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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

BELGIUM

FROM 04 TO 08 MARCH 2013

IN ORDER TO EVALUATE THE SYSTEMS PUT IN PLACE TO GIVE EFFECT TO THE
PROVISIONS OF ART. 8(3) OF REGULATION 882/2004 OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of an audit carried out by the Food and Veterinary Office in Belgium from 4 to 8 March 2013.

The objective of the audit was to evaluate the system put in place to implement article 8(3), on control and verification procedures, of Regulation (EC) No 882/2004 of the European Parliament and of the Council, on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

The scope of the audit covered the procedures put in place by the Federal Agency for the Safety of the Food Chain (FASFC), which is responsible for the vast majority of official controls falling under Regulation (EC) No. 882/2004, as well as the procedures put in place by the Provincial Control Units (PCUs) of the FASFC, responsible for implementing those official controls.

The report concludes that within the overall framework of the FASFC quality management system, extensive procedures have been developed for the purposes of review and the verification of effectiveness of official controls, as required by Article 8(3) of Regulation (EC) No 882/2004. These verification procedures cover all levels of controls within the scope of this audit, and include both the technical as well as the policy aspects. They are supported and facilitated by measurable performance and impact indicators (KPI) which in turn relate to the CCAs strategic and operational objectives, and comprehensive IT tools which allow the necessary qualitative and quantitative analysis. In addition, the system is reinforced by internal audit and coordinated control activities. Necessary corrective actions emanating from any of these review activities are documented, time-bound and where possible linked to KPI, and their progress is equally monitored. Standardised procedures are also in place to review and where necessary correct the performance of official controls by individual staff. The operation of the procedures in place was found to be implemented consistently in the PCUs visited.

The report makes no recommendations.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ABP	Animal by Products
BIP	Border Inspection Post
CA	Competent Authority
CCM (DG Control)	Consultative Committee of Management, <i>Comité de Concertation du Management, Managementoverlegcomité</i>
CDM (FR) - DMO(NL)	Vétérinaire Chargé de Mission - Dierenartsen met opdracht
CEO	Chief Executive Officer
COCO	Coordinated inspections, <i>Contrôles coordonnés, Gecoördineerde controles</i>
DG	General Directorates
EMAS	Environmental Management System
FASFC	Federal Agency for the Safety of the Food Chain, <i>Agence Fédérale pour la Sécurité de la Chaîne Alimentaire, Federaal Agentschap voor de Veiligheid van de Voedselketen</i>
FAMHP	Federal Agency for Medicines and Health Products, <i>Agence Fédérale des Médicaments et des Produits de Santé, Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten</i>
FBO	Food Business Operator
Food Net	Database for management of data on controls
FPS-HSFCE	Federal Public Service for Health, Safety of the Food Chain and Environment, <i>Service public fédéral Santé Publique, Sécurité de la chaîne alimentaire et Environnement, FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu</i>
FVO	Food and Veterinary Office
GMO	Genetic Modified Organisms
IAQMS	Internal Audit and Quality Management Services <i>Service Audit interne, Qualité, Prévention et Service de médiation, Dienst Interne Audit, Kwaliteit, Preventie en Ombudsdienst</i>
IAD	Internal Audit Department <i>Cellule Audit Interne, Cel Interne audit</i>
KPI	Key Performance Indicator
MANCP	Multi Annual National Control Plan

NICU	National Implementation and Co-ordination Unit, <i>Unité Nationale d'Implémentation et de Coordination,</i> <i>Nationale Implementatie- en Coördinatie- eenheid</i>
QMS	Quality Management System
OC	Official Controllers <i>Contrôleurs, Controleurs</i>
OECD	Organisation for Economic Co-operation and Development
OI	Official Inspectors <i>Inspecteur (FR, NL)</i>
PCC	Provincial Consultative Committee <i>Comité de Concertation provincial,</i> <i>Provinciaal Overlegcomité,</i>
PCU	Provincial Control Unit, <i>Les unités provinciales de contrôle,</i> <i>Provinciale controle- eenheden</i>
Plani PRI	Application - allows system transfer of previous control history into the planning process and follow up for Primary sector
Plani TRA	Application - allows system transfer of previous control history into the planning process and follow up for Processing (transformation) sector
Plani DIS	Application - allows system transfer of previous control history into the planning process and follow up for Distribution sector
PPP	Plant Protection Products
RASFF	Rapid Alert System for Food and Feed
SA	Systems Audits
CCS	Consultative Committee of Sector <i>Comité de concertation sectoriel,</i> <i>Sectoraal Overlegcomité,</i>
TCC	Technical Consultative Committee
TBT	Dashboard, <i>Tableau de Bord</i>
VMP	Veterinary Medicinal Products

1 INTRODUCTION

This audit took place in Belgium from 4 to 8 March 2013, as part of the planned audit programme of the Food and Veterinary Office (FVO). The audit team comprised two officials from the FVO. The audit team was accompanied throughout the audit by representatives from the central competent authority (CCA), the Federal Agency for the Safety of the Food Chain (FASFC). An opening meeting was held in Brussels on 4 March 2013 with the CCA, during which the audit objectives, itinerary, and the standard reporting and follow-up procedures were confirmed, and additional information required for the satisfactory completion of the audit was requested.

