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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SPAIN

FROM 09 TO 19 APRIL 2013

IN ORDER TO EVALUATE THE FOLLOW-UP ACTION TAKEN BY THE COMPETENT
AUTHORITIES WITH REGARD TO OFFICIAL CONTROLS RELATED TO SLAUGHTER
AND PROCESSING OF FRESH MEAT, IN PARTICULAR FRESH OVINE AND EQUINE
MEAT

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 a Food and Veterinary Office (FVO) audit in Spain from 9 to 19 April 2013. The objective of the audit was to evaluate the Competent Authorities (CAs) with regard to official controls and enforcement related to the slaughter of equidae and ovine and to the processing of fresh meat. The current audit to Spain was a follow up to the audit carried out in May 2011 (Reference number DG(SANCO)/2011-6021), during which serious deficiencies in the performance of the official controls in the sector evaluated were found. In response the CAs rapidly developed an action plan, the principal part of which was the Strategic Plan for slaughterhouses of small ruminants and equidae, which was an urgent measure to address the non-conformities detected during the audit. In the framework of this Plan, the CAs have assessed 457 slaughterhouses. By May 2013, 31 slaughter lines had their approval withdrawn and 9 were still suspended. The action taken by the Spanish CAs was found by the FVO to be satisfactory at desk analysis. In order to evaluate the effectiveness of this action on-the-spot, the FVO audit team met the authorities and visited six small ruminant and equidae slaughterhouses and cutting plants and one horse fattening farm situated in three Autonomous Communities (AC).

The FVO audit team found that the Strategic Plan was implemented by the AC visited. The approach was well co-ordinated across the AC visited. It included evaluation and verification visits in all establishments concerned and reporting to the CCA. After the formal ending of the Strategic Plan project, the official controls continue in the establishments visited on the basis of the Official Control plans implemented in the AC as a permanent control tool.

A significant effort has been made by the Spanish authorities with the implementation of the Strategic Plan. In particular, co-ordination and control proceedings have improved. A framework for successful official controls has been put in place. The official controls were based on written procedures, carried out frequently, prioritised on a risk basis, and well documented. However, they were not fully effective. The CA concerned did not identify all the relevant deficiencies and the follow up was not always adequate. In most cases, the reports did not reflect the real situation in the establishments.

In four out of six slaughterhouses visited, the FVO audit team found significant deficiencies, related to maintenance, lay out, approval and food business operators' (FBO) understanding of their legal obligations. The deficiencies were considered to be serious in two of them and the information from the FBOs has not been clear and credible. In one of these establishments, suspected illegal activities under unacceptable hygiene conditions took place. The official supervision in this establishment has not been satisfactory. The FVO audit team requested urgent action in both establishments and evidence of this action was received.

The FVO audit team noted deficiencies in relation to approval of establishment procedures. Three out of six establishments did not fulfil the approval conditions. The approval documents indicated activities for which the establishments were approved, but no reference was seen of establishments' rooms, territory and perimeter. This caused serious confusion about the limit of responsibilities of the FBO and the official veterinarian (OV).

The operators in most cases were found to be skilled and well trained in relation to hygiene of operations. Only in a few cases was visible carcass contamination noted. However, excessive splashing in several establishments and poor or non-existing sterilisation of tools could have a negative impact on the hygiene of operations.

No deficiencies in relation to horse identification were found. With regard to the accompanying documentation the FVO audit team noted that the passports and the Food Chain Information (FCI) did not indicate any medical treatment for any of the horses seen by the FVO audit team. Moreover, the FCI document is drafted in such a way, that the owner declares possible medical treatment during the last 30 days only. Deficiencies in the recording of medical treatment were seen in one horse fattening farm visited. Animal welfare rules were in general respected, with the exception of one incident.

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
ABP	Animal By-Products
AC(s)	Autonomous Community(ies)
AESAN	Food Safety and Nutrition Agency (<i>Agencia Española de Seguridad Alimentaria y Nutrición</i>)
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
CCP(s)	Critical Control Point(s)
DG(SANCO)	Health & Consumers Directorate General
EC	European Commission
EU	European Union
FBO(s)	Food Business Operator(s)
FCI	Food Chain Information
FVO	Food and Veterinary Office
HACCP	Hazard Analysis of Critical Control Points
Hygiene Package	Regulations (EC) No 852/2004, No 853/2004 and No 854/2004
MANCP	Multi-Annual National Control Plan
OV	Official Veterinarian
REMO	Database of Animal Movements : Individual or Group)
RIIA	Database of Individual Identification Animals
SCC	Somatic Cell Count
TBC	Total Bacterial Count (Plate count at 30 °C)

1 INTRODUCTION

The audit to evaluate official controls related to the slaughter of equidae and sheep and the processing of fresh meat in Spain formed part of the FVO's planned audit programme. It took place from 9 to 19 April 2013. It is part of a series of audits to Member States related to horse and ovine meat in 2011- 2013 and a follow up to the FVO mission to Spain in 2011. The FVO audit team comprised one auditor from the FVO and one expert from a Member State.

The FVO audit team was accompanied during the whole mission by representatives of the CCA, the AESAN, *Agencia Española de Seguridad Alimentaria y Nutrición*, and the representatives from the CAs from the ACs and Municipalities concerned.

An opening meeting was held on 9 April 2013 with the CCAs. At this meeting, the objectives of, and itinerary for the audit were confirmed by the FVO audit team and the control systems were described by the authorities.

2 OBJECTIVES

The objective of the audit was to evaluate the CAs' official controls and enforcement related to the slaughter of equidae and ovine and to the processing of fresh meat, in particular from equine and ovine animals. Within this overall objective, the actions taken by the Spanish authorities in response to the recommendations of a previous FVO audit carried out in 2011.

In terms of scope, the audit concentrated primarily on the organisation of official controls (Articles 3-7 of Regulation (EC) No 882/2004) control and verification procedures and methods (Articles 8-10 of Regulation (EC) No 882/2004), enforcement (Articles 54-55 of Regulation (EC) No 882/2004) and registration and approval of establishments (Article 31 of Regulation (EC) No 882/2004). The specific area under review and in the framework of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 were controls over fresh meat from equine and ovine animals.

