EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6881 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

BELGIUM

FROM 10 TO 20 SEPTEMBER 2013

IN ORDER TO EVALUATE THE FOLLOW-UP ACTION TAKEN BY THE COMPETENT AUTHORITIES WITH REGARD TO OFFICIAL CONTROLS RELATED TO THE SAFETY OF FOOD OF ANIMAL ORIGIN, IN PARTICULAR MEAT, MILK AND THEIR PRODUCTS

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

The report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Belgium from 10 to 20 September 2013. The main objective of the audit was to evaluate the official controls related to production and storage of food of animal origin and the follow-up action taken by the Competent Authorities (CA(s)) with regard to official controls related to the safety of food of animal origin, in particular meat, milk and their products.

A well developed and generally effective system of official controls is in place. However, significant deficiencies (hygiene, identification of products, traceability) were seen in one establishment. The CA presented an action plan to rectify these deficiencies. Some hygiene shortcomings were identified in other establishments; nevertheless a good level of compliance and level of control with follow up by the CA was noted in the majority of establishments visited.

The calculation of the frequency of inspections to establishments was risk-based, but not all relevant risk factors were taken into account, nor did the system react in a timely manner to factors altering such risks.

A system granting derogations and flexibilities has been established but conditions for applying flexibility are such that costs to small establishments may prevent their application.

Animal welfare standards at time of killing were effectively applied. However the Belgian Authorities are working towards full implementation of Regulation (EC) No 1099/2009 from 01/01/2014.

With regard to Food Business Operators (FBO(s)) with validated auto-control systems, it was noted that procedures exist for the removal of such validation; however, this is only applied in exceptional circumstances and when regular communication of results and/or significant deficiencies to the CA doesn't take place. Moreover, in cases with significant divergences in inspection outcomes between those of the CA and those of the third party accreditation, the calculation of inspection frequencies never resulted in a re-enforced level.

Follow-up to the "Horse Meat Scandal" is in progress with final products and raw materials seized pending the outcome of the investigation and possible subsequent judicial action.

Raw milk quality criteria were fully applied for bovine milk. However no CA procedure was in place for small ruminants' milk intended for the manufacture of products with raw milk.

A number of recommendations have been made to the CA with a view to addressing the deficiencies identified during this audit.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AFSCA-FAVV	*Agence Fédérale pour la Sécurité de la Chaîne Alimentaire* Belgian Federal Agency for the Safety of the Food Chain
CA(s)	Competent Authority(ies)
CCP(s)	Critical Control Point(s)
DG(SANCO)	Health & Consumers Directorate General
DMO	*Dierenarts met Opdracht* (approved veterinarian with official tasks)
EC	European Commission
FBO(s)	Food Business Operator(s)
FVO	Food and Veterinary Office
HACCP	Hazard Analysis of Critical Control Points
OV(s)	Official Veterinarian(s)

1 Introduction

The audit took place in Belgium from 10 to 20 September 2013 as part of the planned audit programme of the FVO. The FVO audit team comprised three auditors from the FVO and one national expert.

The FVO audit team was accompanied throughout the audit by representatives from the Belgian Authorities *Agence Fédérale pour la Sécurité de la Chaîne Alimentaire* (AFSCA-FAVV).

The opening meeting meeting was held on 10 September 2013, with the Belgian Authorities at their headquarters in Brussels. At the opening meeting the FVO audit team confirmed the objectives of, and itinerary for the audit, and additional information required for the satisfactory completion of the audit was requested, whilst at the closing meeting further clarification was provided by the Belgian Authorities and the FVO audit team provided an overview of the main findings

2 Objectives

The main objective of the FVO audit team was to evaluate the implementation of corrective actions in regards to previously raised recommendations in report DG(SANCO)/2008-7938. In addition, the opportunity was also taken to assess and discuss their progress in addressing the recommendations raised in report DG(SANCO)/2012-6353 on the production of farmed rabbit meat and gelatine, and DG(SANCO)/2012-6332 on the official controls on the production of horse meat.

The FVO Audit team also took into account the outcomes of a recent audit specifically covering microbiological criteria for foodstuffs, including the commodities covered by this audit DG(SANCO)/2013-6861, where the CA was in the early stages of addressing the recommendations that had been made.

The FVO Audit Team focused on :

- CA organisation and operation;
- official controls over FBOs' compliance with general and specific rules on the hygiene of food of animal origin.

In particular, controls over meat of domestic ungulates, minced meat, meat preparations, mechanically separated meat, meat products, raw milk and dairy products in the framework of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 were subject to this evaluation.