2 OBJECTIVES

The objective of the audit was to evaluate the system(s) put in place to implement article 8(3), on control and verification procedures, of Regulation (EC) No 882/2004 of the European Parliament and of the Council, on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules¹:

Article 8 (3)

Competent authorities shall have procedures in place:

(a) to verify the effectiveness of official controls that they carry out; and

(b) to ensure that corrective action is taken when needed and that the documentation referred to in paragraph [8.] 1 is updated as appropriate.

The scope was limited to the procedures put in place by the FASFC which is responsible for the majority of official controls (90%) falling under Regulation (EC) No. 882/2004, as well as the procedures put in place by the the Provincial Control Units (PCU) of the FASFC responsible for implementing these official controls.

In pursuit of these objectives, the itinerary included meetings with the following CAs:

Competent Authorities	Number	Comments
Central	1	Federal Agency for the Safety of the Food Chain (FASFC) <i>(within FASFC – representatives of the central administration of DG Control, DG Control policy, the Implementation and Co-ordination Unit (NICU) and Internal Audit Department (IAD),</i>
Provincial	2	Provincial Control Units Namur (Walloon Region) and Leuven (Flemish Region) of FASFC
Local	2	Meetings with representatives of Official Controller (OC), Official Inspector (OI) and “Vétérinaire Chargé de Mission” (CDM-DMOs) in the two provinces visited

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

3 LEGAL BASIS

The audit was carried out under the general provisions of the legislation of the European Union (EU) and, in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

4 BACKGROUND

4.1 SYSTEMS AUDITS

Regulation (EC) No 882/2004 sets out over-arching requirements that systems for official controls as operated by CAs must meet, in order to allow their uniform delivery and consistently high quality. Consequently, deficiencies in or incorrect implementation of core elements of control management systems manifest themselves in non-compliances and other problems on the ground, as these are *inter alia* identified in the course of FVO audits. FVO is developing the Systems Audit (SA) approach in order to better focus upon and address these core issues.

The objectives of the SA are to:

- examine the operation of selected "horizontal" control system elements across the EU;
- identify good practice as well as difficulties encountered in their implementation;
- promote and contribute to a coherent EU-wide approach towards systems aspects of official controls, without imposing excessive burden on Member States;
- contribute to a systems-based approach to FVO audits;
- further expand the FVO's specific Member States' knowledge base, thus providing useful additional input into the prioritisation process for FVO audits; further expanding our specific Member states knowledge base;
- provide useful background information to FVO audit teams on the overall progress made by the Member state in the operation of the selected control system elements.

The SA model consists of an initial phase of desk analysis, (including review of Multi-Annual National Control Plans, Member State Annual Reports, FVO reports and Country Profiles, and other relevant sources of information) followed by a short and targeted series of audits of a sample of Member States for each selected topic, with a view to drawing valid overall conclusions and, where appropriate, to issue recommendations which are relevant to all Member States.

4.2 VERIFICATION OF EFFECTIVENESS

Regulation (EC) No. 882/2004 sets out, in Article 8(3), requirements in relation to control and verification procedures. Official controls must a) be carried out in accordance with documented procedures, and b) Member States must have procedures in place to verify that official controls are effective, and to correct them where shortcomings are identified, including the updating of control procedures and/or documentation. The "verification" requirement regularly features as an issue in FVO reports, across all Member States although, it would appear, more often than not in terms of "verification of compliance with planned arrangements" ("*doing things right*") rather than "verification of effectiveness of official controls" ("*doing the right things*").

Investigation of this theme in recent FVO General Follow-up audits shows that CAs do gather substantial amounts of control data, but the ongoing evaluation of that data in terms of effectiveness

appears vary greatly. Equally, the information contained in MS annual reports suggest a similar variation in the extent to which the effectiveness of controls performed, is evaluated. Given the above, and considering the importance of ensuring uniform and consistently high quality official controls, this first round of SA focuses on procedures to verify the effectiveness of official controls.