COMPETENT AUTHORITIES			Comments
Competent authorities	Central	2	Opening and closing meeting. Officials from the ACs concerned were present via videolink
	ACs and Municipalities	3	
FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES			
Slaughterhouses		6	Three horse and three ovine slaughterhouses not visited before and situated in ACs not visited in 2011
Cutting plants		4	Integrated with the slaughterhouses visited
Official Laboratories		2	Laboratories for <i>Trihinella</i> in the slaughterhouses visited
Horse fattening farm		1	

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

Spain is a significant producer and distributor in the European Union (EU) of fresh equine meat, with 69 600 equidae slaughtered in 2012, a dramatic raise compared to 31 000 slaughtered in 2009. There are no specialised horse slaughterhouses in Spain and all equidae are slaughtered on combined horse and bovine slaughter lines. In general the slaughtering of horses is performed as a service for the meat traders. The majority of the horses slaughtered in Spain are of Spanish origin.

The number of sheep slaughtered in 2012 was 11 467 000.

In 2011, there were 446 ovine and 86 horse slaughter lines in 457 slaughterhouses in Spain.

The previous audit concerning the safety of food of animal origin in Spain (equidae and ovine) was carried out from 3 to 13 May 2011, the results of which are described in report DG(SANCO)/2011-6021 MR Final (hereafter referred to as previous audit report).

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

During this audit serious deficiencies in the performance of the official controls in the sector evaluated were found. The following recommendations were made in the audit report:

- *1. To establish efficient and effective co-ordination between all the CAs involved as is required by Article 4(3) of Regulation (EC) No 882/2004.*
- *2. To enforce Article 8(3) of Regulation (EC) No 882/2004 (which states that the CAs must have procedures in place to verify the effectiveness of official controls, to ensure effectiveness of corrective action and to update documentation where needed) on all levels.*
- *3. To evaluate urgently all slaughterhouses currently approved in Spain for the slaughter of equidae and small ruminants with regard to the requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 and inform Commission services about the outcome of this evaluation.*
- *4. To ensure that only the establishments which fulfil the approval conditions are listed on the lists of approved establishments as is required by Article 31(2) of Regulation (EC) No 882/2004.*
- *5. To ensure that the appropriate corrective action in accordance with Article 54 of Regulation (EC) No 882/2004 is taken when needed and that the sanctions laid down in national legislation are effective, proportionate or dissuasive as required by Article 55 of*

Regulation (EC) No 882/2004.

- *6. To ensure urgently that OVs perform the inspection tasks and audits of good hygiene practices and HACCP-based procedures and any other particular auditing tasks in line with the requirements of Regulation (EC) No 854/2004.*
- *7. To ensure the full implementation of Council Regulation (EC) No 21/2004, including in particular the last paragraph point B.2 of the Annex to ensure traceability of lambs younger than 12 months.*
- *8. To ensure urgently that animal welfare requirements as laid down in Council Directive 93/119/EC are met in slaughterhouses slaughtering horses and small ruminants.*

The CA's response to the recommendations can be found at:
http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2011-6021

In response to the recommendations of the audit report the Spanish CA have developed an action plan.

In particular, as a response to Recommendation 3, a Strategic Plan for slaughterhouses of small ruminants and equidae (hereinafter the Strategic Plan) was developed in the summer of 2011 as an urgent measure to address the non-conformities detected during this audit. Also action in response to several other recommendations has been carried out within the Strategic Plan.

The Strategic Plan comprised four phases:

- Phase 1 - verification (evaluation of compliance with the EU rules) of the FBO activities – to be finished by 30 November 2011. At this stage would also take place
 - update of the lists of approved establishments,
 - review, update and standardisation of the working procedures of all CA,
 - prioritisation of evaluation visits based on risk evaluation,
 - standardisation of evaluation of non-conformities and their consequences,
 - elaboration of a standardised report model for the slaughterhouses,
 - transmission of the individual establishment report to the Commission.
- **Phase 2** - verification of the activities of the CA (OV) in the slaughterhouses – to be finished by 31 March 2012,

At this stage, procedures for the verification of the CA activity would be developed, the procedures already existing in the CA standardised, and reporting models developed. Moreover, the procedures developed this way would be introduced in the National Control Plan for the Food Chain as a permanent working tool.

- **Phase 3** - analysis of results and preparation of a general report of the situation in each AC,

including deficiencies found and action taken in order to address them – to be finished by 31 May 2012,

As this phase would elapse after a six month period (maximum deadline allowed for addressing of non-conformities identified at evaluation phase), the situation in the slaughterhouse would be re-evaluated.

Preparation of a general report of the situation in the country, including action taken in order to address the problems found, to be sent to the European Commission. This phase was expected to be finished by 30 June 2012.

In the framework of the Strategic Plan, the Spanish Authorities withdrew at the very beginning 25 slaughterhouses from the list. They then individually assessed 450 ovine and 88 equine slaughter lines in 457 slaughterhouses. Assessment of each slaughterhouse comprised initial evaluation, verification and follow-up. Deficiencies identified were divided into major (type 1) and minor (type 2), the first requiring suspension of activities. Approval for 13 slaughter lines was withdrawn and 62 (57 ovine and 5 horse) slaughter lines were suspended for various periods of time. In the next stage, the performance of the CA (OV) in the 418 slaughterhouses concerned was assessed (no evaluation took place in the slaughterhouses where the lines had been suspended). The AC reported the results to the CCA using standardised templates. They described the situation in each individual establishment at the moment of the first visit, but did not cover the follow up. The CCA prepared summary reports, providing general figures. They could, however, not be linked back to individual establishments which means that the improvement process could not be followed (by an external auditor). In particular it was not possible to follow the period of suspension and its outcome for individual establishments. In August 2012, the Global report on the situation of the sheep, goat and horse slaughterhouses was sent to the Commission. The CCA have highlighted that all the slaughterhouses had been reviewed and the non-compliances had been resolved. The Plan was considered by the CCA as accomplished and closed and the official controls in the slaughterhouses would continue on a routine basis, as foreseen in the local control plans. However, by this time, a large number of slaughter lines were still suspended.

The outcome of the initially suspended 62 slaughter lines was the following:

- By 15 November 2012, 14 had their approval withdrawn, suspension was lifted for 29 and 19 were still suspended.
- By 10 May 2013, of the 19 still suspended: an additional four lines had their approval withdrawn, six had their suspensions lifted and nine were still suspended (in one of them procedures to withdraw approval had been initiated).

At all stages of the performance of the Plan the ASEAN played a central role for co-ordination of the flow of information, elaboration of procedures and distribution of documents.

The action taken by the Spanish CAs was found by the FVO to be satisfactory at desk analysis, with the exception of one recommendation, no 7, where evidence that national legislation (Royal Decree 947/2005) has been changed accordingly, is still pending.

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 CAs responsible for the purposes and official controls set out in the Regulation. It also lays down operational criteria for the CAs.

Audit findings

An overview of how control systems are organised in Spain is provided in the Country Profile for Spain, and is available at the following link:

http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=ES

The main CCA relevant for this audit is the AESAN, the Spanish National Agency for Food Safety.

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 CAs. 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 system for co-operation and co-ordination activities between the different levels of the CA is described in the County Profile for Spain. The previous audit in their report questioned the efficiency of that system. Therefore, a recommendation was made (no 1) to establish efficient and effective co-operation between all the CAs in Spain. In response to this recommendation, a special working group was created in the scope of the Strategic Plan by decision of the Constitutional Committee in October 2011. The Institutional Committee is the highest-level forum for co-ordination between the AESAN, the Ministry of Agriculture, Food and the Environment, the Ministry of Health, the Social Services and Equality and the ACs. A number of guidelines have been drafted in co-operation between the AESAN and the ACs, approved by the Institutional Committee and distributed to all of the ACs.

The FVO audit team noted that the implementation of the Strategic Plan (as described in section 4) and in particular the performance of evaluation visits nationwide in 457 slaughterhouses, with reporting to the AESAN and follow up within an agreed time schedule, as well as upgrading of several guidelines and instructions required a high level of co-operation between the CA and the AESAN and this was successfully demonstrated. However, the co-operation between the Municipal CA in charge of one slaughterhouse in which serious deficiencies were found, and other CAs could not be considered by the FVO audit team as satisfactory and the information provided as being

complete.

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

During the previous audit four out of eight slaughterhouses visited did not fulfil approval conditions. The conclusion of the report was that the official controls and the system to keep approvals under review did not guarantee that only establishments which fulfil all the approval conditions are in operation and that deficiencies are resolved within a reasonable time. A recommendation (no 4) was made in order to address this situation. In response to this recommendation, the CAs took the following action:

- before that start of the Strategic Plan, they withdrew approval for 25 slaughterhouses, where the FBO could not guarantee that it would resolve deficiencies within a reasonable time period, and removed these establishments from the list in the *Registro General Sanitario de Empresas Alimentarias y Alimentos*, the General Health Register of Food Business Establishments,
- they have developed and agreed within the Institutional Committee a procedure for suspension of establishments. Suspension is considered as a first step to withdraw the approval,
- in the scope of the Strategic Plan, they withdrew approval for another 31 slaughter lines, and suspended 62 (detailed breakdown see section 4). Nine of the 62 slaughter lines were still suspended by 10 May 2013.

The FVO audit team made the following observations in the slaughterhouses visited:

- Three out of six did not fulfil the approval conditions,
- the three establishments that did not fulfil the approval conditions were not suspended during the exercise of the Strategic Plan,
- in two of these establishments ("A" and "E") the documentation available could not confirm that the CA correctly identified or prioritised the existing deficiencies,
- of the establishments visited, only one has been suspended during the exercise of the Strategic Plan (establishment "B"). The deficiencies in this establishment were of a less severe nature than those in other establishments that had not been suspended,
- the individual reports for establishments evaluated in the scope of the Strategic Plan indicate only the situation at first evaluation (autumn 2011). An establishment suspended at a later stage (the case of establishment "B") does not appear in the reporting system. Later

communications from the regions provide only generic figures, which is a limiting factor for the transparency of the reporting system in the scope of the Strategic Plan. From the information available at central level, it is not possible to ascertain the evolution of progress in individual establishments. The follow up of the situation requires a visit on the spot,

- the fact that, by 10 May 2013, there are still nine slaughter lines suspended, indicate that their suspension period was extended at least once,
- the approval decisions only indicated activities for which the establishments were approved, but no reference was seen to establishments' rooms, territory and perimeter. This caused confusion about the limits of the responsibility of the FBO and OV. In one establishment located in a larger building complex, which was also used by other establishments, the FBO and the CA were not able to explain, which rooms belong to this, and which to other establishments. The CA stated that where rooms in the complex mentioned are not rented out, they may be used by the establishment visited. However, this situation was not reflected in any documentation. In another establishment, also located in a large building complex used by several companies, evidence was found, despite a denial by the FBO, that he used the rooms of another establishment. The latter was abandoned by the FBO several months ago and has not been in activity since then. It was still approved but not supervised and maintained in compliance, being heavily infested by rats and endangering the whole building complex.

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

In the previous audit report it was concluded that the official controls to verify FBO compliance with the relevant EU requirements as well as audits required by Article 4(4) of Regulation (EC) No 854/2004 were not carried out at regular intervals and were incomplete.

The system for prioritisation of official controls is described in the Multi-annual National Control Plan (MANCP) for 2011-2015, part B, section III, p. 61.

The MANCP is available at the following link:

http://www.aesan.msssi.gob.es/AESAN/web/control_oficial/seccion/plan_plurianual_control_oficial.shtml

On the basis of this plan, the ACs and Municipalities establish their own control plans. As an example, the AC of Andalucía had established the Risk based Inspection Plan of the Food establishments in Andalucía (*Plan de Inspección basad en el riesgo de los establecimientos alimentarios de Andalucía*). According to this plan, all food establishments based on risk

classification are divided into five categories, with inspection/supervision frequency varying from every six months to more than every two years. The risk is calculated on the basis of a score system based on the product, nature of treatment, production volume, FBO level of compliance including structures, equipment, GMP, HACCP, the FBOs' past records. The Plan also contains procedures for the performance of the inspection and classification of non-conformities. On the basis of the results of the inspection, a new evaluation of the risk in the establishment is carried out, which may influence the frequency of the official controls. The basic frequency for official controls in the slaughterhouses visited in Andalucía was 18 months. During these controls an evaluation of an establishment is carried out and the frequency can be changed accordingly.

5.1.5 Official sampling and laboratory analysis

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires CAs to have, or to have access to, adequate laboratory capacity. Article 11 of the Regulation establishes requirements for sampling and analysis and Article 12 requires the CA to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down accreditation criteria for the laboratories so designated.

Audit findings

In two horse slaughterhouses visited by the FVO audit team samples for *Trichina* examination were examined in the official laboratories adjacent to the establishments. In one of these, the FVO audit team enquired regarding participation in ring test and was informed that these are organised by the provincial authorities.

In addition, the AC of Andalucía stated that they begun procedures to authorise laboratories for Public Health issues. Within this AC, there are currently eight laboratories which perform *Trichina* examinations; four of these are accredited by the national accreditation body, the ENAC. Some of official laboratories adjacent to slaughterhouses are affiliated to the accredited laboratories. This was the case for one laboratory visited; should *Trichinella* be detected, the sample would be sent to an accredited laboratory for confirmation.

In one small ruminant slaughterhouse and two horse slaughterhouses the FVO audit team verified the results of the microbiological examination of carcasses. The frequency of sampling and the results were satisfactory.

5.1.6 Procedures for performance of control activities

Legal requirements

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

Audit findings

The ACs visited by the FVO audit team have developed detailed procedures for the performance of official control activities in slaughterhouses. For example:

- The AC of Andalucía has issued an instruction on official controls of slaughterhouses (*Documento de referencia de los controles oficiales en mataderos de Andalucía*), last update November 2012.
- The AC of Castilla y León has issued an instruction on inspection in slaughterhouses, number 1/2011, last updated 01/01/2012 (*Procedimiento General de Inspección Veterinaria in Mataderos*).
- The AC of Asturias has issued an instruction of December 2010 (*Manual de procedimientos de control oficial en mataderos de carne rojas*).

All these large and detailed documents contain information and instructions to the staff, describing all the elements of official controls, including check lists, guides on how to complete them, sampling plans, and specific programmes related to animal welfare, residue control, Transmissible Spongiform Encephalities and Animal By-Products (ABP), and similar.

There are also documents, some included in the general instructions, and some as separate documents, for establishing frequency of official controls, rules concerning identification of animals in the slaughterhouses, etc.

The procedures applied in practice in different provinces and communities may vary between them. In Andalucía, inspection in slaughterhouses is carried out by the OV. In every slaughterhouse, there is an inspection plan, which is risk based. For daily controls, a check list (*Hoja de control oficial, industrias de control permanente*) is used, according to a model drafted by the AC (at provincial level). This check list refers to the auditing tasks as described in Article 4 and Annex I Chapters 1 and 2 of Council Regulation (EU) 854/2004. If deficiencies are found, an OV produces a report (*Informe sanitario*) which has to be signed by the FBO and is attached as an Annex to the check-list.

Examples were seen that these check-lists are completed in a somewhat mechanical way which means that the results did not reflect the real situation in the establishment.

5.1.7 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 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

During the previous audit it was found that the appropriate action was not always taken by the CAs when needed or/and the request for corrective action was not respected by the FBO. It was concluded in the report that the ability of the CAs to enforce corrective action was questionable. A recommendation (no 5) to address this deficiency was made in the previous audit's report. In response to this recommendation, action was taken by the CAs:

- In order to coordinate the national approach to evaluation of non-compliances and sanctioning, a special working group was created, consisting of representatives of six ACs and led by the AESAN. The group has produced a Guideline for classification of non-compliances and the applying of sanctions in slaughterhouses which was approved in July 2012.
- As indicated in section 4, in the scope of the Strategic Plan 25 establishments had their approval withdrawn from the very beginning, 62 slaughter lines have been suspended, and to date, 9 of them still remain suspended, and 31 had their approval withdrawn after evaluation.
- Moreover, in total 116 administrative procedures have been initiated, 93 during the evaluation phase and 23 during the follow up phase of the plan. The absolute majority of the procedures were related to animal welfare deficiencies and were found to be addressed at follow up. In 10 % of cases the deficiencies were not addressed and the establishments have been suspended.

One slaughterhouse, in which serious deficiencies were found by the FVO audit team, was suspended by the CA after the FVO visit. No details, however, could be obtained about the length of the suspension, to which parts it applied and what was the follow-up. In addition, an administrative procedure against the FBO was initiated. The CA imposed a penalty of 18 000 Euro for carrying out unauthorised activities, poor hygiene, lack of identification and traceability of meat, and sent it to Court, which takes the final decision as to approve or reject the penalty. Moreover, this establishment could not account for more than 6 000 horse carcasses out of 13 000 horses slaughtered there in 2012 - first trimester 2013, despite the fact that the CA has declared to have run a traceability exercise several times. Information on the possible action of the CA in relation to this infringement is still awaited.

Another slaughterhouse, visited by the FVO audit team, was suspended for a period of three weeks in the summer of 2012. On the basis of documents available, the FVO audit team found that it had been suspended even though only minor deficiencies had been found by the CA. The CA explained that this was in conformity with the rules, which foresees suspension, even for minor non conformities, if the FBO doesn't respect the deadlines. During the FVO's visit the slaughterhouse was found to be in conformity, with only minor deficiencies, which were not the same as previously identified by the CA.

5.1.8 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

Recommendation no 2 of the previous audit report requested enforcement of Article 8(3) of Regulation (EC) No 882/2004 which states that the CAs must have procedures in place to verify the effectiveness of official controls, corrective action and document update.

In response to this recommendation, the CAs updated the National Plan for the Official Control of the Food Chain (PNCOCA) for 2011-2015 by introducing a Chapter on Monitoring of Official Controls. This chapter was used by the ACs for the review or the drawing up of their own procedures for the verification of official controls.

Moreover, as indicated in section 4, within the scope of the Strategic Plan 2011-2012, the CAs had carried out an evaluation of the activities of the OVs in 418 slaughterhouses. The following aspects have been assessed: training, procedures, performance of the official controls, application and follow up of measures.

Evaluation of the activities of the OV has also been carried out within the scope of the Strategic Plan for Animal Welfare.

The AC have developed or are developing systems for internal audits of the activities of the CAs.

In the CA of Andalucía, there is an annual audit plan which foresees for the remaining part of 2013 10 audits to be carried out in different administrative bodies in charge of official controls (i.e. at the level of *Distrito Sanitario*, or *Área de Gestión Sanitaria* or *Delegación Teritorial*). Documents were seen of an audit carried out in 2012 in an *Área de Gestión Sanitaria* where four non-conformities were found, one of them major: deficiencies in the performance of the veterinary inspection in the slaughterhouses (12 points, including for example the fact that, when the CA detected the presence of *Salmonella* in an official sample, they did not contact the FBO and no measures were taken). A detailed action plan was drafted afterwards, indicating corrective action for each of the non-conformities detected.

In the AC of Castilla y León, the CA are currently working to create an audit team, which is supposed to be operational by the end of 2013. In the past, the CA had a contract with an external audit company, but the contract expired in 2011 and could not be renewed.

Conclusions on Competent Authorities

The Spanish CA have put in place a framework for a system for official controls, which is based on written procedures, risk based and documented. Action taken in response to the previous audit's recommendations and in particular the implementation of the Strategic Plan significantly improved the quality of the system performance. In particular it demonstrated its ability regarding effective co-operation and co-ordination, last but not least between the CCA and the ACs. The CA in all ACs have verified the effectiveness of official controls in all horse and sheep slaughterhouses in the scope of the Strategic Plan. At the same time a general update of documentation and procedures took place. Some of the CAs have developed and apply their own system for internal audits, and other CAs are in the process of developing such a system. However, as the situation in the establishments visited by the FVO audit team demonstrated, the system of official controls is not always effective and further effort is needed for its full implementation and standardisation. Moreover, despite all efforts made in the scope of the Strategic Plan, the FVO audit team found that 50 % of establishments visited did not fulfil approval conditions. Recommendation no 4 of the previous audit report has not been addressed.

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 FBO carrying out any stage of 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, sitting and size of food premises.

Article 3 of Regulation (EC) No 853/2004 sets out that the FBO 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 FBO's compliance with these requirements.

Audit findings

Six establishments (horse and/or sheep slaughterhouses, four of them with integrated small cutting plants) in three different ACs were visited by the FVO audit team.

All six have been evaluated by the CA in the scope of the Strategic Plan. In five of them deficiencies were found, the reports drafted with corrective action requested using the same template, and deadlines for corrective action established. In the sixth, establishment "C", no deficiencies were found in the scope of the Strategic Plan. However, some deficiencies were identified during an routine inspection shortly afterwards and corrective action was taken.

Establishment "A" was evaluated by the CA in the scope of the Strategic Plan in August 2011 as requiring improvement. A number of minor (type 2) deficiencies were identified, related to maintenance, cleaning, animal welfare, FCI and own checks, with deadlines ending in February 2012 at the latest. Also some deficiencies in the performance of the official controls were identified.

A CA inspection report from January 2013 provides a list of over 20 deficiencies, which are relevant but limited to maintenance issues. Their character indicates that they have been present since a long time and therefore have not been addressed in the scope of the Strategic Plan. Many of these deficiencies were still present during the FVO audit team's visit.

The FVO audit team confirmed the findings related to the maintenance identified by the CA. Moreover, the FVO audit team found significant deficiencies related to the structure, maintenance, hygiene of operations and traceability, not identified by the CA. The establishment was situated in a large building complex, shared by several companies, along a central corridor, with some rooms being in use and some unused. The CA stated that the establishment concerned could use other rooms when empty, but no documentation supporting or explaining the operation of such a system was available. There was damage to floors and doors, gaps in coating of ceilings and walls,

exposed insulation, flaking paint, rusty structures, structures not clean and not easy to clean. The cutting room and some cold stores were dirty and dilapidated. After stunning, horses were dragged on the floor in blood. Visible faecal contamination of carcasses slaughtered a day before was noted. Sterilisation of some equipment was inadequate. A consignment of pigs slaughtered in the morning of the visit had already been sent away to another establishment at midday, before the meat reached the prescribed temperature. The CA did not grant any derogation allowing the FBO to out load and transport warm meat. The FBO delayed access to some parts of the establishment by stating, that it was not in use. When the access was gained, the audit team found traces of activities under unacceptable hygiene conditions, including in rooms not intended for the handling of food. Suspicion was raised about the illegal character of these activities (probably cutting and packing, see section 5.2.4.). The FBO failed to explain the situation to the FVO audit team. In particular, he did not take the responsibility for alleged illegal activities, by stating that people unknown to him entered his establishment, put the padlocks on the doors and carried out unknown activity. The CA in charge of the establishment, with three OV's present full-time, was said to be unaware of the situation and could not be responsible for activities carried out after hours. Moreover, the FBO failed to document the destination of over 6 000 horse carcasses out of 13 000 horses slaughtered in this establishment in 2012-2013.

In general: unsatisfactory, serious deficiencies.

Urgent action was requested by the FVO audit team. The CA suspended the activities of the establishments and initiated an administrative procedure against the FBO.

Establishment "B" was evaluated by the CA in the scope of the Strategic Plan in September 2011 as requiring improvement. A number of minor (type 2) deficiencies were identified, related to structures, maintenance, cleaning, trichinae laboratory equipment, ABP management, training, HACCP implementation, and animal welfare, with deadlines ending in April 2012 at the latest. It has been suspended for a period of three weeks in the summer of 2012. No deficiencies in the performance of the official controls were identified. The establishment was not slaughtering during the visit.

The FVO audit team identified a number of minor deficiencies with the exception of an animal welfare incident (see section 5.2.9) which is considered as significant. Structures, equipment, layout and maintenance were found to be acceptable.

In general: satisfactory

Establishment "C" was evaluated by the CA in the scope of the Strategic Plan in November 2011 as satisfactory. No deficiencies were identified. However, during a scheduled inspection (not in the scope of the Strategic Plan) in January 2012, the CA found some significant deficiencies, related to crossing of flows, hygiene of operations (including functioning of sterilisers), but also rather minor deficiencies related to documentation of own checks. A detailed action plan – 20 pages - has been produced by the FBO after this inspection and accepted by the CA. A similar detailed report was produced for the very small integrated cutting room and for animal welfare issues.

The FVO audit team identified a number of deficiencies related to structure (ceiling in the slaughterhouse not easy to clean, lack of adequate storage room for equipment after cleaning) maintenance (condensation), cleaning (storage of packaging material), hygiene of operation (extensive splashing in the slaughter room with risk of contamination of unprotected meat), managing of ABP (products with EU identification mark and as such expected to be fit for human

consumption in the ABP store).

In general: satisfactory, deficiencies relatively easy to rectify

Establishment "D" was evaluated by the CA in the scope of the Strategic Plan in November 2011 as requiring improvement. A number of minor (type 2) deficiencies were identified, related to structure, maintenance and own checks, with deadlines ending in June 2012 at the latest. Also some deficiencies in the performance of the official controls, application and follow-up of corrective measures were identified.

The FVO audit team identified a number of deficiencies related to maintenance (some ceiling and wall damages, hygiene of operations (poor hygiene in the changing rooms, lack of sterilisation for certain equipment, some dirty sterilisers, some skin roll in, extensive splashing with a risk of contamination of unprotected meat).

In general: satisfactory, deficiencies easy to rectify.

Establishment "E" was evaluated by the CA in the scope of the Strategic Plan in December 2011 as requiring improvement. Two minor (type 2) deficiencies, related to maintenance, were identified with deadline for their correction ending in January 2012 at the latest. Also some deficiencies in the performance of the official controls and application of corrective measures were identified.

The OV in his report of January 2013 identified 27 deficiencies related to maintenance deficiencies, two of which had already been indicated in the evaluation report of the Strategic Plan. The type of the many deficiencies indicates that they may have been present but not identified and dealt with in the scope of the Strategic Plan.

The FVO audit team identified a number of deficiencies related to structure, lay-out, maintenance, hygiene of operations and own checks. The main problem of this establishment, generally run down, is the lack of space in the dirty part of the ovine line (jeopardising hygiene of operations) and a lack of adequate space for cleaning containers, with a risk of cross contamination of equipment. None of these problems was identified by the CA and the issue of flows was not understood by the OV. During the FVO audit the ovine line was seen in operation and the following was noted: leakage of water from pipes and wash basins, extensive use of suspended hoses with splashing and risk of contamination of unprotected meat, some skin roll in, with risk of contamination of sheep carcasses, rusty or very rusty overhead structures, some equipment not adequately sterilised, some equipment rusty and dirty, dirty ceilings, some sterilisers operating under prescribed temperature, the premises not pest proof. The equine line was not in operation but several structural and maintenance deficiencies were noted (insufficient number of sterilisers, wash basins on high platforms not connected to drain). The FBO had no written procedures for the cleaning of equipment or the avoidance of cross contamination due to crossing of flows. The maintenance plan provided by the FBO had no deadlines.

In general: unsatisfactory – deficiencies difficult to rectify and requiring considerable investments. Improvements would probably require removal of one slaughter line (out of the current three).

Establishment "F" was evaluated by the CA in the scope of the Strategic Plan in November 2011 as requiring improvement. A number of minor (type 2) deficiencies were identified, related to maintenance, hygiene of operation (including problems with sterilising of instruments), ABP management, and own checks, with deadlines ending in February 2012 at the latest. Also some

deficiencies in official controls related to training, documented procedures and follow-up of the corrective measures were identified.

This establishment had basically good structures but some parts were not properly maintained. The FVO audit team identified a number of deficiencies related to structure, lay-out, and maintenance, hygiene of operations, pest control and HACCP. The FBO failed to provide a full and clear picture about the activities he carried out. The establishment was generally not pest proof. Evidence was found of the presence of rodents in rooms used by the FBO in the same building complex, abandoned by another company and uncontrolled but still approved. Damage to floors, walls and windows was noted in different places. A number of cold stores were in a very poor state of repair (rusty overhead structures, detached coating of walls, exposed insulation) and were said by the FBO not to be in use but no supporting documentation was available. In the slaughterhouse (equine/bovine line) tools were not sterilised. The FBO stated that he used an alternative system having the equivalent effect, namely ozonised water, but this could not be satisfactorily documented. The documentation provided was a generic study from a professional association and the procedure was not followed by the operators. The procedure was not described in the HACCP, which was required by the CA already in November 2011. The stunning box was not properly designed and stunned horses had to be pulled out of it. The overhead structures including rails were rusty. Several pieces of equipment (wash basins, saws, sterilisers) were not connected to drains leading to leakage and splashing. Signs of improvement were noted by the FVO audit team: the operators were skilled and the slaughter technique adequate, but excessive use of suspended hoses at every working post with splashing and risk of contamination of carcasses, combined with lack of sterilisation, could have a negative impact on the hygiene of operations. The ovine line was not seen in operation but deficiencies related to maintenance and cleaning were noted. Bacteriological examination of carcasses took place every three months only, with the authorisation of the CA.

In general: unsatisfactory, serious deficiencies.

Urgent action was requested by the FVO audit team. The CA withdrew the approval for the abandoned establishment and took urgent action to improve hygiene in the slaughterhouse.

Conclusions

Despite significant effort, the Strategic Plan has not been effective in achieving compliance in all equine and ovine slaughterhouses. Of the six establishments, visited by the FVO audit team, considered by the CA to be compliant, only three were found to be so.

5.2.2 HACCP-based systems

Legal requirements

On the basis of Article 5 of Regulation (EC) No 853/2004 the FBO shall put in place, implement and maintain a permanent procedure or procedures based on the 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

All establishments visited by the FVO audit team have developed HACCP based procedures. However, in the establishments where these procedures were checked, they were found not to have been updated, or adapted to the current activity or were missing (establishments "A", "E" and "F", see section 5.2.1).

Conclusion

In three establishments visited the HACCP based procedures had not been updated or adapted to the current activity or were missing.

5.2.3 Microbiological criteria for foodstuffs

Legal requirements

Microbiological criteria for foodstuffs 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

The carcasses and products were sampled in accordance with Regulation (EC) No 2073/2005 in all establishments visited, with the exception of establishment "F", in which sampling and analysis took place every third month, with the authorisation of the CA. The results were satisfactory or acceptable in all establishments visited. It was noted that in the smaller establishments the sampling and evaluation of the results were practically carried out by the OV and not by the FBO.

Conclusion

The requirements of Regulation (EC) No 2073/2005 concerning testing had been complied with in all but one establishment.

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

Traceability is part of the official controls of the CA. Traceability exercises were carried out by the FVO audit team in three slaughterhouses, with satisfactory results in one horse, and one ovine slaughterhouse.

However, in another horse slaughterhouse, establishment "A", the FBO could not account for the destination of more than 6 000 horse carcasses out of 13 000 horses slaughtered in this slaughterhouse in 2012. Delivery documents were available for 7400 carcasses only. Figures provided by the CA at the FVO's request indicate that five major clients received in total 14 800 carcasses from establishment 'A', which is over 1 000 more than is indicated on the killing lists for 2012 from this establishment. With an absence of delivery documents those summary figures do not allow traceability to be verified. However, documents were provided that the CA in this slaughterhouse carried out traceability controls on a regular basis.

In the same slaughterhouse, in the area where the alleged illegal activity took place copies of identification marks were found by the FVO audit team. According to the OV these marks were illegally copied. In the same area a small quantity of unlabelled bovine meat was found.

Conclusion

In general, the EU requirements for traceability, labelling and identification were satisfactorily implemented. However, in one establishment serious traceability irregularities were found by the FVO audit team. The CA failed to discover or prevent them.

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 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 FCI.

Audit findings

The FVO audit team reviewed FCI in all establishments visited. The FCI did not indicate any medical treatment for any of the horses seen by the FVO audit team. Moreover, the FCI document is drafted in such a way, that the owner declares possible medical treatment during the last 30 days only.

It was noted that in some cases no reference was made to the identify of the horse in the FCI document.

Conclusion

The information contained in the FCI document, related to the medical treatment of animals, can only be ascertained for a maximum of one month.

5.2.6 *Animal identification*

Legal requirement

Article 4(1) of Regulation (EC) No 852/2004 requires that FBOs carrying out primary production shall also comply with some specific requirements provided for in Regulation (EC) No 853/2004 including sending only properly identified animals to the slaughterhouse and to provide slaughterhouse operators with the FCI. FBOs operating slaughterhouses must ensure that the procedures that they have put in place in accordance with the general requirements of Article 5 of Regulation (EC) No 852/2004 guarantee that each animal or, where appropriate, each lot of animals accepted onto the slaughterhouse premises is properly identified (Annex II, Section II of Regulation (EC) No 853/2004). Regulation (EC) No 504/2008 sets out the methods for identification of equine animals.

Audit findings

In the report of the previous audit, a recommendation was made in relation to traceability of lambs younger than 12 months, which did not fulfil the requirements of Regulation (EC) No 21/2004. In response, the CAs announced an amendment to the national legislation (Royal decree 947/2005). The response was found to be unsatisfactory due to the fact that evidence of this amendment had not been provided to date.

The AESAN has issued an instruction dated September 2011 describing means of identification of animals and the obligation of the FBO in this regard.

During the current audit, in the establishments visited, horses arrived electronically identified (transponder) and accompanied with passports and a transport document indicating their unique number. The number of the transponder was read by the FBO prior to stunning and cross-checked with the passport number. All the horses seen by the FVO audit team were of Spanish origin but arriving from different ACs, they presented different passport models. It was noted, however, that independent of their origin, section IX of passports (indicating medical treatment) has not been completed in any passport seen.

All ovine animals seen in the slaughterhouses visited were lambs younger than 12 months. Lambs for slaughter arrived identified with a tag indicating their farm of origin and a transport document indicating number of animals in the batch and the farm of origin.

As described in the Country Profile for Spain, the Spanish CAs have put in place a system for animal traceability, SITRAN (Integrated System of Animal Traceability) which incorporates three databases that link all ACs: REGA (General Multi species Register of all Animal Holdings); RIIA (Database of Individual Identification Animals: (bovine, ovine, caprine, equine) and REMO (Database of Animal Movements: Individual or Group). The FVO audit team noted that:

- the registered holdings update takes place once a year and is based on the farmer's declaration. Figures declared are normally not cross-checked by the CA, except in the case of animal health inspections, when on the spot visits are carried out,

- not all horse movements can be traced in the database as five ACs are not yet connected to the REMO,
- REMO has been developed for epidemiological purposes. No notification of movement is registered in the REMO when animals move within the same municipality (which is one epidemiological unit) or between different holdings in the same ownership.

A number of automatic plausibility checks are included in the RIIA and activated when data are sent from the AC to the central database. In most cases (84 automatic checks) the non-plausible data is rejected back to the originating AC. In some cases (6 automatic checks) the data is accepted but marked (flagged) by the system as “erroneous”. Additional checks are performed when a body that issues the passport is an association that operates a stud book.

There are currently 690 000 horses registered in the database, figures based on declaration and considered by the CA to be up to date.

In one horse fattening farm visited, it was explained to the FVO audit team that all horses arrive with passports, transport document and identified with transponders. Their numbers are cross-checked with the passports by the FBO at arrival and at departure. Notification to the Database REMO has to be done within seven working days. Some delays in notification were noted at the farm visited (14 days in one case and 7 days in another).

Medical treatments, according to the FBO, were unusual at the farm, and concerned mostly painkillers (as for example Fluvex). Withdrawal time for horses is 28 days. The FBO when signing the FCI certifies only for 30 days. The FVO audit team noted that in 2012, the records for medical treatment were not correlated with an identified animal. The CA during an official control noted this fact and suspended the farm for a two-month period. However, afterwards, the farmer did not enter any new treatments in the journal for medical treatments. He kept his own notes instead. The CA confirmed that according to national legislation (Article 8 of Royal Decree 1749/1998 of 31 July), medical treatment information can only be introduced by a veterinarian.

Conclusion

No deficiencies in relation to animal identification were found. Some deficiencies in the recording of medical treatment were noted.

5.2.7 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.

Specific rules on official controls for *Trichinella* in meat are laid down in Regulation (EC) No 2075/2005.

Audit findings

Ante- and Post Mortem Inspection

The FVO audit team did not identify deficiencies in the performance of ante- and post-mortem inspection in the slaughterhouses visited.

Trichina testing

The FVO audit team saw two in-house laboratories in the horse slaughterhouses visited. The equipment and structure of these laboratories was found to be adequate. In one of them, due to the low number of horses slaughtered, the samples from horses were pooled together and examined as one batch with samples from pork. The instruction used was issued by the provincial CA and referred to the reference method laid down in Chapter I of Annex I to Commission Regulation (EC) No 2075/2005. This laboratory participated in ring tests organised by the provincial CA every six months. Validation protocols indicated that the laboratory passed the tests with satisfactory results.

The CA of Andalucía has started a procedure to authorise laboratories for public health examinations. Out of eight laboratories carrying out trichina examinations four have been accredited by the national Accreditation body, ENAC. The slaughterhouse laboratories will be affiliated to one of the accredited laboratories.

Conclusion

Ante- and post-mortem inspections were generally satisfactorily implemented.

5.2.8 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

The FVO audit team did not identify deficiencies in applying health marks in the slaughterhouses visited.

Conclusion

The requirements in relation to health marking have been correctly applied.

5.2.9 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. Council Directive 93/119/EC sets out EU rules with regard to the protection of animals at the time of slaughter or killing.

Audit findings

In the previous audit report, recommendation no 8 was made in relation to respect of animal welfare requirements as laid down in Council Directive 93/119/EC. In response to this recommendation, the CAs refer to the implementation of the Strategic Plan, in which the scope of evaluation included, in all establishments, the animal welfare issues. Moreover, a series of training sessions was proposed.

The current FVO audit team found that the rules of animal welfare were in general respected. Handling of animals and the equipment were satisfactory. However, an incident was seen in one establishment, where two sows unfit for transport were brought to the establishment. One of them, with evidence of *prolapsus uteri necroticans*, was dead in the lairage. Another one, with advanced arthritis and unable to move, was dragged alive across the floor. The OV reacted immediately and gave instructions to the staff, however, he was not obeyed. The animal was inadequately stunned, hoisted and bled when still conscious. This establishment, which was due to be closed, had adequate procedures in place but these were not respected by the staff.

While the operator was very skilful and no cases of inadequate stunning was observed, the fallen animal after stunning had to be dragged out of the box with consequent risk to the personnel. In addition, the inadequate design of the box rendered it difficult and dangerous to check the effectiveness of stunning.

Conclusion

The rules of animal welfare were in general respected, with the exception of an incident in one slaughterhouse.

5.2.10 Documentation of official controls

Legal requirements

Article 9 of Regulation (EC) No 882/2004 requires CAs 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

Very detailed documentation was produced at the time of the official controls (including the exercise of the Strategic Plan) and the reports contained a description of the purpose of controls, the findings, and, when non conformities were identified, a corrective action request, as required by Article 9 of Regulation (EC) No 882/2004. A copy was given to the FBO.

The reports did not always provide a reliable picture of the situation in the establishments. The level of identifying and describing deficiencies reports varied: from incomplete to comprehensive but still not complete and from generic to informative, as it varied the level of their correction. The approach of the CAs and their weighting of non-conformities was also varying, from very detailed (sometimes in relation to less relevant issues as in establishment “B” and “C”) to less detailed, complete and accurate in establishments where significant deficiencies were still present.

Conclusion

Documentation of official controls met the requirements of Article 9 of Regulation (EC) No 882/2004. Its informative quality was varying.

6 OVERALL CONCLUSIONS

A significant effort has been made by the Spanish authorities with the implementation of the Strategic Plan. In particular, co-ordination and control proceedings have improved. A framework for successful official controls has been put in place. A major effort was made by the CAs. The Strategic Plan was a temporary project and is now officially closed. However, practical implementation of controls was not satisfactory or effective in 50% of the establishments visited. Also the action taken by the CAs in relation to recommendations 2 and 4 have not been fully effective and action already initiated has to be continued with the help of ordinary control tools. Action taken in relation to recommendation 7 has not been accomplished.

7 CLOSING MEETING

A closing meeting was held on 19 April 2013 with the CCA, the AESAN and representatives of the CA concerned (some of them via video link). At this meeting the FVO audit team presented the findings and preliminary conclusions of the audit and advised the CCA of the relevant time limits for production of the report and their response.

The representatives of the CCA 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.

Nº.	Recommendation
1.	To complete the actions already initiated to ensure the effectiveness of official controls and, in particular, to develop a documented, standardised approach to evaluation and follow-up of non-conformities, as laid down in Article 4 of Regulation (EC) No 854/2004.
2.	To develop and implement a system for verification and review of official controls and procedures, as indicated in the Strategic Plan and implemented in one of the Autonomous Communities visited, in order to comply with the requirements laid down in Article 8(3) of Regulation (EC) No 882/2004.
3.	To complete the action already initiated to ensure that only the establishments which fulfil the approval conditions are on the lists of approved establishments as is required

N°.	Recommendation
	by Article 31(2) of Regulation (EC) No 882/2004.
4.	To complete the actions already initiated to ensure that official veterinarians perform all necessary tasks, including inspection and audit, in line with the requirements 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=2013-6965

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
Dir. 93/119/EC	OJ L 340, 31.12.1993, p. 21-34	Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or 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

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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