In pursuit of these objectives, the audit itinerary included the following meetings and visits:

Table 1

COMPETENT AUTHORITIES			Comments
Competent authorities	Central	2	Opening and Closing meeting
FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES			
Slaughterhouses		3	1 Small Ruminants; 2 Pig
Cutting premises		6	4 co-located in slaughterhouses or further processing
Minced meat / meat preparation establishments		4	All co-located in other approved activities
Meat products establishments		3	2 co-located in other approved activities
Offal Processing establishments		2	
Mechanically Separated Meat		2	Co-located in other approved activities
Cold stores		2	
Milk processing plants		3	2 cow; 1 goat
Dairy holdings		3	One co-located in cheese processing establishments

3 Legal Basis

The audit was carried out under the general provisions of EU legislation and, in particular Article 45 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.

Full EU legal references are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the latest amended version.

4 Background

The previous audit concerning the safety of food of animal origin in Belgium was carried out from 1 to 12 September 2008, the results of which are described in report DG(SANCO)/2008-7938-MR Final. This report is accessible at:

http://ec.europa.eu/food/fvo/index_en.cfm

The action plans received and the subsequent implementation carried out by the Belgian authorities provided satisfactory guarantees in response to all of the report's recommendations.

In addition, the action plan submitted in response to audit report DG(SANCO)/2012-6332 concerning the official controls on the production of horse meat also provided satisfactory guarantees in response to all of the report's recommendations.

The action plan of another audit (DG(SANCO)/2012-6353) on official controls of the production of gelatin and rabbit meat provided satisfactory guarantees in response to most of the report's recommendations, and for the remaining recommendations some clarification has been requested and is under review.

5 Findings And Conclusions

5.1 Competent Authorities

5.1.1 Designation of Competent Authorities

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the Competent Authorities responsible for the purposes and official controls set out in the Regulation. It also lays down operational criteria for the Competent Authorities.

Audit findings

The designation of CAs and the Belgian organization for the delivery of official controls remains as described in the country profile, which can be access via the following link: http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=BE

5.1.2 Co-operation and co-ordination between and within Competent Authorities

Legal requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination and co-operation between Competent Authorities. Article 4(5) of the Regulation requires that, when, within a CA, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.

Audit findings

The co-operation and co-ordination activities between the different levels of the CA are described in the country profile for Belgium and the FVO audit team found them to be working in accordance with it.

5.1.3 Registration/approval of Food Business establishments

Legal requirements

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration/approval of food and feed business establishments, for reviewing compliance with conditions of approval and for the withdrawal of approvals.

Audit findings

The CA has developed detailed procedures and check-lists to enable officials carrying out the approval visit to assess compliance with legal requirements.

It was noted as best practice that all establishments were statutorily obliged to provide, for official approval, a detailed blue-print of the facilities with clear demarcation of process flows.

In one establishment, where the approval process was assessed, the timings and procedures were aligned to the guidance and in line with legal requirements.

However, in another establishment where the approval was granted in 2008, it was noted that full approval was provided on the basis of one check-list only assessing structure and installations, other checks such as hygiene and traceability checks had not been performed. Furthermore, the official did not assess the actual process for which approval was sought, resulting in a full approval immediately being granted without full assessment of all the parts that are integral to an approval process.

In this same instance after the initial approval inspection where the CA assessed the structure and installation of the facilities; the FBO was told he could start operating prior to receiving the official letter and communication which was sent 16 days later than the given date to start operations.

A finding similar to the latter one was made during the audit DG(SANCO)2012-6353-MR Final, which gave rise to a recommendation to strengthen their procedures. follow-up of the proposed action is on-going.

5.1.4 Prioritisation of official controls

Legal requirements

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. Controls shall be carried out at any of the stages of the production and processing chain and, in general, are to be carried out without prior warning. Controls shall be applied with the same care to exports from the EU, imports into the EU and to product placed on the EU market.

Audit findings

Whereas article 3 of Regulation EC (No) 882/2004 mentions that "*the frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and FBOs under HACCP based control programmes or quality assurance programmes, where such programmes are designed to meet requirements of feed and food law, animal health and animal welfare rules*" the FVO audit team noted that calculation of the frequency of inspections is risk-based but not all relevant risk factors were taken into account; as an example it was noted that factors such as throughput of the establishments and the vulnerable groups of final consumers (i.e. provision to hospitals and children nurseries) were not considered.

It was also observed, and partially linked to be above points, that the number of official inspections was not aligned to the perceived risks of the establishments visited. The FVO audit team noted establishments with significant throughput and/or producing final products for vulnerable groups with inspection frequencies significantly lower than that of very small establishments working for the general public with a more limited range of processes in their approval. As an example, the method calculated the same basic frequency of 8 inspections per year both for a small cutting plant (only beef meat) producing 60kg of minced meat and operating with two persons and a very large establishment with combined activities (cutting of all species, producing different meat preparations, meat products and composite products) for 100 butchers. Nevertheless it was noted that the length of each official inspection was tailored to the size of the establishments in order to allow the OV to reach a consistent level of verification.