4.3 PREVIOUS AUDITS

The FVO has carried out 42 inspections and audits in Belgium since 2005, the reports of which can be found at: http://ec.europa.eu/food/fvo/ir_search_en.cfm

While the topic of procedures to verify the effectiveness of official controls has not been the specific objective of any previous FVO audit, the subject has been considered within the scope of numerous sectoral audits carried out since 2006.

At the time of writing, any recommendations made in relation to verification of the effectiveness of official controls arising from these audits had been closed (the last General Follow-up Audit carried out in Belgium was in September 2012).

5 FINDINGS AND CONCLUSIONS

5.1 LEGAL REQUIREMENTS

Article 8(3) of Regulation (EC) No 882/2004 requires that:

Competent authorities shall have procedures in place:

(a) to verify the effectiveness of official controls that they carry out; and

(b) to ensure that corrective action is taken when needed and that the documentation referred to in paragraph 1 is updated as appropriate.

The paragraph 1, referred to above, is Article 8(1) of the Regulation, which states:

Competent authorities shall carry out official controls in accordance with documented procedures. These procedures shall contain information and instructions for staff performing official controls including, inter alia, the areas referred to in Annex II, Chapter II.

5.2 COMPETENT AUTHORITIES

5.2.1 Findings

Detailed information on the structure and organisation of the Belgium competent authorities can be found in the Country Profile for Belgium at: http://ec.europa.eu/food/fvo/last5_en.cfm?co_id=BE

The FASFC is responsible for the majority of official controls falling under Regulation (EC) No. 882/2004. It carries out controls on food, feed, animal and plant health at all stages of the food chain and some controls are shared with other CAs. The divisions of competences is summarized below:

<i>FASFC</i>	<i>Controls shared with other CAs</i>
Animal Health	-
Food of Animal Origin	-
Imports of animal and food of animal origin	-
Transmissible Spongiform Encephalopathies (TSE) & Animal By Products (ABP)	Waste (including ABP) policy and control is the competence of the three regions (Wallonia, Flanders and Brussels).
Feedingstuffs and animal nutrition	Implementation of controls for genetically modified organisms (GMO) fields, seeds and their contained uses is competence of the regions and the Federal Public Service for Health, Safety of the Food Chain and Environment (FPS-HSFCE).
Food stuffs and food hygiene	-
Veterinary Medicines Products & Residues (VMPs)	Distribution chain of VMPs is shared between FASFC and Federal Agency for Medicines and Health Products (FAMHP) The licensing of veterinary warehouses is the competence of the FPS-HSFCE.
Imports of food of plant origin	-
Plant protection products (PPP) and residues	Authorisation of PPP and control of premises used for storage of PPP is the competence of FPS-HSFCE.
Animal Welfare	FPS-HSFCE is responsible for Animal Welfare legislation. FASFC inspectors carry out the controls within the food chain (farm, slaughterhouse and transport) and their reports are periodically sent to FPS-HSFCE. Animal welfare outside the food chain (pet shops, circuses, zoos) is the competence of FPS-HSFCE.
Plant Health	Seed, seed potato and the control on the issue of plant passports is the competence of the regions.

Based on the strategic objectives, policies and strategic documents developed by the services of the CEO of the FASFC in close collaboration with all DGs (the business plan, the global Quality Manual, the key performance indicators (KPIs)), each DG develops its own operational objectives.

DG Control policy carries out the risk assessment and prepares the official control programme.

DG Control within FASFC, prepares instructions and check-lists and is responsible for coordination and integration of the operational activities carried out by the 11 Provincial Control Units (PCUs) of the FASFC.

The NICU within DG Control, co-ordinates controls, implements instructions and their harmonised application in the PCUs, monitors and evaluates their performance and prepares communicates and reports to the DG Control - NICU, making recommendations to the PCUs when problems undermining effectiveness of controls are identified and their correction is needed.

The internal audits are carried out by the Internal Audit Department (IAD) within the "Internal Audit, Quality and Prevention Service" (IAQMS) of the FASFC, situated in the staff of Chief Executive Officer (CEO). The internal audit section was created in September 2006 and became fully operational after an initial pilot phase in the first half of 2007.

Within DG Control, the Consultative Committee of Management (CCM) composed of the

management of the central administration of DG Control and of the heads of PCUs, is the body that conducts management reviews and takes the relevant policy decisions.(see 5.3.7).

Each PCU is led by a Head of PCU, who reports back to the central administration of DG Control which, in turn, communicates and reports to DG Control Policy concerning the overall outcome of controls carried out at the PCU level.

Control officials (*Official Controller (OC), and Official Inspector (OI)*) and private veterinarians (*Vétérinaire Chargé de Mission (CDM-DMOs)*) assigned to specific tasks by FASFC carry out official control along the food chain.

5.2.2 Conclusion

There is a clear structure and division of responsibilities for the activities necessary for the development and implementation of official controls, for verification of compliance and effectiveness and for review of official controls.

5.3 VERIFICATION PROCEDURES

5.3.1 Quality Management Systems (QMS)

All the FASFC competent authorities and laboratories are certified/accredited to relevant ISO 9001, 17020, 17025 and Environmental Management System (EMAS) as applicable, except the border inspection posts (BIPs) which are in the process of accreditation, to be completed in 2013. The audit team noted that all the procedures put in place by the FASFC to implement the requirements of Article 8(3) (a) and (b) are established in the framework of the quality management systems (QMS) in place and underlying the accreditation.

5.3.2 Development and implementation of the programme of official controls

5.3.2.1 Findings

The FASFC organises the official controls (inspections and sampling) on the basis of the Multi-Annual National Control Plan (MANCP) in the framework of Regulation (EC) No. 882/2004 (correlated with the FASFC Business Plan), which sets 9 strategic objectives for the period 2012-2014. These strategic objectives have been translated into 208 operational objectives. On an annual basis, the DG and PCU adapt the federal framework to their own areas, setting measurable targets per province, and tailored to sector level. The achievement of these operational objectives is monitored and assessed by management through a range of tools and indicators (see 5.3.5).

Based on the 2013 "*Operational Objectives*" and "*Programme*" received from the centre, the Heads of PCU allocate controls to the relevant staff within PCU (primary production, processing and distribution) and reports monthly to the central administration of DG Control.

The controls are carried out by officials (controllers and inspectors) although certain tasks (such as certification, slaughterhouses, BIPs, ship-stores, producing establishments, fish markets, and validation of self-checking system of Food Business Operators (FBOs)) can be performed by CDM-DMO.

The audit team noted that all procedures on the control and sampling programme, methods for reporting and how to record data, instructions on how to manage non-conformities, preventive and corrective actions are generic procedures and developed within in the framework of the QMSs.

Methodologies for controls and sampling for specific areas were provided in "*Notes de Service*" *and* are aligned with the QMS procedures.

Standardized weighted check-lists with automatically calculated compliance statuses are used by staff when are carrying out controls. They are uploaded in the centralised database (see 5.3.4). In general, the check-lists issued by the CDM-DMO are not included in this system but are filed at PCU level, although findings, sampling results, non-compliances and the likelihood of non compliance must be notified to PCUs and uploaded in the database.

Planned deviations from programmed controls (eg; following RASFF, complains) or from the prescribed control interventions (type or frequency) contained in the check lists must be notified and justified, and can be agreed only in coordination with DG Control/the head of PCU as applicable; they must be recorded in the database.

The PCUs and the head of responsible sector must monitor and produce overviews on the progress and compliance with planned arrangements (progress and delays - against the operational objectives and the targets established), the performance of the official control from the perspective of productivity (measuring efficiency, using Key Performance Indicators (KPI)) and quality (i.e. anomalies identified, issues notified by the staff).

The regular overviews are discussed and decisions are taken as applicable, during monthly meetings of all heads of sectors with the appropriate coordinator of the administration of DG Control (Consultative Committee of Sector (CCS)), and monthly meetings of Heads of PCU and sector leaders (the Provincial Consultative Committee (PCC)).

While in most of these cases, these KPIs are used by the PCUs to measure the delivery of planned arrangements (ie the required number of controls actually carried out) they are also used by the CCA to give an indication of their effect (such as: trends in number of non-compliances per sector, success of series of controls in reducing eg. disease incidence, level of rapid alerts etc.).

5.3.2.2 *Conclusions*

The FASFC had clearly defined the strategic and operational objectives and processes to allow the delivery of results set out in the planned arrangements in the framework of the QMS. Clear and measurable targets and indicators had been established in order to monitor and evaluate progress, to compare the outcome against the expected results, and to identify any discrepancies. The arrangements support verification of both compliance as well as effectiveness, and subsequent corrective action in relation to the official control systems in place.

Adequate procedures/methodologies for implementation of the programme of officials controls have been put in place by FASFC, and developed in the framework of QMS. Procedures in place related to deviations from planned control arrangements ensure that such deviations are strictly controlled, and documented. Key performance indicators developed by the FASFC allow progress towards the achievement of the operational objectives and the performance of official controls to be measured, and assessed against targets established by the CCA.

5.3.3 *Monitoring performance – use of IT tools*

5.3.3.1 *Findings*

The official control outputs of OC and OI are reported in an integrated data-base (“FoodNet”). As stated above, the outputs of the CDM – DMOs are reported in FoodNet too, but to a lesser extent (see also 5.3.6).

The audit team noted that the level of detail in relation to official control allows both the central administration of the FASFC and the PCUs staff involved in the monitoring process to detect issues that might affect compliance with the terms/conditions set out in FASFC procedures and legislation, and consequently the effectiveness of official controls performed.

In order to ensure that reports/follow up reports are submitted on time, QMS procedures require that 100% of control reports must be uploaded within 7 days; this is checked by the central administration of the FASFC and PCUs as part of KPI monitoring.

The audit team observed the operation of the FoodNet system at central and local level and noted that it provided efficient queries to track and follow up the relevant information concerning verification of effectiveness (from the record of non-conformities for each checklist to the overview of global trends (expressed in %) of recurrent non-conformities related to a specific sector/policy). As regards both the verification of compliance with planned arrangements and the verification of effectiveness, it was noted that the application allows the CAs to:

- carry out qualitative checks (compliance with documented procedures, use of templates, timely reporting and completeness and correctness of the forms filled) of the control reports/other documents in accordance with strategic objectives of FASFC;
- supervise the progress of implementation of sampling and controls programmes;
- measure and compare results with expectations; to compare the results over the last 2-3 years and establish trends;
- supports decision-making in relation to the official control system (s) in place.

Within the framework of QMS, procedures for validation of data entered in FoodNet, (checks for missing records, checks that the data is in a specified format, checks that all key data are included, checks that the data lie within a specified range of values etc) were put in place by FASFC. FASFC stated that validation of data is carried out before each programming stage of official controls.

Work is in progress on different applications tools (PlaniPRI, PlaniTRA and PlaniDIS) which should allow systematic transfer of the control history, into the planning process and follow up.

5.3.3.2 *Conclusion*

FASFC operates well-advanced IT tools s which allow it to collect, collate and exploit data, both quantitatively and qualitatively (control results/reports/non-conformities) in order to verify both compliance with and effectiveness of planned arrangements. The quality and appropriateness of data collected is supported by QMS procedures and in turn underpin the latter in terms of quality management review.

5.3.4 Monitoring performance – use of indicators and impact barometers

5.3.4.1 Findings

5.3.4.1.1 Key Performance Indicators (KPIs)

The progress made towards the FASFC annual planned outcomes, strategies and objectives (Business Plan, MANCP, Control and Sampling programmes) is measured and assessed by means of KPIs. These are defined within the framework of QMS requirements and include a number of measurable parameters such as time, distance, number of missions carried out, number of inspections, number of missions with warnings, “*Procès Verbal*”, divergent measures, re-visit, closing dates of files etc. The audit team noted that the KPIs are used by PCUs for monitoring the efficiency of the official controls performed by staff from the perspective of productivity and quality, and by FASFC's central administration and PCUs as indicators of performance, benchmarking across PCUs, and sectors. KPI results are reviewed during sectoral and provincial meetings at PCU level, but also during Consultative Committee of Management (CCM) meetings at central level, and are used as support for the decision-making in relation to the efficiency and effectiveness of the official control system(s) in place.

5.3.4.1.2 Barometers (impact indicators)

Since the second half of 2010, FASFC uses 3 impact indicators - "Barometers" for food, animal and plant health. These tools were developed by a working group of the FASFC Scientific Committee (activated in April 2009), in consultation with FASFC Management and the Advisory Committee of FASFC. In their development, FASFC followed the “Pressure – State – Response” concept developed in 1980s by the Organisation for Economic Co-operation and Development (OECD) to classify environmental indicators, integration, scoring and ranking of information along the food chain, resulting in selection and prioritization of measurable indicators (30 indicators for the “food barometer”, 12 indicators for the “animal health barometer”, and 13 indicators for the “plant health barometer”). These tools give an indication of the outcome of the overall food policy over the last 2 years. The audit team noted that they are also used by DG Control policy as a communication tool with major stakeholders.

5.3.4.2 Conclusion

Measurable key performance indicators and impact indicators have been developed which allow FASFC to measure processes, compare outcomes against the expected results. In turn, this allows an assessment of the overall impact of the official control system(s) to be made and thus supports the FASFC system for verification of effectiveness, and corrective action.

5.3.5 Supervision

5.3.5.1 Findings

According to the 2013 objectives for PCUs, and in line with the requirements of ISO 17020/17025/9001, each Head of PCU/Head of sector shall carry out/organise documentary checks, joint inspections on-the-spot, meetings, annual evaluation of the performance of staff, and shall monitor the performance indicators (KPIs).

These requirements and their application are summarized below:

	Documentary check for each employee/ per year (reports or other documents uploaded in Data Bases)*	Joint inspections on the spot **/per year	Annual Evaluation ***	Performance indicators - KPI (only for officials)	Information and Debriefing Meetings & Training (per year)
CDM-DMOs	At least : 1 report with enforcement measures (PV, warnings, divergent measures) & 1 report without measures	Primary sector = 1 time Transformation sector = 1 time Distribution sector = 0 (no CDM-DMOs was employed in this sector)	Procedures developed within QMS	-	Information meetings*****: 10 Sector debriefing meetings: Monthly Training : 50 hours in 3 years with a minimum of 12 hours/year
Inspectors	same	2 times	Federal Public Administration procedures	Efficiency**** indicators : together give an overview of the work for each PCU	Meetings same Training: 10 days
Controllers	same	same	Federal Public Administration procedures		Meetings : same Training: 10 days
PIF staff (CDM-DMO)	At least: 2 reports with enforcement measures (PV, warnings, divergent measures) & 2 reports without measures	same (started from January 2013)	Procedures developed within QMS	-	Meetings : same Training: first year is 1 month and then is 10 days /year (started from January 2013)

* When a problem is found in a folder, a file verification will be performed every 3 months for the employee concerned, and for one year from the finding.

** The reports of the joint inspections are filed in the Evaluation file of each employee.

*** The annual evaluation of the staff is the competence of PCUs. The annual assessment of the CDM-DMO is made before renewing their annual contract with the PCU and aims to evaluate if the veterinarian is meeting the objectives of his contract and respects its conditions. The annual evaluation could lead to

- a renewal of the "*Convention de execution*" with or/without changes to "*Cahier de charge*"
- a proposal to the management of PCU to interrupt the "*Convention de execution*" after hearing the CDM-DMO
- a refuse to renew the "*Convention de execution*".

Any decision must be motivated by the head of PCU.

**** Individual results of OC/OI/DMOs-CDMs are examined at PCU level and overall figures concerning sectors are reviewed during cascade meetings (CCS, PCC, CCM).

***** According to "*Cahier des Charges and Specification*" the CDM takes part in meetings with the FASFC, only if is necessary.

The audit team noted that the PCUs are responsible for supervising their own staff. Standardised procedures and instructions for the verification/assessment of the performance of individual official controls carried out by staff (quantitative and qualitative) were put in place by the central administration of DG Control, and the audit team observed that these procedures were consistently implemented in both PCUs visited. In general, the measures described above were planned, monitored and reported by PCUs in the central database, with the exception of documents concerning the CDM-DMO evaluation, which were dealt with and filed at the PCU level.

Since 2011, FASFC has introduced a new approach, the "*co-ordinated inspections (COCO)*", a task attributed to the NICU. Their aim is to verify and improve the quality of controls, and to streamline

the work between PCUs and inspectors. According to FASFC, this is one of the mechanism that verifies the consistency of the implementation of procedures through observation of controls carried by the PCUs, but also indentifies and evaluates any problems that may weaken the effectiveness of controls.

The audit team noted that these inspections are performed in accordance with a standardised framework, developed within QMS, and in establishments across the country performing the same activity (i.e slaughterhouses, feed sector etc). The annual programme (nature, timing and operation reports) and the teams are determined by the Regional Director on the basis of a specific procedure ("*Establishing the annual controls programme coordinated by NICU*"). COCO are carried out by officials and experts of the central administration of DG Control, representatives of NICU and PCUs. FASFC explained, and demonstrated, how the outcome of COCO was used both for the verification and improvement of both individual official controls, as well as for the verification and improvement of parts/processes of the official control system(s). The audit team noted that COCO findings and conclusions led to actions/recommendations (horizontal and vertical) for all levels (Central administration of FASFC and PCUs).

5.3.5.2 Conclusion

There are procedures in place for the qualitative assessment of the performance of individual control staff as well as the official controls they carry out, and for the verification of the effectiveness of parts/processes of the official control system(s) put in place by FASFC, at PCUs level. These processes also contribute to harmonisation of the controls carried out in PCUs.

5.3.6 Feed-back and corrective actions

5.3.6.1 Findings

5.3.6.1.1 Feedback

For the purposes of ensuring that (line) management is kept aware of the main outputs of the controls systems put in place, QMS procedures provide for meetings to be organised, which cover all levels:

- At Agency level, in each DG within FASFC, at regional, provincial level and sectoral level;
- all Heads of sector (primary production, processing and distribution) meet every month with the appropriate coordinator of the administration of DG Control, within the context of the CCS;
- the PCC is composed of the Head of UPC and sector leaders. The PCC meet monthly;
- at regional level, meetings are held between the Regional Director and the heads of all UPC of that region (Regional Consultative Committee – RCC); the RCC are held monthly;
- every two weeks a meeting is organized within the DG Control staff. Files discussed at these meetings relates to services of the central administration of the DG Control.

The overview of the objectives and the KPIs/results of control plans for each PCU and by sector are also sent quarterly to the two regional directors, for review.

Bilateral meetings can take place to prepare the regular meetings or other non-anticipated events (RASFF, crisis etc).

5.3.6.1.2 *Reviews by management*

The organization and the functioning of management reviews within DG Control are determined by QMS procedure (ie. "*Organisation du Comité de Concertation du Management*" of DG Control), through the Consultative Committee of Management (CCM). The CCM meets every month and is chaired by the DG of the DG Control. The CCM monitors and reviews both the the strategic and operational framework, and takes policy decisions as appropriate.

Various tools and indicators are used by DG Control as the basis for these discussions:

- "*XL table(s)*" ("dashboards") which are defined in QMS procedures (ie. "*La gestion du tableau de bord (TBT) à la DG Contrôle*") and which are maintained both at Agency as well as at each DG level. They are used to help the management to focus on priorities, to keep track of issues identified, to communicate progress, to enable specific actions in timely manner, to highlight exceptions and provide alerts when problems occur. The "*XLs*" also contain recommendations made by internal and external auditors. They are updated 3 times per year in relation to non-conformities, and once a year for operational objectives (other than those of the PCUs).
- overview of global trends (expressed in %) of compliance and/or recurrent non-conformities/ KPIs, and which are reported as pie-charts, diagrams, tables, etc.

The audit team noted that the issues most frequently discussed during these meetings, were:

- progress of individual KPIs by the PCUs;
- progress of the global figures concerning the sectors or PCUs by the provincial CAs and the center;
- progress with the follow up of internal/external audits, COCO recommendations;
- overview of global trends (expressed in %) of compliance.

The overview of overall trends concerning recurrent non-conformities (expressed in %) is also available, and is reviewed occasionally by the CCA management.

Documentary reviews take place during the "*Technical Consultative Committees*" (TCC), the organization and functioning of which are equally governed by the QMS procedures. During these meetings the Committees review the implementing checklists. The latter must be reviewed whenever considered necessary but in any event, at least every three years. The TCC also provide clarifications on technical issues that may be encountered by agents in the course of performing their supervisory functions.

The procedure on "*Gestion du tableau de bord (TBT) à la DG Contrôle*" provides for other issues which might create implementing problems and/or undermine the effectiveness of official controls (e.g. staff observations on implementing procedures/instructions, or interpretation issues) to be brought to the attention of higher management. The audit team was provided with examples of these both by the central administration of the DG Control, and by the PCUs visited. Any issues raised by

the PCU were reviewed first by the PCU. If it was not possible to resolve these at provincial level, and were considered a priority by the Head of PCU, then they were forwarded to the CCT or/and CCM. The examples provided to the audit team demonstrated that the TCC were capable of identifying issues that might affect the effectiveness of official controls, and to review them.

At Agency level, a quality review cf. ISO 9001 by the Board of the Directors is undertaken at least once a year.

5.3.6.1.3 *Corrective actions*

As part of QMS a set of generic procedures/and measures had been put in place for "*Management of non-conformities*", "*Preventive and corrective actions*", "*Internal Audit*" , "*Management of consumer complaints*", "*Management of media complaints*", "*Management of records*".

The audit team noted that during CCM/TCC review meetings, any necessary corrective actions are decided upon, with a timetable for their implementation and an indication as to who is/are responsible. All these decisions are documented, and followed using the *XL* tables.

5.3.6.2 *Conclusion*

Within the context of the QMS, extensive procedures for monitoring and review, including management review, have been set up. These procedures, supported by KPI, trend analysis and performance “dashboards” allow both line as well as central management to remain up-to-date with the overall as well as technical performance of the official control system(s), and to correct where necessary at policy and/or technical level. Monitoring of progress with corrective actions is facilitated by clear attribution and establishment of deadlines.

5.3.7 *Internal Audit*

5.3.7.1 *Findings*

According to FASFC, internal audit constitutes the main mechanism through which whose the appropriateness and the effectiveness of the official control systems and their implementation.

The FASFC audit system achieved ISO 9001 certification in 2008, EMAS in 2011, ISO 17020 accreditation in 2010 and EMAS in 2011. It is subject to regular quality audits in the context of maintenance of accreditation and certification. The IAD performance and the follow up of recommendations are subject to KPI indicators.

The audit team noted that during the first 5 year cycle (2007-2012) a wide range of topics and operations (technical, cross-cutting and support activities) were selected and audited, such as "*Management of the CDM-DMOs*", "*Management of coordinated inspections carried out by NICU*", the "*Implementation of the validated self-checking system by operators*", "*the follow up and the supervision of activities carried out by the PCUs*". These audits demonstrated that the IAD examined *inter alia* the appropriateness and/or the effectiveness of the implementation mechanisms for official controls. The audit team noted that the audit findings (instances of lack of communication between the CDM-DMOs and PCUs, insufficient supervision or training, inadequate corrective actions or follow up measures etc) and conclusions led to recommendations designed to improve the effectiveness of the official control system(s) put in place by FASFC, and were addressed to all the FASFC levels (Central administration of FASFC and PCUs).

5.3.7.2 Conclusion

Internal audits carried out by the IAD assess the quality of official control performance and the impacts as a consequence of control activities. Audit findings result in recommendations aimed at improving control performance, addressing all relevant services. Linking these recommendations to KPIs allows their progress and impact to be monitored and measured. Thus, the internal audits support the verification of effectiveness of official controls.

5.3.8 Training and competence management

5.3.8.1 Findings

In summary, there are two different training systems, one for officials and one for CDM-DMOs.

For federal staff training is centrally co-ordinated by the training services of DG Corporate Services of the FASFC. The central administration of DG Control and the co-ordinators of the PCUs are responsible for deciding whether training must be provided, or extended. The training needs identified by FASFC (eg. through new control areas for FASFC, or on foot of findings from different sources such as internal/external audits, or COCO) may be included in training plans for the following year, or may be organised immediately, depending on the needs. All Agency staff avail of 10 days training/year.

At individual level, the training needs of controllers/inspectors are determined at PCU level, in the framework of the annual appraisal system. The system takes account of the operational objectives and the organisation of the work of the relevant PCU. During the appraisal process, the functional superior and the staff members discuss and decide what kind of training should be provided and/or repeated. Based on this exercise, the themes, the periods of coaching, as well as the coaches are set individually.

As regards CDM-DMOs, these are obliged to ensure their own continued training, without FASFC intervention, and at their own expense. Basis for training is a general document "*Principles of Training*", which sets out a number of requirements which must be met: for the first period following the signature of his/her contract, the CDM-DMO must have completed at least 4 days (25 hours) of training, to be followed by 50 hours of training in the next 3 years, with a minimum of 12 hours per year. The Head of PCU and /or head of sector must evaluate performance and training on an annual basis, in the context of individual appraisal. Depending on the outcome of the appraisal, the contract may be extended. Although the contract may also be terminated by the Head of PCU, no examples of such terminations were seen by the audit team in the two PCUs visited.

5.3.8.2 Conclusion

There is a system put in place for the training of the staff performing official controls. The results of the appraisal process are taken into account when subsequent training programmes are developed at PCU level. The results of internal, external audit, COCO are taken into account when the subsequent training programme is developed by FASFC.

5.3.9 Difficulties encountered by the Member State in Implementing Article 8 (3)

5.3.9.1 Findings

Neither the central administration of the FASFC, nor the PCUs visited reported any particular difficulties in relation to implementing article 8 (3) of Regulation 882/2004.

6 OVERALL CONCLUSIONS

Within the overall framework of the FASFC quality management system, extensive procedures have been developed for the purposes of review and the verification of effectiveness of official controls as required by Article 8(3)(a) and (b) of Regulation (EC) No 882/2004. These verification procedures cover all levels of controls within the scope of this audit, and include both the technical as well as the policy aspects. They are supported and facilitated by measurable performance and impact indicators (KPI) which in turn relate to the CCAs strategic and operational objectives, and comprehensive IT tools which allow the necessary qualitative and quantitative analysis. In addition, the system is reinforced by internal audit and coordinated control activities. Necessary corrective actions emanating from any of these review activities are documented, time-bound and where possible linked to KPI, and their progress is equally monitored. Standardised procedures are also in place to review and where necessary correct the performance of official controls by individual staff. The operation of the procedures in place was found to be implemented consistently in the PCUs visited.

7 CLOSING MEETING

A closing meeting was held on 8 March with the FASFC. At this meeting, the audit team presented its findings and preliminary conclusions.

The representatives of the FASFC acknowledged these, and emphasised that the search for quality and standardisation is permanently included in the strategic targets of the FASFC.

RECOMMENDATIONS

No recommendations are made.

N°.	Recommendation
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The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6855

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules