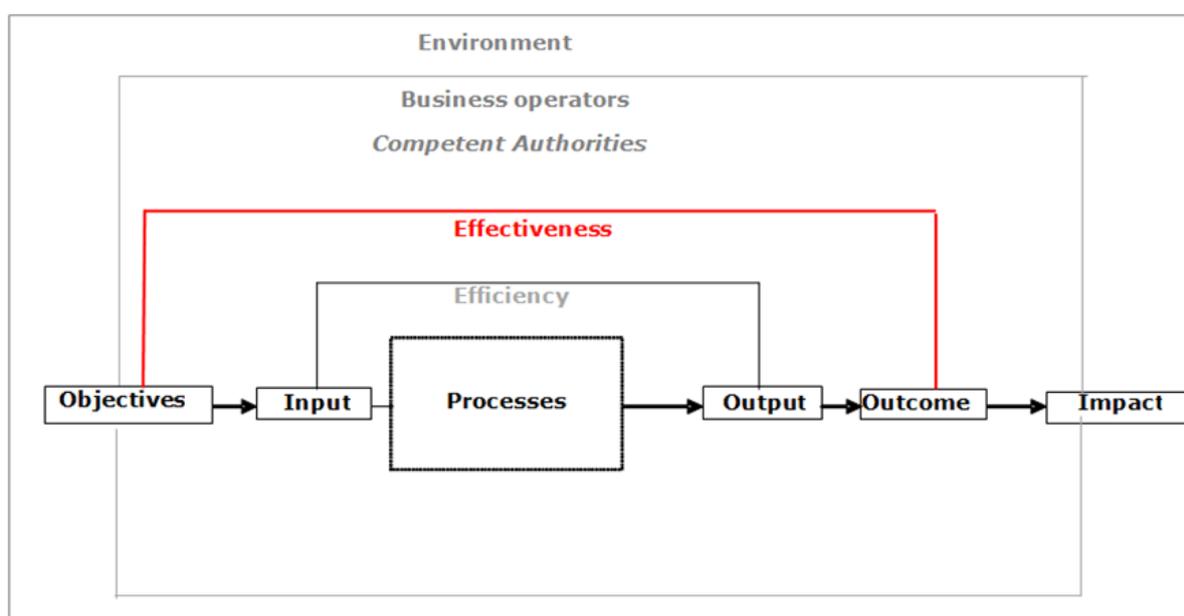
The objective of this reference document is to provide guidance for CAs at all levels in order to assist them to identify and/or develop suitable procedures and approaches to verify the effectiveness of official controls in the context of objectives and outcomes (see diagram 1).

The document describes a possible approach for verification of effectiveness, in particular:

- pre-requisites
- collection and analysis of data
- interpretation of results
- reporting and follow-up actions

The document supports the development and sharing of good practice in the verification of effectiveness of official controls.

Diagram 1 below illustrates the logic model applied to official control systems³.



DEFINITIONS

This document should be read in conjunction with the definitions contained in Regulation (EC) No 882/2004 and Commission Decisions 2007/363/EC⁴ and 2008/654/EC⁵ bearing in mind that the definitions of those documents apply.

Effectiveness: The extent to which official control systems' objectives or related outcomes were achieved, or, are expected to be achieved, taking into account their relative importance.⁶

Verification of effectiveness: Is an assessment of specific activities/procedures (which can include on-the-spot components) with a view to determining the extent to which they achieve the intended objectives or outcomes.

³ MANCP Network reference document "Developing Objectives and Indicators, April 2015, Version 1".

⁴ OJ L 138, 24-49, 30.5.2007

⁵ OJ L 214, 56-65, 9.8.2008

⁶ Effectiveness is not to be confused with efficiency, which is normally used when the CAs want to refer to input-output ratio i.e. cost and/or resources required to produce an output. This document does not cover efficiency of official controls.

1. PRE-REQUISITES

In order to start the process of verifying effectiveness of official controls certain pre-requisites should be in place. If these pre-requisites are not confirmed, the validity of the assessment could be open to question because it may be based on flawed basis.

Objectives and indicators

A pre-requisite for verification of effectiveness is to have in place objectives and indicators for the official control system that relate to the intended outcomes. Guidance on developing objectives and indicators is available in the MANCP Network reference document "Developing Objectives and Indicators, April 2015, Version 1".

Plan for data collection

Another pre-requisite is to have in place a plan for the purpose of collecting, monitoring and analysing data in order to verify effectiveness. When creating the plan, the CA should keep in mind that the data should be relevant for verifying effectiveness. (for guidance on the components of this plan see section 2)

If the data generated by official controls and/or activities that are already in place is clearly identified and formalised in the monitoring plan, CAs can use this data to contribute to the verification of effectiveness.

Compliance with planned arrangements

Another pre-requisite is compliance with planned arrangements. Once the aspects mentioned above have been incorporated in the official controls programmes, the output of the official controls will confirm if they have been performed in accordance with planned arrangements.

Quality of official controls

To ensure the quality of a system of official controls, certain elements should be in place, such as:

- Risk-based targeting.
- Documented procedures.
- Impartiality.
- Uniformity and consistency.
- Reliable detection and recording of non-compliance.
- Take actions to improve compliance.
- Follow-up.

As part of the CAs' continuous improvement of their official control system, these elements should be reviewed and if necessary changed to improve the quality .

Annex II gives examples of activities to assess the quality of the official controls.

2. COLLECTION AND ANALYSIS OF DATA

In order to ensure the validity of the evaluation it is necessary to take a systematic approach to collection and analysis of data and reflect this in the plan for data collection (see section 1). The following should be considered:

Identify appropriate data

The data - which can be both qualitative and quantitative – should be reliable, easily obtainable, high-quality and unbiased, providing a user friendly management tool.

To measure the extent to which objectives are being achieved, CA should use data that relates to the identified indicators for outputs and outcomes. This data should be appropriate and suitable for the methods of analysis proposed. Indicators that have associated baselines, targets and/or milestones will provide for a more focused data analysis and eventually more reliable results.

CAs may have activities already in place (such as supervision⁷, monitoring of individual official controls by line managers, internal audits, detection of non-compliances, actions taken and follow-up)⁸ that if coordinated and looked at in a holistic way will generate data that contributes to demonstrate effectiveness. Such data might be the only data being regularly recorded in a standardised way. CAs will be able to use this data to begin their data analysis for verifying effectiveness.

Relevant external sources of data (such as other public authorities or government agencies (health, customs, police, etc.), European Commission (DG Health and Food Safety), Non-Governmental Organisations, industry associations, universities or other research institutes) could equally contribute to the analytical process (e.g. as additional data for verification of effectiveness, as new indicators, etc.).

Record data

Data that supports the identified indicators needs to be captured in a timely and consistent manner to allow its analysis. Different recording mechanisms, with various degrees of complexity, can be used for this purpose (IT centralised databases, hard copy based systems, etc...). These systems should be user friendly and facilitate the reliable and comprehensive recording of data. (See a practical example in Annex IV.1).

Store data

Data that supports the identified indicators should be stored in a consistent and easily retrievable manner to allow its analysis.

Data should also be stored in a manner that enables it to be shared between relevant services within the competent authority and with other relevant authorities (or control bodies) with competences for the implementation of Regulation (EC) No 882/2004 requirements (e.g. officials carrying out control activities and officials analysing data for verifying effectiveness).

Data should be stored securely and in accordance with data protection requirements.

⁷ Supervision is intended to be interpreted as the expression is commonly used in the context of oversight by a manager or supervisor and not in the specific context of Commission Implementing Regulation (EU) No 392/2013 of 29 April 2013 amending Regulation (EC) No 889/2008 as regards the control system for organic production. OJ L 118, 5–14, 30.4.2013.

⁸ See section 1

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Prepare data

Before starting to analyse the data there is a need to check its quality (completeness, reliability, accuracy), adjust it if necessary and prepare it in a way it can be used for the purpose of analysis. A data preparation process example is given in the box below.

The first step is to check the quality of the raw data. Depending on the complexity of the data, the following might be checked:

- *Missing data*
- *Data outliers*
- *Strange combinations of results*
- *[...]*

The second step is to adjust the data in accordance with established criteria, recording the adjustments made and the reasons therefore, for example:

- *Data outliers should not be disregarded during the data analysis as they can point to potential issues that need specific attention.*
- *[...]*

The third step is to prepare the data for the analysis. Depending on the complexity of the data the following actions might be required:

- *Create new answer categories, redistributing data*
- *Create new indicators or variables based on more than one question*
- *Combine several datasets into one*
- *[...]*

Methods of analysis

The methods used to analyse the data are dependent on what is to be examined, what data is available and how causal linkages are to be proven.

In general, data analysis compares the current data to both baselines and the intended targets, as well as assessing trends over a time period.

Depending on the objectives and the corresponding indicators the CA might use different baselines (e.g. "random baseline" or a "risk-based baseline") for different purposes. The data collection should take into account such differences and clearly report it in the results to enable an unbiased interpretation.

To assess the effect of a particular intervention⁹ it is necessary to include a "control group" to prove the effect. The baseline data is compared with both the data collected from the "intervention group" and from the "control group" at the end of the intervention, to measure differences. Where a control group was not included it is necessary to collect additional "qualitative" data to demonstrate of the effect of the intervention.

Annex III includes examples of different methodologies.

Annex IV includes practical examples provided by Network members.

⁹ Interventions such as change in methodology, reinforced inspections, awareness campaigns, etc.

3. INTERPRETATION OF RESULTS

The aim of interpreting the results of the data analysis is to know if the CA has achieved, or moved towards achieving, the objectives initially defined.

However, the results of the data analysis have to be considered in a broader context to fully understand them.

The interpretation of the results can be done by asking the following main questions. These will help CAs to determine the effectiveness of the official controls and to draw conclusions. They can also identify elements that have influenced either positively or negatively the achievement of the objectives. The suggested questions in the tables below are intended to assist the CAs in answering the main questions. However, they are illustrative and non-exhaustive.

1. Did we (CA) do what we said we would do, in the way we said we would do it?

The answer to this question relates to a quality check on the pre-requisites mentioned in section 1 and should give indications on: the design of the control system; its fitness for purpose/appropriateness; the quality and suitability of the official controls carried out and if they were carried out in accordance with planned arrangements.

<i>Suggested questions (non-exhaustive list)</i>
<ul style="list-style-type: none">• <i>Have the CAs defined objectives and indicators for their official controls?</i>• <i>Have the CAs considered the relevant risks when planning their official controls?</i>• <i>Have the CAs carried out the official controls in accordance with their procedures?</i>• <i>Have the planned official controls been delivered?</i>• <i>Is the quality of the inspections in accordance with the policy rules? (right locations inspected, the risk-based control-points inspected, the quality of the sanctions, etc.)</i>• <i>Are the right interventions / measures taken in case of non-compliance?</i>• <i>Is there a good follow-up of the corrective actions after non-compliances are detected (re-inspected in time)?</i>• <i>[...]</i>

2. To what extent did we (CA) achieve the intended outcome?

The answer to this question should give indications on to which degree CAs achieved the objective by comparing the baseline and the current situation and then evaluating that current situation against the target/intended outcome.

Alternatively, evaluating a trend against the target/intended outcome can also indicate to which degree CAs achieved an objective.

<i>Suggested questions (non-exhaustive list)</i>
<ul style="list-style-type: none">• <i>Have the CAs used the relevant indicators to measure the identified objectives?</i>• <i>Have the CAs established baselines for those indicators?</i>• <i>How does data on the current situation compare with the baseline? Is the comparison pointing in the direction of the intended outcome?</i>• <i>How does the data on the current situation compare with the milestones/targets?</i>• <i>In case the objectives were not reached are there indications that the developments are going in the intended direction?</i>• <i>Is the data pointing to other (side) effects? And are they positive or negative? How can the side effects be taken into account?</i>• <i>[...]</i>

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3. Do we know which elements contributed directly to achieve the objective?

The answer to this question should give indications of the extent to which achievement of the objectives can be attributed to the CA's controls and/or other activities or where influenced by external factors.

<i>Suggested questions (non-exhaustive list)</i>
<ul style="list-style-type: none">• <i>What proportion of the improvement can be attributed to the CA's official controls?</i>• <i>How have other elements contributed to achieve the objectives (inter alia, other activities of the CA, other CAs and stakeholders actions, change in consumer behaviour)?</i>• <i>Are there other elements which might also have influenced the intended outcome? (i.e. media attention, an outbreak, activities of stakeholders, etc.)</i>• <i>And were these elements working in favour of the intended outcome or against it (interrupting)?</i>• <i>Without these elements, would the CA's official controls/activities achieve the objectives to a lesser or greater extent?</i>• <i>Is there a measurable difference in the outcome between the "control group" and the "intervention group"?</i>• <i>[...]</i>

4. REPORTING AND FOLLOW-UP ACTIONS

Ideally the verification of effectiveness of official controls that was carried out and the interpretation of results should be reported, preferably in a clear and understandable format, and eventually presented in a manner that the CAs consider appropriate (see example in Annex IV.5).

The report should outline the extent to which the controls were effective and reached the objectives. It should also identify areas where shortcomings need to be addressed or where there is potential for further improvement. The report may include recommendations depending on CAs' internal arrangements.

Reporting the outcome of the verification will contribute to meeting the obligation for both internal¹⁰ and external¹¹ accountability.

The CAs should, in line with legal requirements, take follow-up actions to correct shortcomings identified. Additionally, the verification process may also identify areas with potential for improvement and these can be addressed in the context of quality management (PDCA cycle)/ continuous improvement approach.

The findings of the verification process should feed into the planning/design and development/implementation of the official control system, for example: in the future planning of official controls, changing existing documented procedures for official controls, improve supervision activities, sharing good practices, setting new objectives and indicators, etc. This enables a systematic approach to continuous improvement.

Root cause analysis is a useful tool to assist in identifying reasons for shortcomings or lack of effectiveness. This in turn will help with determining the appropriate follow-up actions.

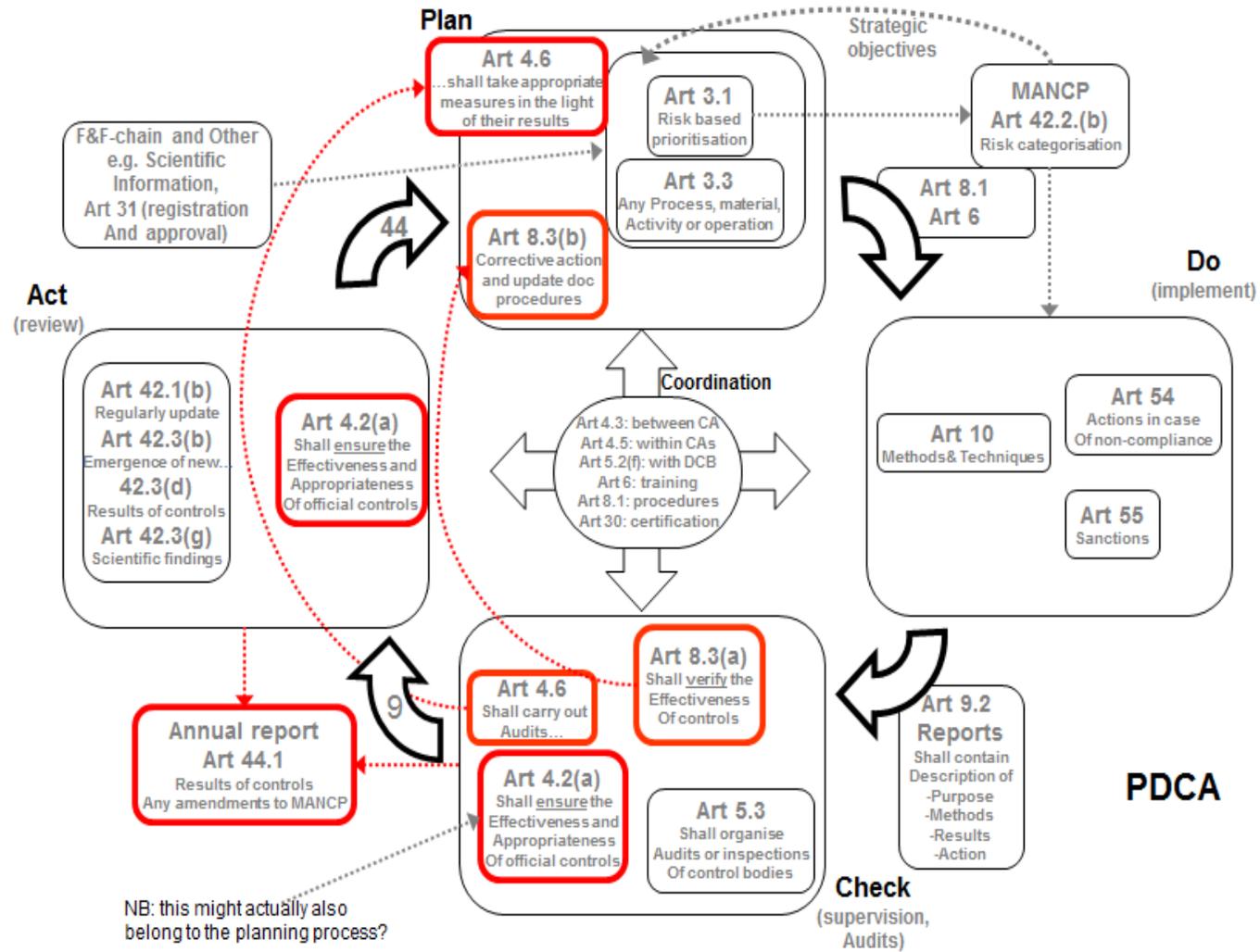
¹⁰ Officials (or control bodies) are accountable for how they have used resources to meet obligations – to higher-level management/ministry

¹¹ Accountable to consumers, businesses and other stakeholders.

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ANNEX I – PDCA cycle

The PDCA cycle shown below incorporates the articles of Regulation (EC) No 882/2004 and highlights the elements of the official control system that are part of the verification of effectiveness process.



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ANNEX II – Assessment of quality

This annex illustrates the main elements of an official control system and how the quality of their implementation can be assessed. For each element, examples of intended results are given along with activities on how and where to assess if such results have been achieved.

The examples presented are not exhaustive or meant to be prescriptive, as it is recognised that each Member State has its own tools to assess the quality of its official control system.

	<u>Intended result</u>	<u>Activities to assess result</u>
Risk-based targeting of official controls	Targeting the object of CAs official controls with the right risk (tolerance) levels.	<ul style="list-style-type: none"> • Checking if a documented risk analysis has been done. • Checking if implementation of official controls reflects the risk categorisation/rating defined by the CA and has the adequate support (laboratory support for example). • Results of audits (Internal, NAS, DG Health and Food Safety, Third party, etc.). • Data analysis: data generated by the CA or external. • Outputs of official controls compared with indicators indicate appropriateness of risk categorisation/rating (clear link between high risk categories and probability and severity (or impact) of non-compliances) • [...]
Official controls take place on the basis of documented procedures	<p>Official controls are carried out uniformly and are of a consistently high quality.</p> <p>Official controls in all areas of 882 and covering whole territory of MS.</p> <p>Official controls that when facing similar situations, reach similar conclusions/results.</p>	<ul style="list-style-type: none"> • Checking if planning is fit for purpose and procedures are clear, updated, and communicated to all CA levels. • Checking the suitability and impact of the training. • Checking if the implementation of procedures is suitable and sufficient. • Checking if official staff, following the same procedures, carry out official controls uniformly. • Checking if official staff, following different procedures, carry out official controls of consistently high quality. • Accurate official controls reporting, including what was checked and which non-compliances were identified. • Results of "frameworks" for official controls in targeted sectors point to same quality of those controls. • Checking the monitoring/supervision of official controls (including on-site). • Results of audits (Internal, NAS, DG Health and Food Safety, Third party, etc.) • Data analysis • [...]
Impartiality of controls and decisions	<p>Consistency of controls and decisions.</p> <p>Quality of controls and decisions (reduction in challenge to CAs controls and decisions).</p> <p>Positive perception of CAs credibility (by stakeholders).</p>	<ul style="list-style-type: none"> • Conflict of interest policy communicated, understood and followed by staff at all levels. • Results of peer review and/or quality assessment of decisions (procedures followed or appropriateness of the decision taken). • Results of studies (academia) on official staff decisions. • Checking levels of transparency (for procedures and official controls) applied by the CAs. • Results of audits (Internal, NAS, DG Health and Food Safety, Third party, etc.) • Checking the procedure to address complaints (from consumers, from FBOs) • Results of surveys to stakeholders. • Data analysis • [...]

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	<u>Intended result</u>	<u>Activities to assess result</u>
Reliable detection and recording of non-compliance	<p>Official controls detect non-compliances that are linked to risks and can be acted upon.</p> <p>Official controls reduce/mitigate the possibility of non-compliances not being identified.</p>	<ul style="list-style-type: none"> • Checking how CAs deal with type and number of non-compliances identified (lower risk vs high risk?). • Looking at how official staff identify non-compliances (simulation exercises?). • Results of surveys to stakeholders. • Results of audits (Internal, NAS, DG Health and Food Safety, Third party, etc.). • Data analysis • [...]
Take actions to improve compliance / Impose corrective measures or sanctions	<p>Change of behaviour of FBOs, from non-compliant to compliant.</p> <p>Proportionate and persuasive measures/sanctions to turn non-compliance into compliance.</p>	<ul style="list-style-type: none"> • Assessing the results of CAs actions to improve compliance (transparency, training, awareness campaigns). • CAs clear rules/procedures on how and which measures to apply when non-compliances identified. • Results of surveys to stakeholders. • Results of audits (Internal, NAS, DG Health and Food Safety, Third party, etc.) • Data analysis • [...] •
Follow-up of actions to improve compliance	<p>Turn identified non-compliance to compliance.</p> <p>Prevention of re-occurrence of identified non-compliances.</p>	<ul style="list-style-type: none"> • "Enforcement plans" of FBOs to implement actions to address CAs recommendations. • Results of audits (Internal, NAS, DG Health and Food Safety, Third party, etc.) • Data analysis • [...]

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ANNEX III

The examples provided do not intend to present prescriptive or/and compulsory ways/methods to collect or analyse data in order to verify the effectiveness of official control systems, or parts thereof, across Member States.

ANNEX III . 1 Random and risk-based baseline.

	<u>Random baseline</u>	<u>Risk-based baseline</u>
<i>What?</i>	<p>The level of compliance in a randomly selected target group, in the timeframe the data was collected.</p> <p>This represents the average level of compliance for the whole population.</p>	<p>The level of compliance in a specifically risk-based selected target group in the timeframe the data was collected.</p> <p>This represents the level of compliance in the risk-based selected part of the population.</p>
<i>When?</i>	<p>The random baseline is useful when CAs want to use the results for:</p> <ul style="list-style-type: none"> - assessing (objective) risk-analysis - comparing different target groups on compliance - verification of effectiveness (pre- and post measurement or trend analysis) 	<p>The risk-based baseline is useful when CAs want to use the results for:</p> <ul style="list-style-type: none"> - following CAs' risk-based approaches during the "intervention period"(for management) - comparing the results with a random baseline CAs have measured before to see if their risk based approach is effective. - verification of effectiveness (trend analysis)
<i>How?</i>	<p>From a homogenous target group, CAs select a representative random/select sample of the population to assess the level of compliance of certain parameters.</p> <p>From the results, CAs assess the average level of the compliance, including the standard deviation.</p>	<p>CAs carry out risk-based inspections and measure the amount (percentage) of non-compliances detected.</p>
<i>Examples</i>	<p><u>Indicator with a "random" baseline</u></p> <p>A representative number of FBOs (i.e. n=350) (for the total number of FBOs in the population (i.e. n=15000)) is selected randomly for official controls to establish the level of compliance.</p> <p>Data generated on the compliance level in the target FBO group selected each 4 years is used to see trends in the population.</p>	<p><u>Indicator with a "risk-based" baseline</u></p> <p>A representative number of FBOs (for the total number of FBOs within a specify risk) is selected for official controls to establish the level of detected non-compliance.</p> <p>Data generated on non-compliance levels in FBOs is classified according to risk and used to see (continued) trends within a defined situation (risk).</p>

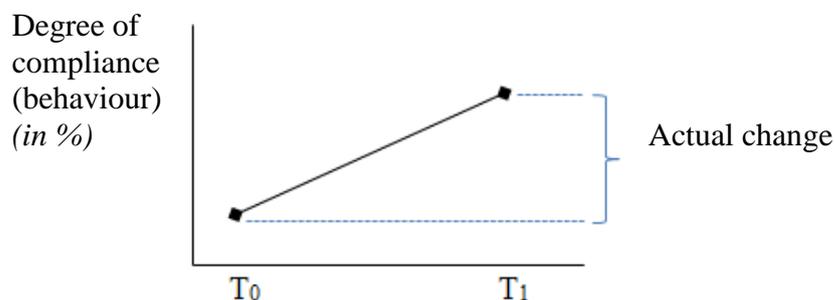
ANNEX III . 2 Proces of pre- and post-measurement and trend analysis

Pre- and post-measurement

To assess the effect of a (new) intervention among a specific target group a pre- and post-test is needed. This method does not assess if the found effect is caused by the intervention or by other conditions that contribute to the objective.



If there is a significant difference between the degree of compliance at T0 and T1, there is an occurred effect, the actual change. However, in this research design it is not clear whether this difference is due to the intervention performed or (also) to other (external) factors that have influenced the outcome. When interpreting the results, the effect of the intervention must be made plausible. This can be done by describing other influences which might have played a role (or not) or by additional data, such as information from inspectors or additional qualitative research.



A practical example is presented in Annex IV.2.

Trend analysis

If you want to follow the developments of a specific subject among a target group you might use trend analysis or set up a monitor. Depending on the purpose and the suspected developments you might construct your trend analysis / monitor differently. You might consider the following options:

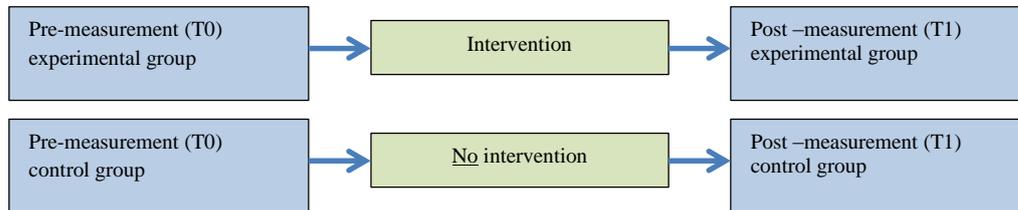
- the method of data collection (inspection data, observations, interviews, data from external parties);
- the selection of the data collection (at random or risk-based);
- indicators (degree of compliance, degree of found abnormalities, behaviour, knowledge);
- frequency (continuously, periodic);
- timeframe (real-time, quarterly, twice a year, etc.);
- methods of presentation (tables, infographic, dashboards).

A practical example is presented in Annex IV.3.

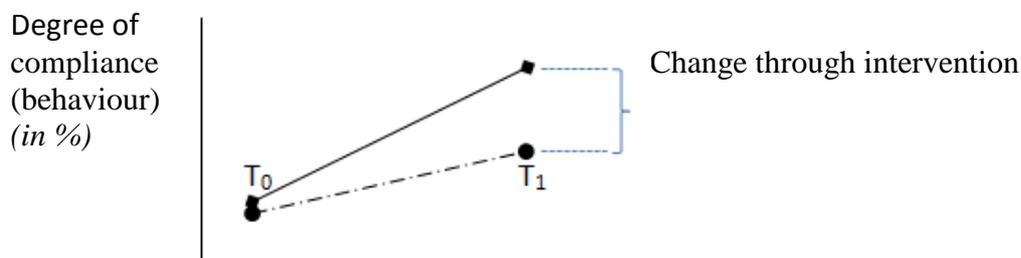
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Pre- and post-measurement with control groups

If you want to assess the effect of a (new) intervention among a specific target group and you are interested in the contribution of the intervention itself, the use of a pre- and post-test with an added control group is needed.



By adding a control group in the study design, it is possible to demonstrate the specific contribution of the (new) intervention. If in the intervention group a (larger) effect has been demonstrated between T0 and T1 than in the control group, the difference is due to the intervention performed and not to other possible (external) factors, because this is corrected for these influences.



A practical example is presented in Annex IV.4.

Verification of effectiveness

ANNEX IV

This Annex contains some practical examples relating to the different sections of the document.

The examples provided do not intend to present prescriptive or/and compulsory actions/interventions to verify the effectiveness of official control systems, or parts thereof, across Member States.

Additional examples will be added to the MANCP Network Interest Group in CIRCABC.

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ANNEX IV.1 – Data collection

Example from the Performance Management Framework for the Official Veterinarians (UK) on how to collect data in a consistent manner for analysis .

RAG	Status	Description
Green (9 to 10)	On track	Successful delivery to time, cost and quality is on or above standard and all key deliverables within the contract specification for service delivery are routinely met or exceeded. Integrity of service delivery and reputation is stable, consistent and regularly met.
Green Amber (5 to 8)	Broadly on track	Delivery to time, cost and quality is broadly on standard and there are no key deliverables within the contract specification that are falling significantly below standard or presenting serious risk to service delivery. Integrity of service delivery and reputation is maintained at an acceptable level.
Amber Red (2 to 4)	Off track	Delivery to time, cost and quality is being impacted on a periodic basis and there are various key deliverables within the contract specification that have fallen off track and are presenting significant and sustained risk to standards and service delivery. Integrity of service delivery and reputation is below acceptable standards.
Red (0 to 1)	Very clearly off track	Delivery to time, cost and quality is being seriously impacted on a constant basis with significant aspects of the contract specification failing to be delivered, presenting serious and high risk to standards and service delivery. Integrity of service delivery and reputation is seriously off-track and at significant risk.

The contract provision includes routine attendance by Official Veterinarians (OVs) in approved slaughterhouses and approved game handling establishments for veterinary and inspection functions and duties, the delivery of official controls and the delivery of services on behalf of Other Government Departments (OGD).

To support this, the Performance Management Framework (PMF) is centred on three pillars and these in turn will be supported by the information pack.



Attendance

The first provision of the contract is that the right person is deployed to the right place at the right time. This will be reported by exception at a local level and discussed during the monthly meetings. If there is a significant issue this will be escalated to the Head of Delivery / Service Delivery Partner meeting for resolution



Quality of Delivery

The key pillar of the PMF is the quality of the delivery of services provided by the Service Delivery Partner. This pillar includes accurate and proportionate enforcement to improve compliance standards in line with Hygiene Legislation which if not met has an impact on Exports to Third Countries. Enforcement and compliance data will be provided in the data pack and will be reviewed with a focus on quality and quantity of enforcement. Spot checks will be performed on the quality of the enforcement against an agreed minimum quality standard for each enforcement approach (written notice, Hygiene Improvement Notice, Remedial Action Notice and recommendation for prosecution) by the Field Veterinary Co-ordinator (FVL)/Legal and will be recorded in 2 categories: Administrative (spelling, grammar) and Technical (legislation, evidence). Unannounced Inspection reports and Veterinarian feedback from the audit will also be provided in the management information.

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Reporting

The reporting requirements of the contract include:

Timely submission of timesheets and throughput

Reporting requirements for OGD including Cattle ID checks and Animal Welfare Exception reporting.

Information Pack Contents:

- Compliance and enforcement data
- Post Mortem Inspection Verification and Contamination data
- Throughput and Timesheet reporting data
- Unannounced Inspection and Audit Feedback report
- OGD reports (Cattle ID, Animal Welfare Exception,) for timeliness, consistency, accuracy.

Weighting - Weighted scoring will be applied to the three pillars as below:

- Attendance – 10%
- Quality of Delivery - 70%
- Reporting – 20%

Verification of effectiveness

ANNEX IV.2 – Example of a pre- and post-measurement

This is an example from the NVWA¹² of the application of pre- and post-measurements to a new intervention approach for the degree of copper in feed for pigs of 12 weeks of age and older.

Problem and intervention approach

The European Regulation set its standards to the use of additives, such as copper, in animal feed. The NVWA found in 2014 that only 67% of the producers (farmers) of pig meat gave animal feed to the pigs of 12 weeks of age and older, which comply with the standard for copper. Subsequently, the NVWA conducted root cause analyses (target group analyses) to find out why producers had this problem. On the basis of the results NVWA has chosen for a communication strategy in conjunction with official controls. The producers were, both personally and through other media informed about the legal standard, the upcoming inspections, the consequences of violating the norm and an action perspective (to discuss with the feed supplier the content of copper) was offered. Then official controls were conducted whereby inspectors evaluated in addition what was done with the information sent by NVWA.

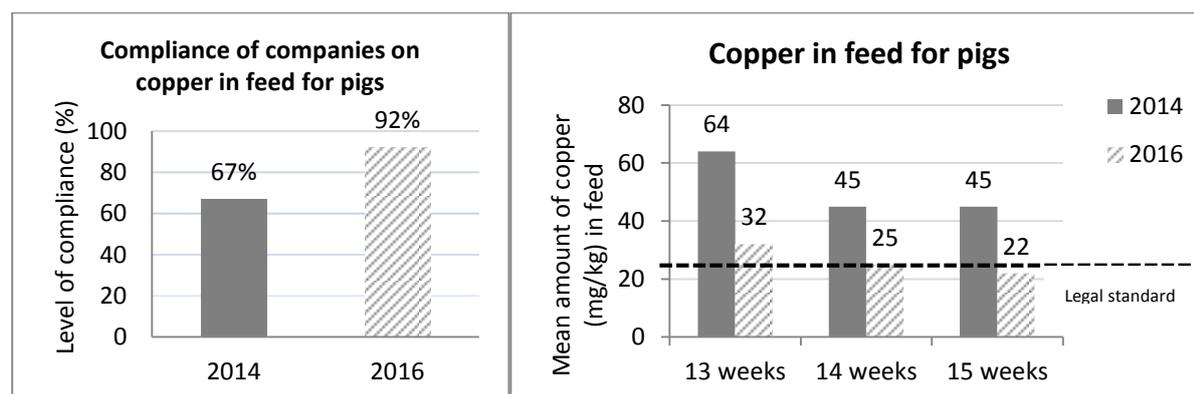
Approach to impact assessment

In 2014 approximately 80 randomly selected companies were inspected, which include samples taken from feed, water and manure to check the content of i.a. copper. The results are used to determine compliance at T0. In 2016, the personal communication was addressed to all producers of pig meat (approximately 1400 companies) and thereafter 100 companies were randomly inspected. In addition re-inspections of the pre-test were conducted, which were not captured in this measurement.

The data of the pre- and post-measurement were compared with each other. The information of the evaluation of the personal communication was used to interpret the results related to the contribution of the intervention to make it plausible.

Results

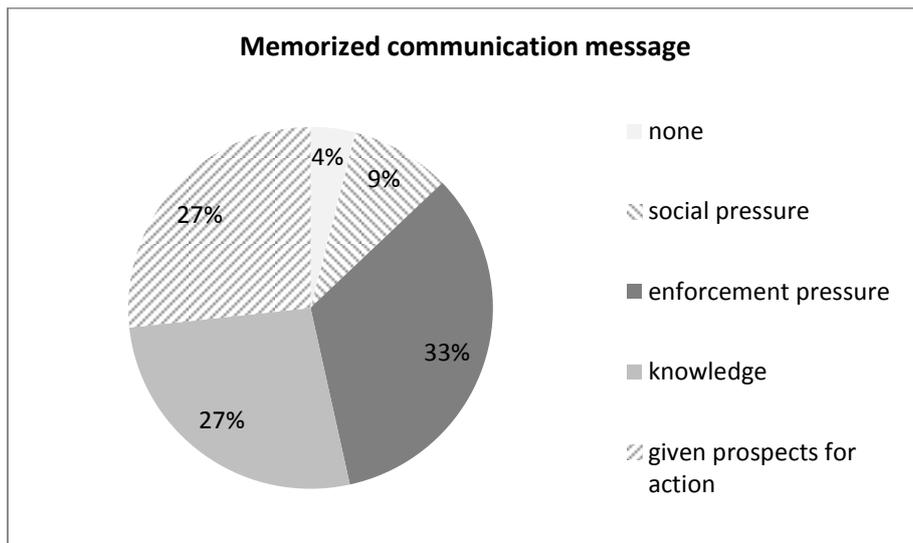
The compliance of this topic by the producers (farmers) of pig meat increased from 67% to 92%. The mean amount of copper in feed for pigs of 13, 14 and 15 weeks of age is approximately halved and is nearly below the legal standard of 25 mg copper/kg feed.



Subsequently, inspectors identified which communication message is remembered best. This demonstrated both the enforcement pressure (33%), knowledge (27%) as the given prospects for action (27%) was called most. Additionally, results showed that 76% of entrepreneurs have gone into conversation with his feed supplier or veterinarian.

¹² Nederlandse Voedsel- en Warenautoriteit / Netherlands Food and Consumer Product Safety Authority

Verification of effectiveness



Conclusions

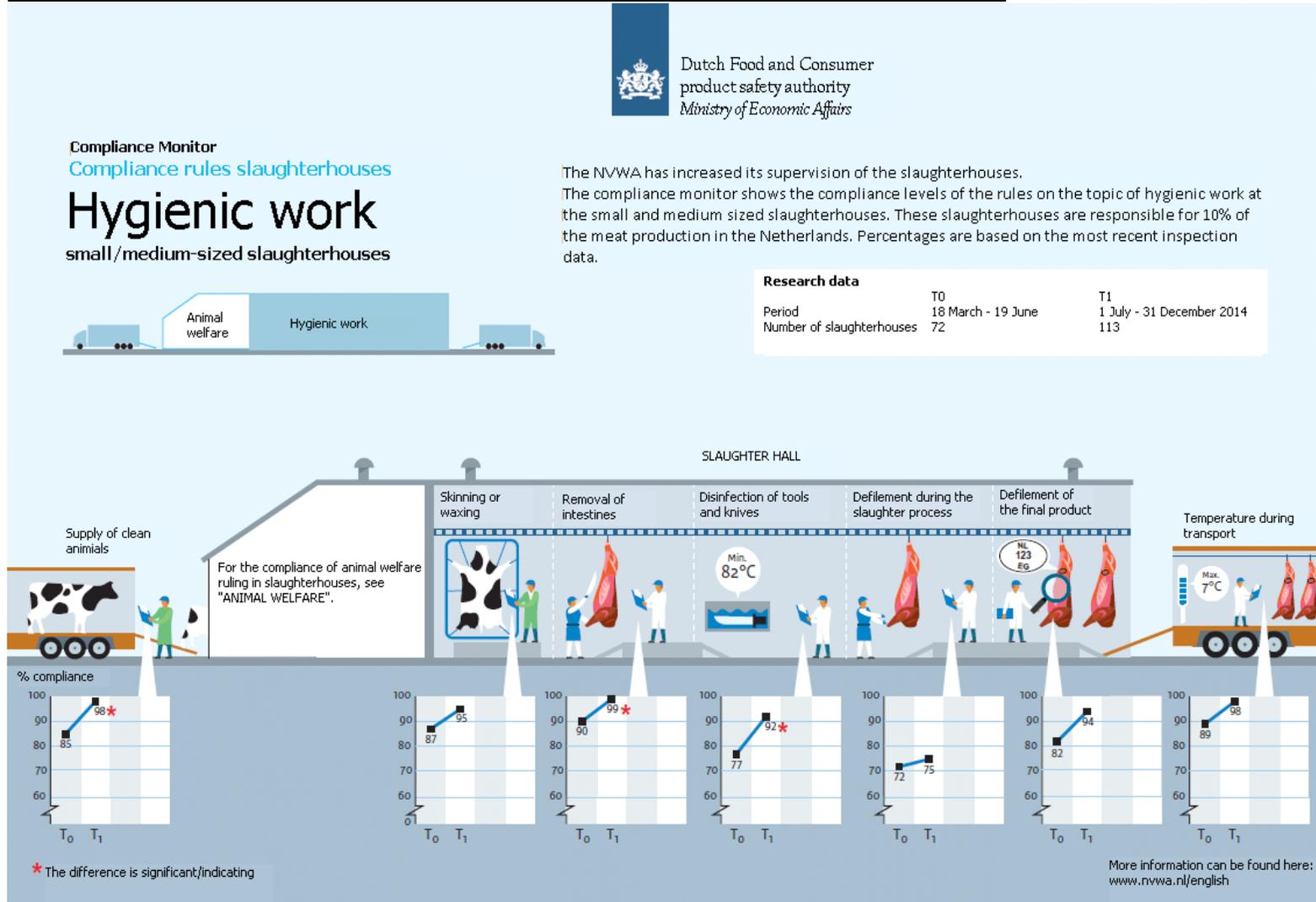
The compliance is much higher (92%), 25% more than before the new intervention approach and 76% of the producers of pig meat discussed the content of copper in feed with the feed supplier. It can be concluded that it is likely that among producers of pig meat the intervention in the form of the communication approach has led to a higher compliance on copper in feed.

Verification of effectiveness

ANNEX IV.3 – Trend analysis

NVWA examples on different types of trend analysis.

○ **COMPLIANCE MONITORING OF HYGIENE AMONG SLAUGHTERHOUSES BASED ON RISK-BASED INSPECTION DATA**



Verification of effectiveness

Inspectors have carried out official controls on the risky process steps of the slaughtering process. The findings are recorded on (digital) questionnaires via smartphones for each inspection subject (hygiene, animal welfare, etc.). On behalf of the compliance-monitor there is a distinction between small and medium-sized slaughterhouses and large(r) slaughterhouses with permanent supervision because of the varying inspection frequencies.

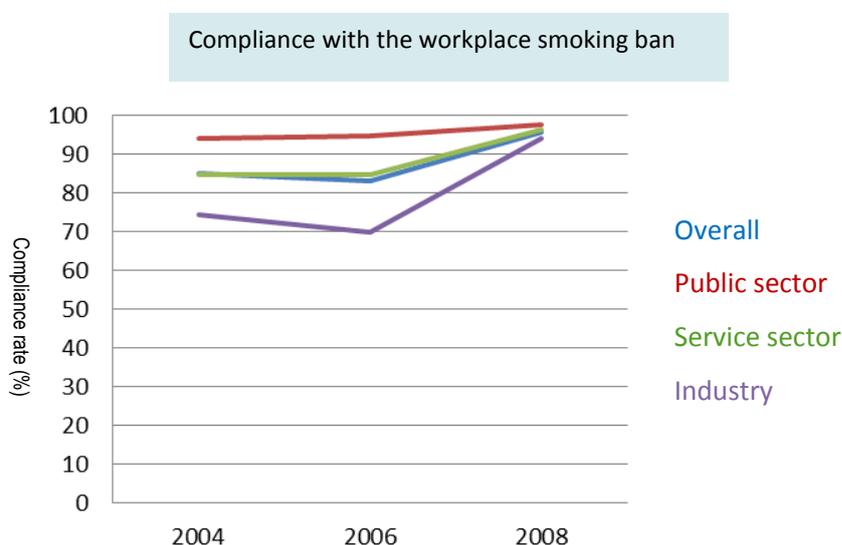
At the small and medium-sized slaughter houses (n = 135) the average compliance percentage of all final inspection results per slaughterhouse is calculated within half a year. In slaughterhouses with permanent supervision (n = 22) first we calculated the average percentage of compliance per month and there after the average of six months (with 6 data per slaughterhouse) to correct for the risk-based inspection.

The visualization of the monitor for small and medium sized slaughterhouses is attached as an example.

Verification of effectiveness

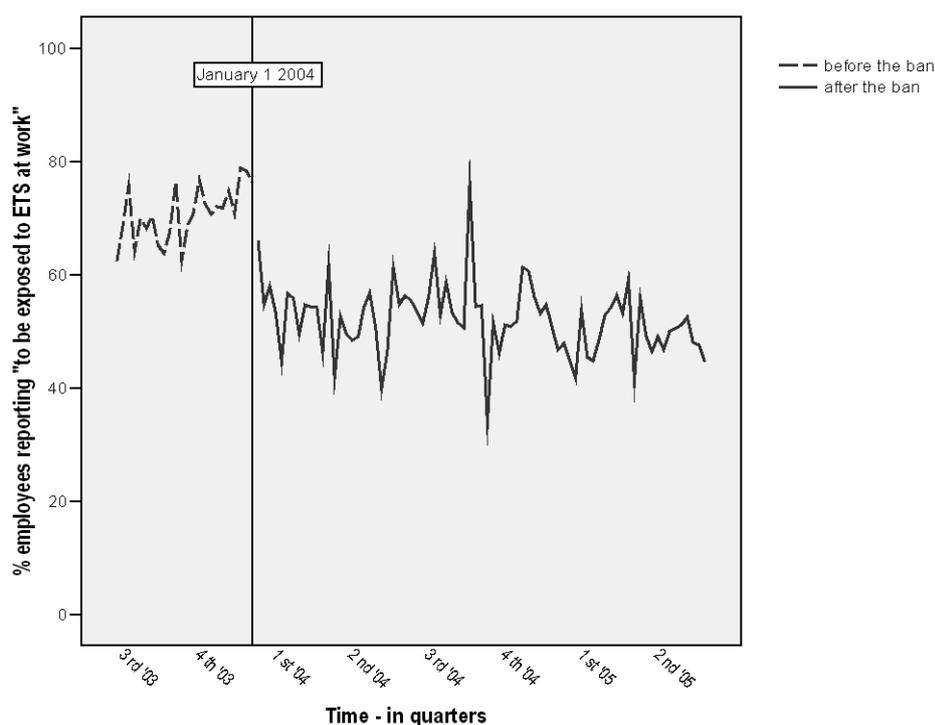
○ COMPLIANCE MONITORING OF WORKPLACE SMOKING BAN BASED ON RANDOM TELEPHONIC INTERVIEWS

To monitor the compliance of the workplace smoking ban ($n \approx 700.000$) we set up a telephone survey every two years. We followed the level of compliance in various subpopulations as well as the motives for complying with the legislation. Based on this information and on complaints of employees we carried out risk-based inspections. An example of the compliance monitoring is added.



○ COMPLIANCE MONITORING OF TOBACCO SMOKE BASED ON CONTINUOUS DATA FROM AN EXTERNAL PARTY

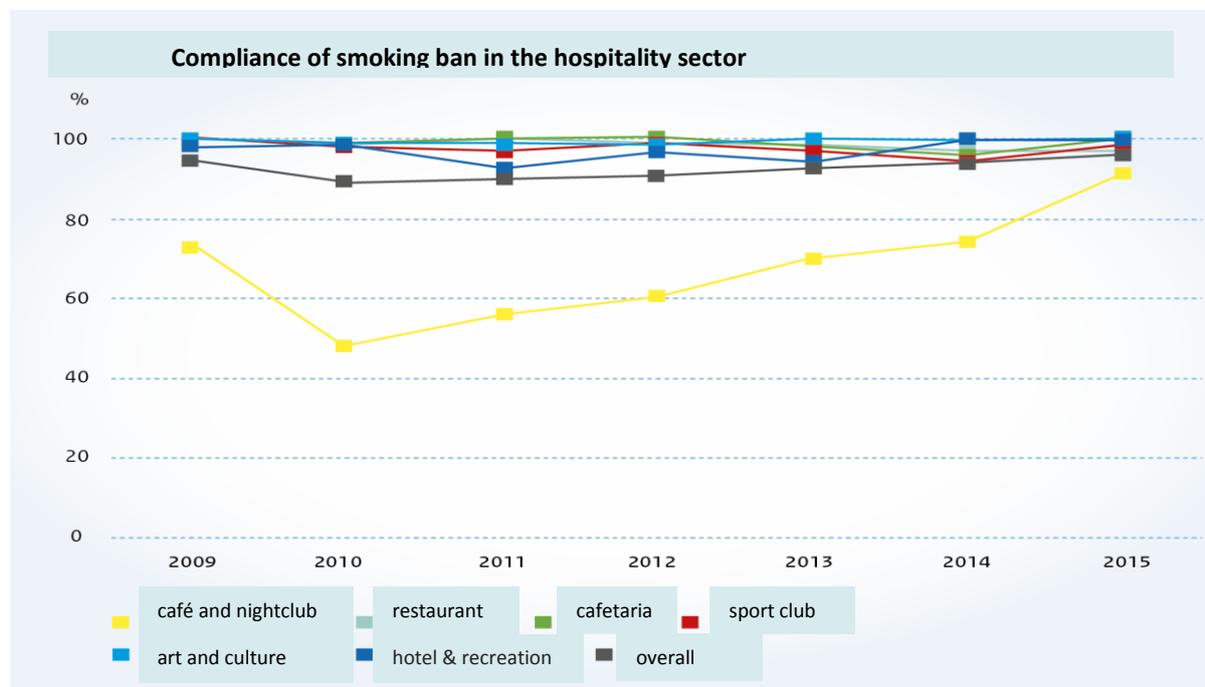
To measure the (outcome) effect of the workplace smoking ban, we used data from an external party (NGO). This dataset contains data of a digital survey among employees who report how often they are exposed to environmental tobacco smoke (ETS) at work, an indicator for the direct effect of compliance of the smoking ban.



Verification of effectiveness

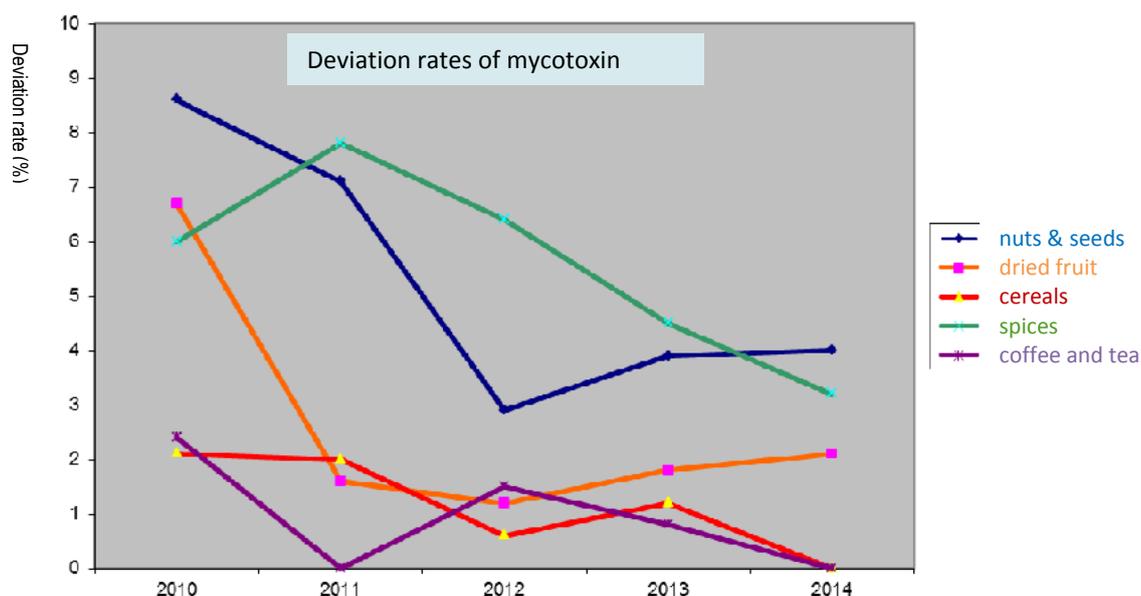
○ COMPLIANCE MONITORING OF SMOKE-FREE HOSPITALITY BASED ON RANDOM OBSERVATIONS

To follow the compliance of the smoking ban in the hospitality we set up a survey with observations. Because of the low compliance in the café's we made a further breakdown by categories and we lowered the frequencies in other categories. We used this information to observe the effects of our interventions and of other influences, like major litigation and legislative changes.



○ DEVIATION RATES OF THE PRESENCE OF MYCOTOXIN

The European legislation requires Member States to make sure the import of food of non-animal origin is below the mycotoxin limits. These checks take place on the basis of sampling and laboratory research. By presenting these results trends can be observed. To establish effects (trend reversals), it is important not to change the sample over time (randomly or risk based).



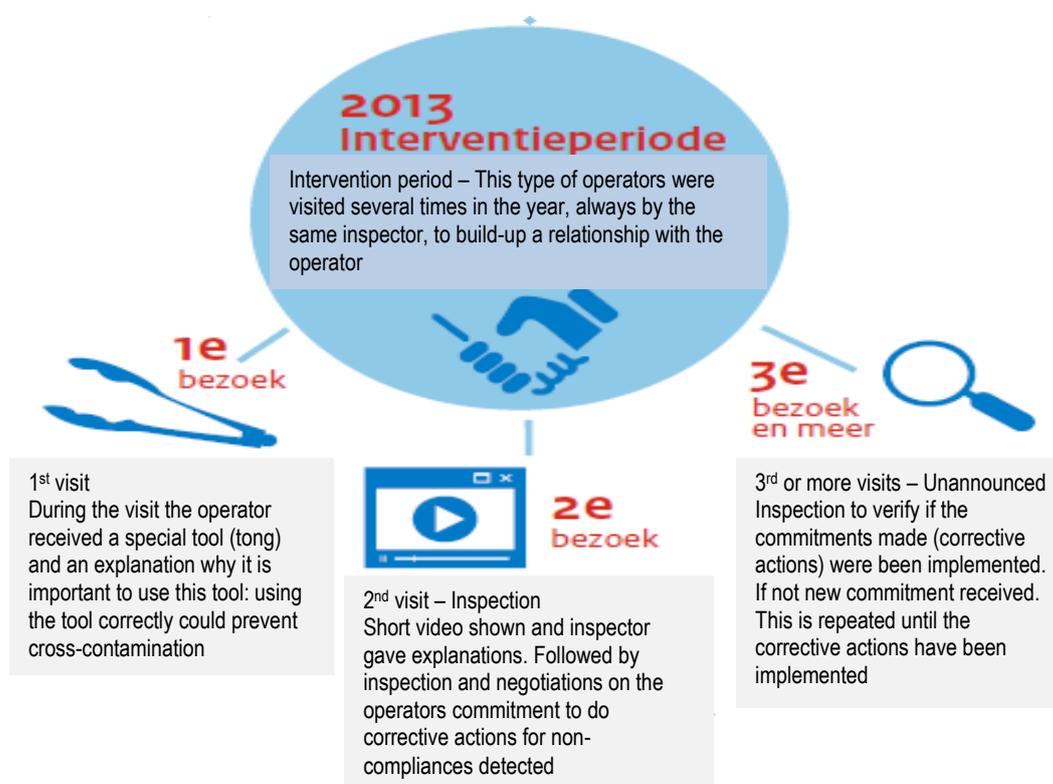
Verification of effectiveness

ANNEX IV.4 - Example of pre- and post-measurement with control groups

NVWA example of the application of pre- and post-measurement with control groups to a new intervention approach for shawarma/kebab entrepreneurs.

Problem and intervention approach

In 2011 it appeared that only 60% of shawarma/kebab entrepreneurs complied with the food safety legislation as result of official controls. The NVWA developed a new approach based on a risk and root cause analyses, whereby regular inspections, influencing behaviour techniques and cultural aspects were combined. The new approach consisted of multiple inspections (to build relationships), addressing the owner directly (to respect hierarchical culture), use of video material (to overcome the language barrier) and negotiating and agreeing time frames for correcting shortcomings (to integrate cultural aspects).

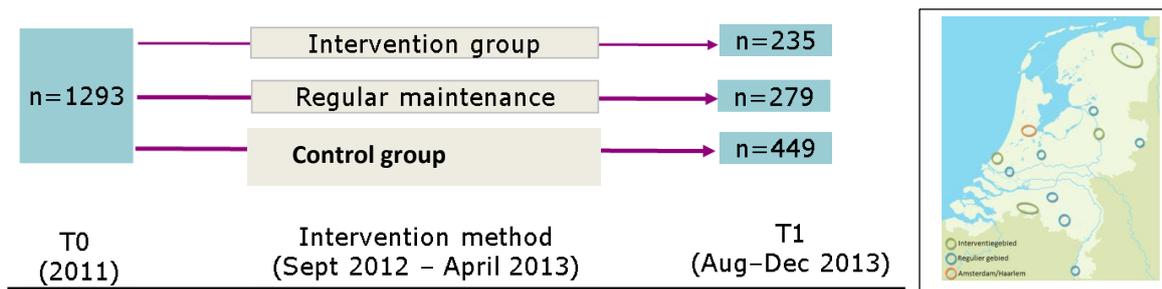


Impact assessment

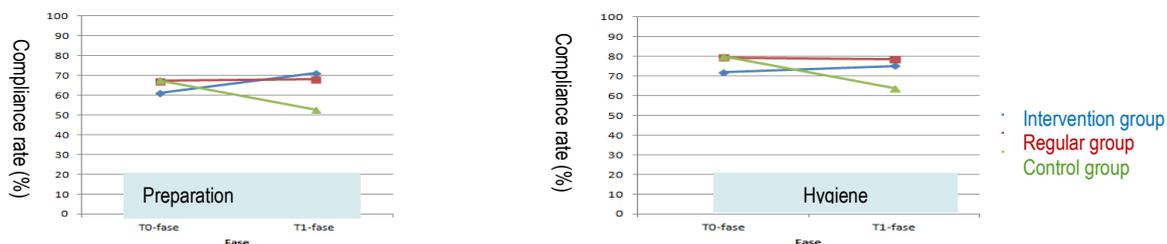
In 2011, we determined the level of compliance on the basis of retrospective inspection data from the overall compliance and more specifically in the areas of 1) hygiene regulations, 2) the correct preparation of food and 3) pest prevention. We then split the shawarma/ kebab entrepreneurs into 3 groups: the new intervention, the official controls, or no intervention was performed. The distribution was carried out to cities and regions within the Netherlands. In 2013, all shawarma/ kebab entrepreneurs were visited again in the same manner as in 2011, whereby the degree of compliance was recorded in the same subjects.

The data of the pre- and post-measurement of the various groups were compared, as well as the differences between the groups on T0 and T1 to assess the contribution of the intervention.

Verification of effectiveness



Results



- The new intervention approach led to a significant increase in compliance of the correct preparation of food and did not lead to a (significant) difference in hygiene compliance.
- In the control group (without intervention) there was a significant decrease in compliance.

Conclusion:

The results led to three conclusions:

1. the new intervention led to an increase in compliance in the correct preparation;
2. the regular official controls stabilised the level of current compliance;
3. no official controls led to a drop in compliance.

These conclusions meant that the added value of the new intervention worked in the preparation of food and that the added value of official controls is demonstrated in the difference in compliance between the regular and the control group.

Verification of effectiveness

ANNEX IV.5 - Example of reporting

FSA¹³ example of performance reporting to verify the effectiveness of contamination recording.

1. Contamination data is recorded at an establishment level by Official Veterinarians and Meat Hygiene Inspectors, who assess whether the Carcase or Offal have any visible contamination, and whether that contamination is Broadly within Control (BC) or that Controls are Inadequate (CI).
2. The findings are input on a web-based application against the total throughput on a daily basis for every establishment processing cattle, sheep or pigs.

Contamination

View Graphs

Transaction Date: 04/11/2015

Approval Number:

Find Approval Number

Record already existis with Ref: 134392

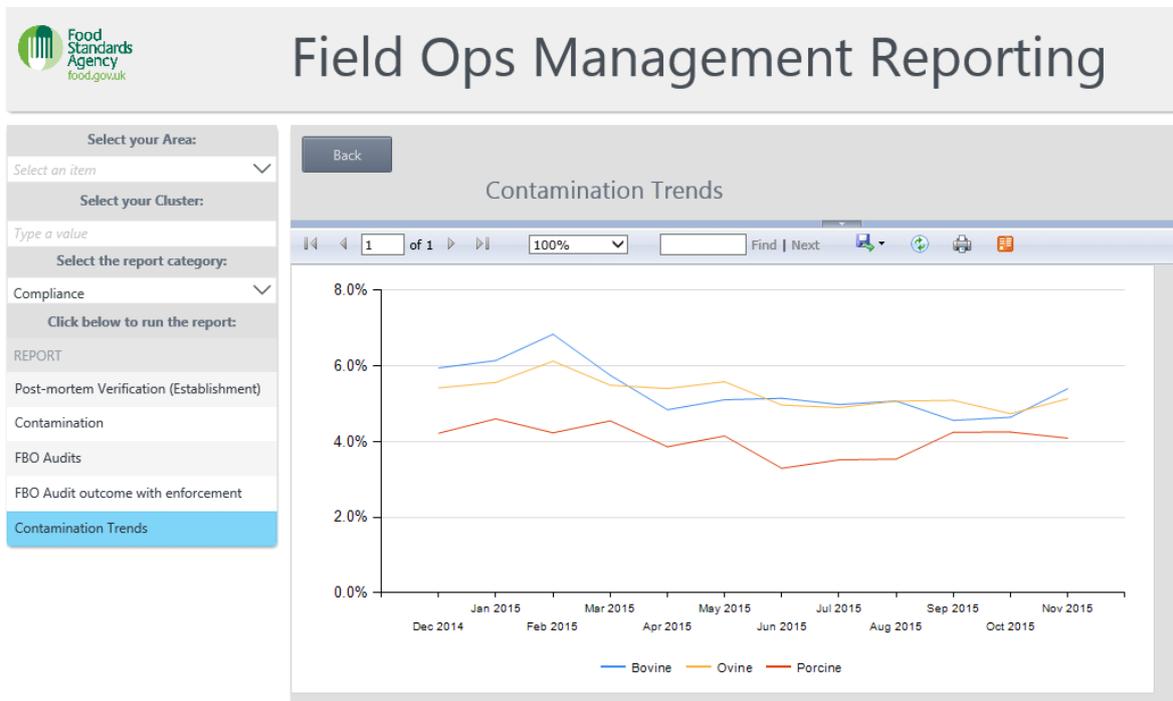
Not Applicable

	TP			BC	CI
Bovine	160	Carcase	Faecal	0	2
			Hair	0	0
			Bile	0	0
			Other	0	0
			Total	2	
Offal			Faecal	10	
			Bile	0	
			Other	0	
			Total	10	

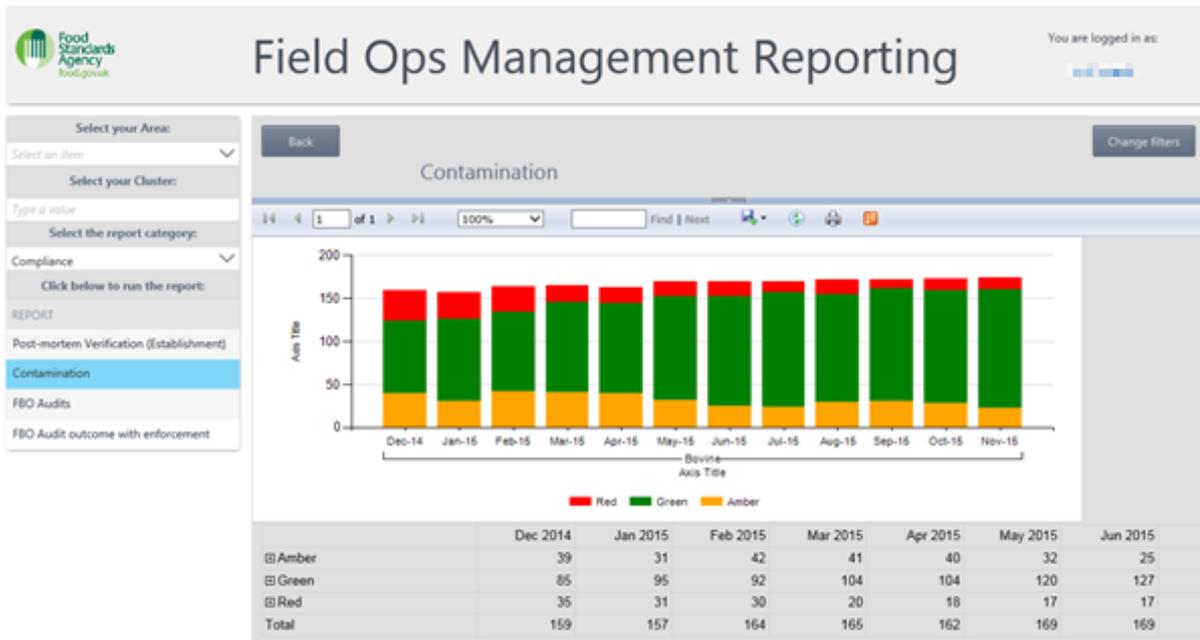
¹³ UK's Food Standards Agency (FSA)

Verification of effectiveness

3. Data from the application is stored in a database which is aggregated to provide data for operational managers, including:
 - i. Monthly national contamination trends by species:



- ii. Monthly trends for establishment performance according to contamination Red / Amber / Green levels:

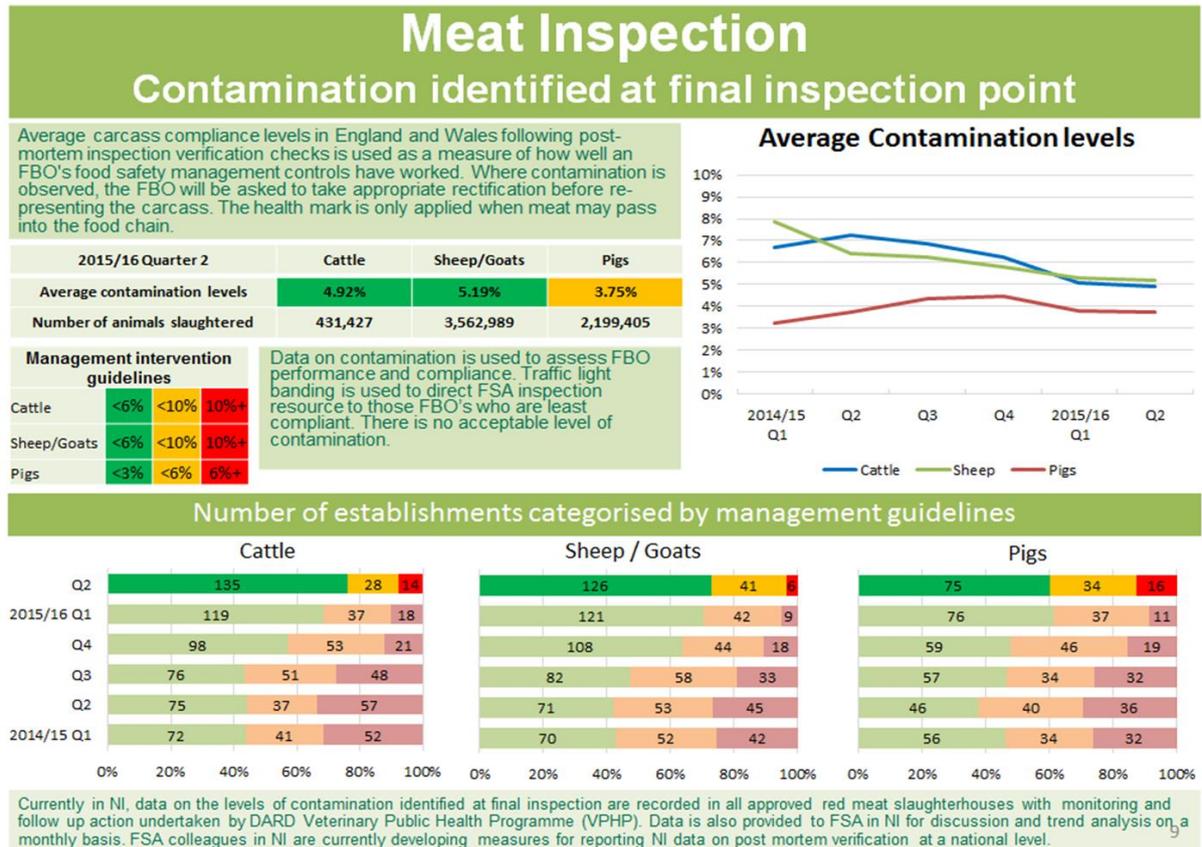


Verification of effectiveness

iii. Specific contamination levels at individual establishments:



4. This Data is then used as part of a performance report which is discussed by Operational Senior Management. This information is condensed and summarised and aims to show trend analysis over the period in the following way:



Verification of effectiveness

5. The final stage of reporting is to the Food Standards Agency Board (available to the general public). The information is presented in this report to give an overview of the operational activity of the agency to the public: <https://www.food.gov.uk/sites/default/files/fsa151109a.pdf>. The below diagram illustrates how the collection of data verifies the effectiveness of the performance from a plant/collection level to hierarchical Agency level.