There was also a significant delay between the determination of the frequency and the availability of some of the data on which it is based, (up to a two year delay in taking inspection results into account) whilst other relevant factors with the likely outcome of reducing the number of official inspections to FBOs were taken into account almost instantly (FBO's validation system by third party accreditation updated on a monthly basis).

These findings are similar to those made during audit DG(SANCO)2013-6861-MR Final.

5.1.5 Procedures for performance of control activities

Legal requirements

Article 8 of Regulation (EC) No 882/2004 requires that Competent Authorities carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Audit findings

The Belgian CAs have developed comprehensive documented procedures, which were found to be in place. These procedures which are based around guidance, circulars and check-lists are regularly updated and are all available on-line.

The Official Veterinarians (OVs) and Approved Veterinarians (DMOs) delivering official controls at establishment level had full access to all relevant information and the FVO audit team noted that these procedures were generally followed.

A system of validation of auto-control systems by third party accreditation bodies (which are accredited by the national accreditation body BELAC) is in place. FBOs may opt to participate in this system (currently around 12% of approved establishments participate). Where an auto-control system has been validated, the number of CA inspections is generally reduced by 50%.

The FVO audit team was informed that the relevant third party accreditation bodies will inform the CA of cases of major non compliances, but whilst the results of the audit are communicated (positive or negative outcome) the reports and its findings are not accessible to the OV delivering OCs.[1]

A procedure exists for the removal of validation of an auto-control system. However, the FVO audit team noted that this was applied in exceptional circumstances only and that, where significant weaknesses in the auto-control systems were identified during official controls, this did not result in a re-evaluation of the validation originally granted.

Furthermore, in those cases where there was a clear divergence between the findings made by the CA and those of the accreditation bodies (< 2% of validated establishments where significant or major non compliances were found during delivery of Official Controls), no evidence was seen of a procedure that enables a meaningful change to the calculation on the frequency of inspections. However, it was noted that the CA carried out re-visits above the set frequency of inspections on those cases where formal enforcement was taking place.

5.1.6 Enforcement measures

Legal requirements

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation. Article 55 of the

1 In their comments to the draft report the CA noted that a procedure exists for the notification of significant infringements by the accreditation bodies to the CA in the context or Royal Decree on self checks. The procedure stipulates the immediate notification of all A1 non-compliances (i.e. those which represent danger to the health of persons, animals and plants), likewise when it is noted that the operator is engaging in activities of which the CA is unaware.

Regulation states that Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Audit findings

There were detailed procedures to deal with non-compliances raised, which resulted in a range of actions being taken by the CA depending on their severity. These ranged from written comments on reports to more formal letters and, in some cases, direct financial penalties and legal action. Procedures were noted to be in place on the follow-up action and subsequent inspections (if relevant) to verify FBOs' compliance with official requests. In addition, the calculated frequencies for inspection, could be raised from "basic" to "high" in such situations.

Evidence was seen of follow-up action taken by the CAs with regard to Rapid Alert System for Food and Feed alerts. A joint investigation between the AFSCA-FAVV and the Belgian Ministry for Economic Affairs is still on-going on the "Horse Meat Scandal" and final product and raw materials are under official detention pending the conclusion of the investigation and possible subsequent judicial action.

5.1.7 Verification and review of official controls and procedures

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires the CAs to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure effectiveness of corrective action and to update documentation where needed. Under Article 4 of the Regulation CAs are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Audit findings

An internal audit system is in place with regular audits taking place across the different food sectors in question, information was seen where regular audits are planned and carried out to follow-up on the recommendations. As of 31/12/2012 70% (1 062) of previously raised recommendations had been followed, of which 89% were closed, 6% in execution, 3% reformulated, and in 2% action was still required.

Procedures and records on the evaluation on the performance of the Approved Veterinarians (DMOs) were seen. Some examples were seen where this had led to further action.

5.1.8 Flexibilities and derogations.

Legal requirements

Article 4 of Regulation (EC) No 2073/2005 foresees that, "*when justified on the basis of a risk analysis and consequently authorised by the CA, small slaughterhouses and establishments producing minced meat, meat preparations in small quantities may be exempted from the prescribed sampling frequencies"*.

Audit findings

The Belgian authorities have developed a strategy for the granting of flexibility and derogations to small establishments. The majority of these possibilities (e.g. reduced frequency of microbiological sampling, listing for export) are available only to establishments with a validated auto-control system (currently approximately 12% of establishments).

The FVO audit team was informed that for the upkeep of such a validated system, FBOs will incur additional financial costs and possibly the need for additional staff or the administration of the system. As a consequence, this is likely to have a negative impact in the likelihood, for micro, small and majority of medium enterprises, to participate and to avail of the flexibility and derogations on offer[2].

For example, two small cutting plants each with two operators, producing 60 and 150kg of minced meat per week, were obliged to carry out all the required microbiological tests on a weekly basis.

Conclusions on Competent Authorities

The Belgian Authorities have developed a detailed and comprehensive system for the delivery of official controls which the FVO audit team found to be, in the majority of cases, implemented in a satisfactory manner.

However, the system for determination of inspection frequencies is not fully risk-based as it does not take into account all necessary parameters (throughput, vulnerability groups of final consumers) and does not react in a timely manner to factors (e.g. results of official controls) which would tend to increase frequency (while factors that may lead to a reduction of frequency are taken into account immediately). In addition, the system does not result in a follow up to the small number of cases where there is a divergence of inspection results between an accreditation body and the CA which could plausibly result in an increase in official inspection frequency. There is no functioning mechanism for the communication of significant findings by the accreditation bodies to the CA.

Nevertheless a procedure is in place and regularly used to follow-up and carry out inspections that go beyond those set in the calculation when relevant non-compliances are found. These repeated checks, go beyond the pre-set frequency of inspections and are run until the operator achieves compliance

The strategy followed by the CA concerning the application of flexibilities and derogations, as foreseen in Regulation EC (No) 2073/2005, does not, in practice, result in the granting of the majority of such derogations/flexibilities to the target establishments.

5.2 Official controls over food Business Operators' compliance with hygiene rules at establishment level

5.2.1 General and specific hygiene requirements

Legal requirements

Article 4(2) of Regulation (EC) No 852/2004 establish that the FBOs carrying out any stage of

2 In their response to the draft report the CA noted that the Ministerial Decree of 22 March 2013 on more flexible arrangements for self-checks and traceability in certain establishments in the food chain provides that, for the processing sector, businesses with a maximum of two full-time equivalents can benefit from a lighter HACCP. This allows the simple application of the risk assessment proposed in the guide. They are also exempt from the requirement to systematically record CCP monitoring: The recording of non compliances is enough.

production, processing and distribution of food after the stage of primary production/associated operations shall comply with general hygiene requirements as set out in Annex II to Regulation (EC) No 852/2004. These provisions relate to cleaning and maintenance, layout, design, construction, siting and size of food premises.

Article 3 of Regulation (EC) No 853/2004 sets out that the FBOs shall comply with the specific requirements of Annexes II and III to this Regulation. Article 4(3) of Regulation (EC) No 852/2004 states that FBOs shall adopt specific hygiene measures regarding compliance with microbiological criteria for foodstuffs, compliance with temperature control requirements and sampling and analyses.

Article 4(2) of Regulation (EC) No 854/2004 specifies that the CA shall carry out official controls in respect of products of animal origin to verify the FBOs compliance with these requirements.

Audit findings

Most of the establishments visited, with a few exceptions, were largely in compliance with the requirements. The majority of the deficiencies noted by the FVO audit team had already been identified by the CA who had taken follow-up action. Nevertheless, a number of additional deficiencies were seen:

- Dripping of condensation over exposed product stored underneath;
- Systematic soiling with rail grease of parts of carcasses, dirty overhead structures, rusty and dirty chilling units above exposed final product;
- meat cuts, mincemeat and meat preparations being kept too long in production rooms resulting in temperatures above the legal limits;
- insufficient number of hand-wash basins at particular workstations and no appropriate facilities for sterilization of working tools (i.e. splitting saw);
- storage of edible co-products above maximum legal temperature;
- contaminated carcasses due to inadequate slaughter technique presented at post-mortem inspection.

In one establishment the CA had failed to identify significant non- compliances such as insufficient space for the volume and number of activities with inadequate raw material, final product and personnel flows, untidy changing rooms with mixing of working clothes and protective clothing, poor state of maintenance and cleanliness in several areas and tools.

In one sheep slaughterhouse, the slaughter hygiene was unsatisfactory and many carcasses were contaminated. Many of them had, however, passed post-mortem inspection. This establishment had a history of non-compliances with periods of varying compliance. An infringement procedure was in progress and action was announced.

Nevertheless and despite the number of findings and remarks made by the FVO audit team at the different establishments, and with the exception of the aforementioned establishment with significant non-compliances, the FVO audit team found that FBOs were mostly in compliance with legal requirements and that the CA had identified and appropriately followed up the majority of instances where non-compliances had been highlighted.

Conclusion

The official controls carried out in the establishments visited were generally satisfactory as they had identified the majority of deficiencies.

In one meat processing establishment, in particular, significant non-compliances had not been identified during regular official controls, the officials accompanying the FVO audit team agreed with the shortcomings identified and a satisfactory action plan was received during the closing meeting to address the situation.

5.2.2 HACCP-based systems

Legal requirements

On the basis of Article 5 of Regulation (EC) No 852/2004 the FBOs shall put in place, implement and maintain a permanent procedure or procedures based on the Hazard Analysis of Critical Control point (HACCP) principles. Section II of Annex II to Regulation (EC) No 853/2004 lays down the specific requirements for HACCP-based procedures in slaughterhouses. Official controls in respect of all products of animal origin in the scope of Regulation (EC) No 854/2004 shall include audits of HACCP-based procedures (Article 4 (3)(a) and (5) of Regulation (EC) No 854/2004).

Audit findings

In all establishments visited HACCP-based procedures were implemented and aligned with legal requirements. Official Controls on such procedures were carried out by the officials as part of their periodical audits. In the majority of cases where these were reviewed by the FVO audit team no significant deficiencies were identified.

However, at one dairy plant visited, official controls carried out immediately preceding this audit found that the CCP correlation temperature-time for pasteurization could not be demonstrated and a warning was issued. This shortcoming had not been identified in previous inspections by either the officials or third party accreditation. In another establishment with same defined CCP, neither the FBO nor the OV understood how to read and monitor the pasteurizer print-out linking the temperature-time control. In another large establishment with several activities, the HACCP plan was too general and the particularities of some products had not been considered.

Conclusion

FBOs had developed and implemented HACCP based procedures which complied with the legislative requirements and legal limits as set out in the relevant Regulations, nevertheless weaknesses were noted in the understanding, and monitoring of major CCPs in the dairy sector both by the FBOs and the Officials carrying out the verification.

5.2.3 Microbiological criteria for foodstuffs

Legal requirements

Details on the microbiological criteria foodstuffs shall comply with are set out in Regulation (EC) No 2073/2005. Article 1 of Regulation (EC) No 2073/2005 specifies that the CA shall verify compliance with the rules and criteria laid down in that Regulation. These cover a range of items with regard to requirements for slaughterhouses, cutting plants, emergency slaughter, game

handling, raw milk and dairy products and other products of animal origin.

Audit findings

It was noted that in various establishments visited, shortcomings in the frequency and method of sampling by the FBOs had been highlighted during their last official inspection which immediately preceded the visit by FVO audit team and appropriate action had started to take place.

In one slaughterhouse health-marked carcasses consistently presented with faecal contamination were stored in the chillers but the FVO audit team was presented with long standing good results for process hygiene criteria which were at odds with the processing standards witnessed.

Conclusion

Action was seen to be under way to address deficiencies highlighted in audit DG(SANCO)/2013-6861 on microbiological criteria. However, the detection of faecal contamination on carcasses, raises questions in regards to the effectiveness and reliability of the updated systems and its monitoring by the CA in relation to process hygiene criteria.

5.2.4 Traceability, labelling and identification marking

Legal requirements

According to Article 18 of Regulation (EC) No 178/2002 the traceability of food and food-producing animals and any other substance intended to be incorporated into a food shall be established at all stages of production, processing and distribution. The FBO shall have in place systems and procedures to identify from whom they have been supplied and the other businesses to which their products have been supplied. Article 4(6) of Regulation (EC) No 854/2004 requires that the verification of compliance with traceability requirements takes place in all approved establishments.

Provisions for the identification marking of a product of animal origin are made in Article 5 and Annex II, Section I to Regulation (EC) No 853/2004 and verification of compliance with these requirements is foreseen by Article 4(6) of Regulation (EC) No 854/2004. Article 3 of Directive 2000/13/EC sets out the particulars on the labelling of foodstuffs to be delivered as such to the ultimate consumer. Regulations (EC) No 1760/2000 and 1825/2000 set out specific labelling requirements for beef meat.

Audit findings

In all establishments visited, traceability systems were found to be in place. They were mainly based on slaughter date at slaughterhouse level, and the date of the incoming product at other establishments where further processing was taking place. The majority of establishments had invested in computerised systems with software enabling them to correlate incoming raw materials and outgoing final products. In those establishments where no such systems were in place it was due to the low throughput of such establishments and the relative simplicity of achieving the outcome via a paper-based system. In a number of instances the systems were able to go two steps backwards or even to the farms of origin, which was beyond the minimum legal requirements.

The official control of the traceability is carried out once per year using a specific check-list. Evidence was seen of deficiencies identified and of the follow-up of the corrective action.

The FVO audit team carried out several traceability exercises which were satisfactory in all but one establishment where although the link to the incoming meat could be made, the total quantities did not match.

With very few exceptions all products (intermediate and final) were correctly identified. Labelling for final consumers was assessed in several establishments and found to be satisfactory with all the necessary ID marking.

Conclusion

A good level of compliance of FBOs was noted in the areas of traceability, labelling and identification marking. This was also regularly verified by the CA and appropriate and timely actions taken when non-compliances had been identified.

5.2.5 Food Chain Information

Legal requirements

According to Article 3 of Regulation (EC) No 853/2004, the FBO shall comply with the relevant provisions of Annex II and III to this Regulation. In particular the FBOs operating slaughterhouses must as appropriate, request, receive, check and act upon food chain information (FCI) in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse. According to Article 5(1) of Regulation (EC) No 854/2004 the OV shall carry out inspection tasks in slaughterhouses also as regards Food Chain Information.

Audit findings

In the slaughterhouses visited, the food chain information was available for animals presented for slaughter. Regarding the treatment of animals, the food chain information contained fields for therapeutic treatment that took place more than or less than two months prior to the foreseen slaughter date and a number of documents were seen with such entries. The food chain information documents were sent 24 hours in advance and contained the required information and signatures in the large majority of cases.

Conclusion

The requirements concerning the food chain information are fulfilled in a satisfactory manner.

5.2.6 Ante-mortem and post-mortem inspection

Legal requirements

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including ante-mortem inspection of all animals before slaughter in accordance with the general requirements of Section I, Chapter II of Annex I to Regulation (EC) No 854/2004 and post-mortem inspection in accordance with the general requirements of Section I, Chapter II of Annex I and the specific requirements of Section IV, Regulation (EC) No 854/2004.

Audit findings

Ante- and post-mortem inspection were carried out as required in the slaughterhouses visited, and records of results of ante-mortem inspection and post-mortem were well maintained and included in the database.

In one slaughterhouse however, a significant number of sheep carcasses with visual contamination had passed the post-mortem inspection. The FBO had not put in place a system to remove the contamination that had occurred due to faulty slaughter hygiene and the OV had not taken the required action to prevent contaminated carcasses being placed on the market. Immediate action was requested by the FVO audit team.

In regards to *Trichinella* testing, Proficiency tests have been organised but not all the in-house laboratories are yet accredited. Corrective action was taken by the four laboratories where non-compliances were identified. In the two pig slaughterhouses visited, 100% of the pigs are sampled and tested which is in line with the requirements.

Conclusion

The requirements concerning ante- and post-mortem inspection are complied with, likewise those for *Trichinella* examination. It is however to be noted that not all laboratories carrying out *Trichinella* examination are yet accredited.

5.2.7 Health marking

Legal requirements

Article 5(2) of Regulation (EC) No 854/2004 requires that health marking of carcasses of domestic ungulates, farmed game mammals other than lagomorphs and large wild game as well as half-carcasses, quarters and wholesale cuts shall be carried out in slaughterhouses and game-handling establishments by, or under the responsibility of, the OV when official controls have not identified any deficiencies that would make the meat unfit for human consumption.

Audit findings

Carcasses and quarters were found to be Health Marked and with generally good visibility and legibility.

The CA explained their internal procedures and guidance given to officials carrying out post-mortem inspection on the procedures to be followed in instances of carcass contamination. Nevertheless in one establishment it was noted that the majority of carcasses slaughtered in the preceding day, stored in the chiller and fully Health Marked, presented visible faecal contamination on various parts and this could be linked to poor dressing technique.

Conclusion

There is an effective system in place to ensure that health-marking takes place; nevertheless it failed to ensure in specific cases that the health mark is only applied to carcasses that are free from visible contamination.

5.2.8 Animal welfare at the time of slaughter or killing

Legal requirements

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including animal welfare. Regulation (EC) No 1099/2009 sets out EU rules with regard to the protection of animals at the time of killing.

Audit findings

During the opening meeting the implementation of Regulation (EC) No 1099/2009 was discussed; the CA mentioned that due to logistical reasons there has been a delay of one year in its implementation. The training of animal welfare officers has already started to take place and a procedure has been drawn up for the training, examination and subsequent authorization of staff dealing with live animals in the slaughterhouse.

A procedure has also been drawn up for the authorisation of abattoir personnel that were already dealing with live animals for more than three years. This procedure places the onus on the FBOs to inform the CA of all the staff already working at the establishments (based on a declaration on their honour).

The FVO audit team noted that the standards of animal welfare at the time of killing were complied with, and evidence was seen of frequent checks by the CA and that warning and subsequent action was taken in cases of non-compliance.

One establishment was visited where Halal slaughter of small ruminants was taking place, the animals were mechanically restrained by a conveyor belt during slaughtering and bleeding processes prior to shackling; no signs of consciousness were noted on the shackled animals. The situation had been improved as a response to a previous recommendation (No. 7) of FVO audit report DG(SANCO)2011-6039 covering the restraint during ritual slaughter as one of its points.

Conclusion

The required standards for animal welfare at the time of killing were seen to be complied by FBOs and evidence was seen of regular checks by CA Officials with warnings given in cases of non-compliance.

The Belgian CA is in the process of fully implementing the requirements of Regulation (EC) 1099/2009 with a deadline of 01/01/2014 to verify fully the legal requirements, which is one year later than was required. This delay has been mainly caused by the difficulty of setting up training courses for animal welfare officers and slaughterhouse personnel. Nevertheless efforts are being made towards compliance and procedures were being drawn up to that effect.

5.2.9 Control of milk production holdings and of raw milk upon collection

Legal requirements

Article 8 of Regulation (EC) No 854/2004 requires that Member States shall ensure that official controls with respect to raw milk and dairy products take place in accordance with Annex IV to Regulation (EC) No 854/2004. The CA shall carry out official controls to verify that health requirements and hygiene requirements for raw milk and colostrum are complied with and monitor the checks carried out for plate count, somatic cell count and residues of antibiotic substances.

Audit findings

Official controls in the 3 holdings visited by the FVO audit team were carried out according to the CA procedures (base frequency once every 8 years and once every 12 years if a validated auto-control system is in place). The check-lists covered all the relevant areas, nevertheless it was noted that parts of such check-lists could be filled in on the basis of FBO responses rather than the verification of the actual process as the activities in question were rarely done during inspection times (i.e. milking of animals)

Official controls included checks on animal welfare, identification of animals and registration, veterinary treatments and medicines, keeping and breeding of animals. These may be carried out at different times, as was the case for one of the three holdings visited. In addition to the above official controls, controls on animal health and on the register of veterinary treatments are carried out by the contracted private veterinarian every four months.

In case of non-compliance with the raw milk criteria, the laboratory performing the tests, the dairy plant receiving the milk and the business operator producing the milk are obliged to notify the CA, which in turn must inspect 10% of such cases. CA inspection is obligatory in all cases when a milk supplier is suspended by the dairy plant.

The following observations were made:

- The general hygiene conditions, identification and registration of animals were found to be adequate. Also, in those places where raw milk was directly sold to local consumers, regular checks for zoonotic diseases such as Q-fever, Tuberculosis (cattle) and Brucellosis were carried out.
- Systems were in place to identify animals under medical treatment and to separate their milk, which was generally used to feed calves. Records of treatments did not include the withdrawal period, which was however indicated on the veterinary prescription. The CA stressed that this requirement is met by linking the register of treatments with the veterinary prescriptions.
- Adequate facilities were available for the storage of milk awaiting collection. Temperature of milk on collection at the goat farm as witnessed by the FVO audit team was 2.8 degrees Celsius and all the relevant procedures were followed in regards to taking of samples for subsequent laboratory analysis.
- Both cattle holdings had a long-term record of compliance with the raw milk criteria. In the goat farm the results of the tests performed by the accredited laboratory showed that the plate count at 30 degrees was around 900 000/ml. The tests were performed on behalf of the collector, a dairy plant producing pasteurised dairy products, and met the criteria for those kinds of products. Therefore the laboratory did not notify the CA of the results, which did not meet the criteria for the production of raw milk-based dairy products, of which production was also taking place.

Conclusion

Official controls of milk and colostrum production holdings were generally in line with legal requirements with regard to the health status of the animals, the use of veterinary medicinal products, the hygiene requirements of holdings and raw milk criteria.

However, in the marginal manufacture of products with raw milk from small ruminants, the CA's monitoring on FBOs' checks on the raw milk failed to identify that it did not meet the relevant criteria and no internal procedures had been developed to that effect.

5.2.10 Control over animal by-products

Legal requirements

Article 5(1) of Regulation (EC) No 854/2004 requires that the Official Veterinarian carries out inspection tasks including Animal by-products. Regulation (EC) No 1069/2009 sets out the requirements for identification, records and the use of commercial documentation.

Audit findings

Animal by-products were identified and correctly categorised at the establishments visited. FBOs had procedures in place where by-products were handled within their establishments in a clear way and followed a separate route to that of products fit for human consumption. The accompanying commercial documentation provided the required information.

It was noted that various meat establishments stored animal by-product bins in the chillers while waiting for collection, where fit product was also being kept, as a way to avoid their degradation and subsequent foul odour and pest attraction. However in one instance such containers were in a state of disrepair and had contaminated outer surfaces posing a risk of contamination to the exposed meat stored in the same areas.

The CA had well defined procedures for the assessment of controls of by-products and officials showed a clear understanding of the requirements.

Conclusion

Animal by-products were correctly categorised and generally well controlled within approved establishments, likewise all relevant information for transportation and rendering was present.

5.2.11 Documentation of official controls

Legal requirements

Article 9 of Regulation (EC) No 882/2004 requires Competent Authorities to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Audit findings

Official controls were comprehensively documented and appropriately communicated with the support of a centralised computerised system that enabled all the relevant people to have access to previously completed official controls. The system also pre-defined actions to be taken by the officials in case of non-compliances based on a pre-determined weight scoring.

For each activity (slaughtering, cutting of different species, meat preparations etc.) separate sets of check-lists have been developed and are filled in and registered in the on-line database. However a high level of repetition occurs in complex companies with multiple activities. The extreme example was in one establishment where in total 113 pages of check-lists were generated during one official visit. The Belgian Authorities informed the FVO audit team that they are aware of the evolution to an overly bureaucratic system and that a project is underway to develop more dynamic check-lists.

The FVO audit team noted in some instances a difference in the level of quality, and the correctness

of the judgement on the categorisation of deficiencies and consequently action to be taken by Approved Veterinarians (DMOs) against those of AFSCA-FAVV OVs.

The annual inspection reports from AFSCA-FAVV OVs provided a more accurate and comprehensive picture of the level of compliance in establishments, with deficiencies and more complex problems better described, with the result that corrective actions by the FBOs will be more effective.

It was also noted that those FBOs under increased frequency of inspections due to non-compliances, received an increased number of inspections by Approved Veterinarians (DMOs) but none from AFSCA-FAVV OVs.

Conclusion

A satisfactory documentary system is in place with a detailed description of findings made during delivery of official controls, the gathered data is further analysed and weighted to ensure assessment of findings in a harmonised way across the different sectors in the country.

6 Overall Conclusions

A well developed and generally effective system of official controls is in place. However, significant deficiencies (hygiene, identification of products, traceability) were seen in one establishment. The CA presented an action plan to rectify these deficiencies. Some hygiene shortcomings were identified in other establishments; nevertheless a good level of compliance and level of control with follow up by the CA was noted in the majority of establishments visited.

The calculation of the frequency of inspections to establishments was risk-based, but not all relevant risk factors were taken into account, nor did the system react in a timely manner to factors altering such risks.

A system granting derogations and flexibilities has been established but conditions for applying flexibility are such that costs to small establishments may prevent their application.

Animal welfare standards at time of killing were effectively applied. The Belgian Authorities are working towards full implementation of Regulation (EC) No 1099/2009 from 01/01/2014, one year later than prescribed.

With regard to FBOs with validated auto-control systems, it was noted that procedures exist for the removal of such validation; however, this is only applied in exceptional circumstances and when regular communication of results and/or significant deficiencies to the CA does not take place. Moreover, in cases with significant divergences in inspection outcomes between those of the CA and those of the third party accreditation, the calculation of inspection frequencies never resulted in a re-enforced level.

Follow-up to the "Horse Meat Scandal" is in progress with final products and raw materials seized pending the outcome of the investigation and possible subsequent judicial action.

Raw milk quality criteria were fully applied for bovine milk but not for small ruminants' milk intended for the manufacture of products with raw milk - for which no CA procedure was in place.

7 Closing Meeting

A closing meeting was held on 20 September 2013 with the Belgian Authorities (AFSCA-FAVV). At this meeting the FVO audit team presented the findings and preliminary conclusions of the audit and advised on the relevant time limits for production of the report and their response.

The representatives of the Belgian Authorities (AFSCA-FAVV) acknowledged the findings and conclusions presented by the FVO audit team. In addition, information on action already taken and planned in order to address particular findings in the establishments visited was provided.

8 Recommendations

An action plan describing the action taken or planned in response to the recommendations of this report and setting out a time table to correct the deficiencies found should be presented to the Commission within 25 working days of receipt of the report.

N°.	Recommendation
1.	To ensure that the calculation of the frequency of inspections for the delivery of official controls takes into account all the relevant risk factors, up to date information on Food Business Operator level of compliance, together with the results of official inspections as required by Article 3 (1) of Regulation (EC) No 882/2004.
2.	To ensure regular and without undue delay communication is made to the Competent Authority of the audit results, principally of any significant non-compliances found during Food Business Operators' Validation by accredited third parties as required by Article 5 (2) of Regulation (EC) No 882/2004.
3.	To ensure that the Competent Authority develops documented procedures in regards to the monitoring of compliance and actions to be taken covering the criteria for raw milk from species other than cows intended for the manufacture of products with raw milk without heat treatment as required by Annex IV, Chapter II of Regulation (EC) No 854/2004.

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=2013-6881

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Reg. 1760/2000	OJ L 204, 11.8.2000, p. 1-10	Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
Reg. 1825/2000	OJ L 216, 26.8.2000, p. 8-12	Commission Regulation (EC) No 1825/2000 of 25 August 2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
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

Legal Reference	Official Journal	Title
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Reg. 2075/2005	OJ L 338, 22.12.2005, p. 60-82	Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for Trichinella in meat
Reg. 1162/2009	OJ L 314, 1.12.2009, p. 10–12	Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council
Reg. 1099/2009	OJ L 303, 18.11.2009, p. 1-30	Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Dir. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

Legal Reference	Official Journal	Title
Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs