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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
ROMANIA
FROM 07 TO 18 FEBRUARY 2011
IN ORDER TO EVALUATE MEASURES CONCERNING BOVINE SPONGIFORM
ENCEPHALOPATHY (BSE)

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

Executive Summary

This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Romania, from 7 to 18 February 2011.

The objective of the audit was to evaluate the implementation of requirements concerning Bovine Spongiform Encephalopathy (BSE), as laid down in Regulation (EC) No 999/2001.

In terms of scope, the audit concentrated on BSE epidemio-surveillance in bovines, measures taken after suspicion/confirmation of BSE, removal and handling of specified risk material (SRM) from bovines, and the prohibition of feeding products of animal origin to farmed animals and exceptions applicable to this ban. The evaluation included measures taken in response to the recommendations made in a previous FVO audit regarding the afore-mentioned issues.

Overall, the report concludes that very limited progress has been made in order to address the recommendations of the previous FVO audit. In particular, BSE active epidemio-surveillance and compliance with SRM rules are significantly affected by the lack of arrangements for the collection of brain samples and SRM at backyard farms, where the majority of the bovine population is kept. There are also weaknesses concerning feed-ban controls.

The report makes a number of recommendations addressed to the Romanian competent authorities, aimed at rectifying the shortcomings identified and further enhancing the implementing and control measures in place.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ABP	Animal by-products
BSE	Bovine Spongiform Encephalopathy
Category 1, 2 and 3 material	Different Categories of ABP as defined in Article 4, 5 and 6 of Regulation (EC) No 1774/2002, respectively
CRL	Community Reference Laboratory
County Directorate	County Sanitary-Veterinary and Food Safety Directorate
Fallen stock	Dead on-farm bovines
FVO	Food and Veterinary Office
IHVPH	Institute for Hygiene and Veterinary Public Health
NAIRS	National Animal Identification and Registration System
NRL	National Reference Laboratory
NSVFSA	National Sanitary-Veterinary Food Safety Authority (<i>Autoritatea Națională Sanitar-Veterinara si pentru Siguranța Alimentelor</i>), the central competent authority
Report 2009-8111	Report of an audit carried out in Romania from 21 – 28 April 2009 in order to evaluate control measures on BSE
Report 2011-8941	Report of an audit carried out in Romania from 7 to 18 February 2011, in order to evaluate the implementation of health rules on ABP
SRM	Specified risk material
Total feed ban	Prohibition of feeding proteins derived from animals to farmed animals and exceptions applicable to this ban

1 INTRODUCTION

The audit took place in Romania from 7 to 18 February 2011 as part of the regular audit programme. The audit was run in parallel with another Food and Veterinary Office (FVO) audit DG(SANCO)/2011-8941 in order to evaluate the implementation of health rules on animal by-products (ABP).

The audit team comprised three auditors from FVO, and was accompanied throughout the audit by representatives from the central competent authority, the National Sanitary-Veterinary Food Safety Authority (*Autoritatea Națională Sanitar-Veterinara si pentru Siguranța Alimentelor* – NSVFSA).

An opening meeting was held on 7 February 2011 with the competent authorities, during which the audit objectives, itinerary, and the standard reporting and follow-up procedures were confirmed, and additional information required for the satisfactory completion of the audit was requested.

2 OBJECTIVES OF THE MISSION

The overall objective of the audit was to evaluate the measures concerning prevention, control and eradication of Bovine Spongiform Encephalopathy (BSE), as laid down in Regulation (EC) No 999/2001 of the European Parliament and of the Council.

In terms of scope, the audit concentrated on BSE epidemio-surveillance in bovines, including animal identification insofar as it is relevant to BSE protective measures, measures taken after suspicion and/or confirmation of BSE, removal and handling of specified risk material (SRM) from bovines, and the prohibition of feeding proteins derived from animals to farmed animals and exceptions applicable to this ban (hereafter: total feed ban).

The evaluation included measures taken in response to recommendations made in previous FVO audit which addressed the above issues.

The audit itinerary included the following visits:

Competent authorities visits		Comments
Central	✓	Opening and closing (de-briefing) meetings
Regional	✓	Meetings held in six counties
Local	✓	Discussions held in the course of visits to premises
Laboratory	✓	Discussions held in the course of the visits to county directorates
Establishments handling ABP		
Feed manufacturers	1	A feed mill using fishmeal and producing feed for ruminants and non-ruminants
Food processing establishments		
Slaughterhouses	2	Two bovine slaughterhouses also slaughtering other species with attached meat cutting plants (one harvesting head meat)
ABP plants		
Processing plant	3	One for Category 3 and two for Category 2 material
Intermediaries	4	One for Category 1 and 2, one for Category 3, one for Categories 1, 2 and 3, and one for Category 1 and 3 material
Incineration plant	2	Incinerating ABP
Storage plant	1	For Category 3 material
Other		

Retail shop	1	A supermarket with cutting unit
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3 LEGAL BASIS FOR THE MISSION

The audit was carried out under the general provisions of Community legislation and, in particular:

- Article 21 of Regulation (EC) No 999/2001;
- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

A full list of the legal instruments referred to in this report is provided in the Annex and refers, where applicable, to the last amended version.

4 BACKGROUND

The previous audit concerning BSE in Romania was carried out from 21 – 28 April 2009, the results of which are described in report DG(SANCO)/2009-8111 - MR Final (hereafter: report 2009-8111). This report is accessible at:

http://ec.europa.eu/comm/food/fvo/ir_search_en.cfm

In response to audit report 2009-8111, the central competent authority provided the FVO with the actions planned and/or undertaken to address the recommendations made following the audit (hereafter: action plan). Where appropriate, the relevant recommendations made in report 2009-8111 are indicated under the appropriate section headings in section 5 below. The corresponding actions as announced in the action plan are outlined thereafter.

5 FINDINGS AND CONCLUSIONS

5.1 BSE SITUATION

BSE has never been recorded. The results of the Romanian BSE testing programme can be found at:

http://ec.europa.eu/food/food/biosafety/tse_bse/monitoring_annual_reports_en.htm

5.2 COMPETENT AUTHORITIES

5.2.1 Organisation and responsibilities

Legal requirements

Article 4.1 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for official controls.

Findings

The structure of the NSVFSA remains as described in the Country Profile for Romania, which is accessible at:

http://ec.europa.eu/food/fvo/last5_en.cfm?co_id=RO

Within the central competent authority, three directorates of the Sanitary Veterinary Directorate General are involved in BSE controls; these are:

- the Animal Health and Welfare Directorate, responsible for the organisation of the BSE epidemio-surveillance programme,
- the Technical Directorate for Coordination of National Reference Laboratory, County State Veterinary Food Safety Laboratories, Farmacovigilance and Animal nutrition, responsible for sampling for feed ban controls, and
- the Sanitary Veterinary Supervision and Monitoring Directorate, responsible for administration and maintenance of the National Animal Identification and Registration System (NAIRS).

In addition the Hygiene Veterinary and Epidemiology Directorate together with its Hygiene and Veterinary Service are responsible for controls of measures concerning proper handling and disposal of ABP, including SRM, in slaughterhouses, cutting plants and butcher shops.

At county level, the County Sanitary-Veterinary Food Safety Directorates (thereafter: County Directorates) mirror, in principle, the structure of the central level.

The National Reference Laboratory (NRL) for BSE is a part of the Institute of Diagnosis and Animal Health and carries out laboratory analyses for BSE.

The following was observed:

- According to the representatives of the county directorates visited, the organisational structure of each County Directorate and the allocation of the human resources is determined by the county director.
- The audit team found that the responsibilities were well understood by the officials of the competent authorities met.

Conclusions

The requirements concerning competent authorities laid down by Article 4.1 of Regulation (EC) No 882/2004 are largely complied with.

5.2.2 Cooperation and coordination

Legal requirements

Article 4.3 of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities. Article 4.5 of the said Regulation requires that, when, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Findings

The relevant recommendation of report 2009-8111 concerned coordination and cooperation. In response to this recommendation, NSVFSA has addressed to various services a number of service notes containing instructions concerning exchange of information and results of BSE epidemio-surveillance.

According to the officials met, complete communication and coordination between central and county levels are ensured by service notes which are distributed to counties wherever it is necessary. In addition internal orders are used between the Directorates and services at the central level.

The following was observed:

- Numerous examples of service notes sent from the central level containing instructions concerning sampling of cattle for BSE, handling of SRM as well as instructions for controls on implementation of the feed ban were seen by the audit team.
- According to the inspectors from the counties visited, between different services within County Directorates regular contacts are organized depending on the needs. Within one county, a direct communication or ad-hoc meeting are used for this purpose. Coordination between counties is possible; however, inspectors met by the audit team did not consider it essential since most of their responsibilities are related to establishments and operators located on the territory of their county. The audit team confirmed that information concerning customers (farms and retailers) buying feedingstuffs containing fish meal and located in counties other than the supplying feed mill has never been communicated to relevant inspectors from another counties.

Conclusions

Although there are some gaps in the exchange of information relevant for the feed-ban controls, the requirements concerning coordination and cooperation within and between competent authorities laid down by Article 4.3 and Article 4.5 of Regulation (EC) No 882/2004 are largely complied with. Therefore the relevant recommendation of the previous report has been satisfactorily addressed.

5.2.3 Resources and training

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires the competent authority to ensure that they have access to a sufficient number of suitably qualified and experienced staff, and that appropriate and properly maintained facilities and equipment are available. Article 6 of the said Regulation requires competent authorities to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

Findings

According to the competent authority, training sessions concerning BSE epidemio-surveillance issues and analyses for the presence of proteins derived from animals were organised in 2009 and 2010, but financial difficulties influenced the number of training sessions.

The following was observed:

- According to NSVFSA one training session for county inspectors concerning controls on implementation of the feed ban, BSE suspect cases and general rules for reporting on BSE programme was organised in 2009.
- The NRL for BSE organised two and nine such training sessions concerning various methods for detection of BSE in 2009 and in 2010 respectively. Moreover, the NRL organised training sessions on detection of processed animal proteins: one in 2009 and one in 2010.
- The staff of the county laboratory for feed visited, presented profound knowledge of laboratory procedures and legislation concerning analytical methods for feed including analyses for proteins derived from animals. The laboratory have participated in numerous comparative tests organised by Community Reference Laboratory (CRL), with satisfactory results.

- In all counties visited the officials met confirmed availability of diagnostic kits required for BSE examination.

Conclusions

The requirements concerning facilities, equipment and qualified staff laid down in Article 4 and Article 6 of Regulation (EC) No 882/2004 are complied with.

5.2.4 Internal supervision

Legal requirements

Article 8(3) of Regulation (EC) No 882/2004 requires competent authorities to have procedures in place to verify the effectiveness of official controls that they carry out.

Findings

The relevant recommendation of report 2009-8111 concerned internal supervision. In response to this recommendation, NSVFSA issued an instruction concerning verification of the effectiveness of official controls and the rules how the verification should be recorded. The procedures are published on the NSVFSA web site.

Heads of the Inspection and Controls Service at county level are responsible for the organisation of internal controls on inspectors from other technical services, including zonal veterinarians.

The following was observed:

- The audit team noted that in the counties visited the procedures were followed and were in accordance with an annual control plan agreed with Inspection and Border Inspection Posts Coordination Directorate of the NSVFSA. Verifications were documented in inspection reports where verification scope and possible shortcomings of inspectors' activities were mentioned. Summary results of these verifications were reported to the afore-mentioned Directorate on a monthly basis.

Conclusions

The requirements concerning the official controls verification procedures laid down by Article 8(3) of Regulation (EC) No 882/2004 are largely complied with. The relevant recommendation of the previous report has been satisfactory addressed.

5.3 BSE EPIDEMIO-SURVEILLANCE

5.3.1 Identification and registration

Legal requirements

Regulation (EC) No 1760/2000 establishes a system for the identification and registration of bovine animals. The said identification and registration is essential for BSE control measures concerning monitoring and eradication, as laid done in Annex III and VII to Regulation (EC) No 999/2001.

Findings

The relevant recommendation of report 2009-8111 concerned NAIRS. In their response to this recommendation NSVFSA issued service notes requesting the cross-checking of notifications to NAIRS with the situation found in animal herds when these are visited by county inspectors. In addition a service note regarding the corrective actions to be taken in case of non compliances has been issued.

The following was observed:

- The figures for the number of animals in the bovine population have changed. In particular a significant decrease in 2011 in comparison with 2009 and 2010, was noted by the audit team. NSVFSA stated that the higher number of bovine animals in 2009 and 2010 was due to the reluctance of the bovine owners to notify off-movement events such as deaths or sales (the owners were interested in maintaining in the database a high number of animals in their herds due to financial reasons).
- According to NSVFSA, the most recent data resulting from cross-check controls between the number of animals kept at farms and numbers recorded in NAIRS, reflect the real situation on the farms. To support this statement NSVFSA provided the audit team with the data which are shown in the table below:

Bovine population	Valid as for December 2009	Valid as for December 2010	Valid as for February 2011
Total:	3,889,936	4,007,782	2,982,176
> 24 months	3,422,040	2,988,047	2,088,476
> 30 months	3,291,707	2,877,047	1,996,950

- The audit team noted also that the data concerning the bovine population submitted to EUROSTAT by the National Statistical Office of Romania, were very close to the corrected animal population obtained in 2011. According to NSVFSA, the National Statistical Office requests the data directly from the councils, where the heads of the councils keep their own records (independent from NAIRS) as regards the bovine population in the councils.
- NSVFSA confirmed that in general the number of event notifications to NAIRS by bovine owners has dropped (see section 5.3.3). The county inspectors met, confirmed also that the owners either omitted any notification or they did not respect the obligatory deadlines. The delays observed varied from few weeks up to few months. The audit team performed verification of the reliability of the data in NAIRS using identification numbers of animals, which were previously collected as dead in the counties visited during this audit. The exercise revealed that only a few animals were updated in the database with their status as “dead”. A number of animals were found with their status as “alive” while some other animals were not even registered in NAIRS.
- According to the officials met, verification of animal movement and other events concerning bovines is possible only in commercial farms for which a herd register in a statutory defined form is required. These officials also stated that verification on backyard farms is difficult since these farms are allowed to keep a collection of various documents referring to animals movement which, in many cases, are not kept in a tidy and chronological manner. Additionally, the county inspectors stated that they cannot directly extract from NAIRS the individual numbers of the animals existing in a particular farm. They also flagged other issues as for example the lack of possibilities to extract from the database the individual identification number of the animals notified as fallen stock or traditionally slaughtered in a

specified period of time with the link to their last location; this information could be useful for identification of bovines eligible for BSE testing. The NSVFSA representative explained that some of the operations are possible only from the central level due to limitations of the current database interface. As a consequence, this type of query has to be requested to NSVFSA by county inspectors in advance.

- The total number of bovine farms broken down by commercial and backyard farms is shown in the table below (data provided by NSVFSA).

Year	Bovine farms (total)	Commercial farms	Backyard farms
2009	1.086.855	838	1.086.017
2010	823,965	4,907	819,058

- According to NSVFSA approximately 91.1% of the entire bovine population (2,715,384 animals) is kept in back-yard farms (NAIRS data valid as for February 2011).
- In the slaughterhouses visited, the audit team noted that bovine animals were properly identified and arrived with their passports.
- In one of the above-mentioned slaughterhouses, there were also situations when instead of passports bovine animals have had a document issued by a private veterinarian with handwritten numbers of the animals. According to the operator met, in 2011 there were two bovines without ear tags, coming on the same day and from the same farm. The animals were delivered without passports but with a single document containing two identification numbers. In such case the official veterinarian had no possibility to verify the identity of the animals prior to the slaughter.

Conclusions

A system for identification and registration of bovine animals is in place as required by Regulation (EC) No 1760/2000. However, existing limitation in extraction of up-to-date data concerning bovines' movement combined with frequentative difficulties in obtaining whole set of documents concerning animals movement at backyard farm (where a significant proportion of bovine animals is kept) could affect the BSE control measures concerning monitoring and eradication, as laid done in Annex III and VII to Regulation (EC) No 999/2001. Therefore the relevant recommendation of the previous report is not satisfactorily addressed.

5.3.2 Passive surveillance

Legal requirements

Article 10 of Regulation (EC) No 999/2001 requires competent authorities to organise training in, among others, clinical signs and epidemiology of BSE. Article 11 of the said Regulation sets out the requirements for the notification of suspect cases.

Findings

According to NSVFSA the last training concerning reporting procedures of BSE suspect and administrative measures to be taken in such cases was delivered to county inspectors in 2009.

The following was observed:

- According to NSVFSA, out of 2,982,176 bovines in Romania, there were eight (in 2009) and seven (in 2010) animals notified with clinical signs and considered as BSE suspects. With exception of one animal from 2009 which recovered completely and its clinical signs disappeared, all other animals were sampled, and tested with negative results (2009).
- According to the county inspectors met BSE is not considered by private practitioners and zonal veterinarians as the most plausible differential diagnosis where nervous signs are presented.
- The NSVFSA representative stated that the BSE suspicion is not primarily considered if the epidemiological inquiry indicated direct contact with wild animal (rabies), a recent treatment or surgery (e.g. tympania, traumatic reticulo-pericarditis) or other conditions identified during post-mortem examination (toxaemia, encephalitis, fibroblastic meningioma).
- In one of the County Directorates visited the inspector met stated that in 2010, six bovine animals manifested abnormal behaviour before they had died. These animals were considered primarily as rabies suspects. Although all of them were eligible for BSE testing, two of them were not tested.

Conclusions

The requirements concerning training and for the notification of BSE suspect cases laid down by Article 10 and Article 11 of Regulation (EC) No 999/2001 are largely complied with, but there is still reluctance to notify animals that could be considered as BSE suspects.

5.3.3 Active surveillance

Legal requirements

Points I.2 and I.3 of Chapter A of Annex III Regulation (EC) No 999/2001 set out requirements for the monitoring of BSE. Point I.6 of the said chapter lays down the measures that should be taken following testing.

Findings

The relevant recommendations made following the last BSE audit concerned testing of all eligible bovines at farm level. In response to these recommendations NSVFSA produced a procedure concerning reporting in such cases and allowing for sampling on-the-spot by private practitioners or official veterinarians.

The following was observed:

- The audit team noted that there are still significant differences between counties as regards sampling of fallen stock in comparison with the bovine population kept in these counties.
- The audit team noted that there are differences between amount of fallen animals notified to NAIRS and animals sampled. The number of fallen bovines eligible for BSE examination recorded in NAIRS and the animals sampled is shown in the table below.

Year	Fallen stock recorded	Fallen stock sampled
2008	15,377	2,289
2009	4,186	1,731

2010	2,124	1,611
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- The audit team noted that in 2008, approximately 0.08% of all bovines over 24 months were sampled in the sub-population of fallen stock. In 2009 and 2010 this percent decreased again to approximately 0.05%.
- Operators of all ABP intermediate plants visited confirmed that fallen bovines are collected occasionally; on average up to four adult bovines per month. The audit team examined records and commercial documents kept by the operators and confirmed that these bovines were collected only from commercial farms.
- All county inspectors met stated that all fallen bovines notified to them are sampled for BSE. They were also aware that there was a significant drop in notifications both to NAIRS as well as to County Directorates. According to them this is due to increased prices for collection of fallen stock; the collection costs are almost unaffordable for the owners of backyard farm animals (see report 2011-8941).
- The audit team noted that in total there were four and three bovine animals sampled in slaughterhouses as found sick at ante-mortem in 2009 and 2010 respectively. In two slaughterhouses visited ante-mortem examination records did not contain logs on bovines from this sub-population. The operators met stated that they purchase only healthy animals to be slaughtered.
- Those operators stated also that unhealthy bovines can be delivered for emergency slaughter; however, such practice is rather seldom and in most cases only a slaughtering service is provided following which the carcasses are returned to their owners. The number of bovines sampled in this sub-population is shown in the table below.

Year:	2008	2009	2010
Slaughter on emergency:	780	397	497

- According to the officials met the majority of emergency slaughtered bovines come from commercial farms. Injured bovines from backyard farms are usually slaughtered on-farm for own consumption. The audit team noted that, although there are some data concerning on-farm slaughtering, the true scale of this activity remains largely unknown to the competent authorities (see 5.5.1).
- The audit team noted that in 2009 and 2010 the number of samples taken from healthy slaughter bovines eligible for BSE testing decreased significantly in comparison with 2008. NSVFSA is not aware of the reason for this drop. In the slaughterhouses visited relevant records presented to the audit team show that, although there was some decrease in the number of slaughtered bovines this was not as significant, moreover the age proportion (below and over 30 months) remained at the same level.
- According to NSVFSA all samples from healthy bovines are taken in slaughterhouses. The numbers of bovines sampled in slaughterhouses and the numbers of bovines notified to NAIRS as slaughtered in slaughterhouses and at farm level are shown in the table below.

Year	Sampled in slaughterhouses (NSVFSA)	Slaughtered in slaughterhouses (NAIRS)	Slaughtered at farm (NAIRS)
2008	127,951	104,025	35,548
2009	71,209	57,852	34,688
2010	77,498	58,294	28,383

- The county inspectors met confirmed that bovines (including those over 30 months) are slaughtered on-farms (see section 5.5.1). The inspectors stated that while commercial farms notify such activity it takes place only incidentally and mainly due to emergency reasons, the notifications from backyard farms are rather seldom. According to NSVFSA, in 2010 there were approximately 300 such notifications from backyard farms, of which all eligible animals were sampled and tested.

Conclusions

The requirements concerning BSE monitoring laid down by Points I.2, I.3 and I.6 of Chapter A of Annex III Regulation (EC) No 999/2001 are largely complied at slaughterhouses and commercial farms. However, these requirements are not followed in backyard farms, where the vast majority of bovine animals are kept. Therefore, the relevant recommendations of the previous report are not satisfactorily addressed.

5.4 MEASURES FOLLOWING SUSPICION/CONFIRMATION OF BSE

Legal requirements

Articles 12 and 13 of Regulation (EC) No 999/2001 establish, respectively, the measures to be taken with respect to suspect animals and following confirmation of BSE. Moreover, points I.6.4 to I.6.6 of Chapter A of Annex III to the said Regulation set out the measures to be taken if positive or inconclusive result is found following a rapid test.

Findings

The following was observed:

- NSVFSA stated that so far, no single case of BSE has been confirmed.
- In one of the County Directorates visited two clinical BSE suspects were recorded in 2009. These animals had died during observations. Both of them were sampled and tested in accordance with the procedure foreseen for suspect cases. The veterinary inquiries and movement restrictions were recorded in the investigation reports but these referred only to the last location of the animals to which there were moved temporarily for grazing. According to the inspector met, the veterinary inquiries were carried out also in the place of origin of the animals but no evidence of such action could be provided. No issues concerning feed or cohort were mentioned in the investigation reports. In addition, after sampling, these animals were buried on-the-spot. The NSVFSA representative took immediate actions in order to improve the situation and presented to the audit team a proposal for a service note concerning this issue.

Conclusions

Although there are procedures concerning BSE suspects and the measures to be taken following suspicion of BSE, which in principle, are in line with the requirements of 12 and 13 of Regulation (EC) No 999/2001, these are not always properly implemented.

5.5 SPECIFIED RISK MATERIAL

5.5.1 Requirements

Legal requirements

Article 8 and Annex V to Regulation (EC) No 999/2001 set out the requirements for removal and disposal of SRM.

Findings

The relevant recommendation of report 2009-8111 concerned handling of SRM generated during on-farm slaughter. In their response NSVFSA undertook to develop a chain of intermediary plans under administration of local councils.

The following was observed:

- According to NSVFSA the chain of intermediary plants was not developed due to financial obstacles. No other arrangement was put in place neither by the state nor local councils. There is no declared deadline to remedy current situation. According to the officials met SRM obtained during home slaughtering is buried at farms or fed to dogs.
- NSVFSA stated that the home slaughtering of bovine animals is not allowed; however, the County Directorates officials met as well as the data obtained from NAIRS shown that home slaughtering is still going on a large scale. In total there were 87,535 and 62,274 bovines (all ages) notified to NAIRS as slaughtered at home in 2009 and in 2010 respectively. The amount of bovines broken down by age notified to NAIRS are showed in the table below:

Year	home slaughtered < 12 months	home slaughtered 12 to 24 months	home slaughtered 24 to 30 months	home slaughtered > 30 months
2009	26,699	20,492	5,656	34,688
2010	16,682	13,169	4,040	28,383

- The audit team noted that the delays in the notification of off-movements to the database (see section 5.3.1) and the fact that on-farm slaughtering is carried out without the involvement of the competent authorities, imply that the true scale of on-farm slaughtering could be higher (see section 5.3.3).
- The audit team noted that in all slaughterhouses and cutting plants visited, removal, collection, staining with dye and handling of SRM were in line with the BSE protective measures in this respect. The operators and officials met were aware their duties and presented satisfactory knowledge concerning these requirements. Moreover, removal of SRM was also controlled during dispatch to the retail sector and proper labelling was implemented where required.

- According to the NSVFSA representative, only 31 slaughterhouses are authorised for head meat harvesting but not all of them performed this activity on regular basis. In most of the cases the meat is harvested only on particular customers' request. The NSVFSA representative stated that the procedure concerning this operation was distributed to all the slaughterhouses concerned. The procedure was also in place in one of the slaughterhouses visited which harvested head meat during the audit visit. A sampling programme to check possible contamination by central nervous tissue, has been regularly carried out.

Conclusions

The requirements concerning SRM laid down by Article 8 and Annex V to Regulation (EC) No 999/2001 are satisfactorily complied with at meat establishments. However, these requirements are not followed at backyard farms, where the vast majority of bovine animals are kept and slaughtering takes place on a significant scale. Therefore the relevant recommendation of the previous report is still not addressed.

5.5.2 Official controls

Legal requirements

Point 11 of Annex V to Regulation (EC) No 999/2001 requires competent authorities to carry out frequent official controls to verify the correct application of this Annex.

Findings

The following was observed:

- Hygiene Service of County Directorate, in accordance with an annual control plan, carries out regular inspections in slaughterhouses, cutting plants and butcher shops, during which the correct application of measures on SRM is verified. The appropriate check-lists are used and results of inspections are recorded in inspection reports.
- The Hygiene Service officials met stated that there are no specific inspections carried out in this respect at farms, in particular backyard ones.

Conclusions

The requirements concerning official controls on SRM set out by Article 8 and Annex V to Regulation (EC) No 999/2001 are satisfactorily complied with at meat establishments. However, these requirements are not followed at backyard farms.

5.6 TOTAL FEED BAN

5.6.1 Requirements along the chain

Legal requirements

Article 7 of Regulation (EC) No 999/2001 prohibits the feeding to farmed animals of proteins derived from animals, in accordance with the conditions established in its Annex IV. In particular, Annex IV establishes a number of derogations from the said prohibition and specific conditions for the application of such derogations.

Findings

The relevant recommendation of report 2009-8111 concerned the warning sentences in the commercial documents and labels on feed containing certain proteins derived from animals. In response to these recommendations, the central competent authority decided to rearrange the organisation of the official controls programme accordingly and reinforce documentary checks on feed.

The following was observed:

- According to data delivered by NSVFSA there were 11 consignments of fish meal imported to Romania in 2010 (1,340 tons in total).
- The audit team noted that at county level there are up-dated lists of operators using fish meal for the production of feedingstuffs.
- In the feed mill visited there are two separated production lines, one for compound feed for ruminants, and the other for non-ruminants. The storage facilities for raw feed materials were common for both lines while they are separated for the final products. Storage for fish meal is separated from other feed materials.
- In the same feed mill the commercial documents and packaging labels contained the warning sentences required for feed containing proteins derived from animals. Inspection reports seen by the audit team contained information on the checks in this respect carried out during inspection visits.

Conclusions

The specific conditions established in Annex IV to Regulation (EC) No 999/2001 for the application of the derogation from the feed ban set out by Article 7 of the said Regulation are largely complied with. Therefore, the relevant requirement of the previous report has been satisfactorily addressed.

5.6.2 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, taking account of identified risks, operators' past records, the reliability of own check and any information that might indicate non-compliance.

Point F of Annex IV to Regulation (EC) No 999/2001 requires competent authorities to carry out documentary and physical checks throughout the feedingstuffs production and distribution chain in order to control compliance with the provisions of the said Regulation.

Findings

The relevant recommendations of report 2009-8111 concerned prioritisation of official controls, and physical check on feedingstuffs. In response to these recommendations, the central competent authority decided to rearrange the organisation of the official control programmes accordingly and reinforce documentary checks on feed.

The following was observed:

- In the counties visited the audit team confirmed that relevant risk criteria were taken into account when official controls were programmed, although the reliability of the operators' own checks is not considered.

- The audit team noted that physical checks, in particular testing on feedingstuffs to verify implementation of the feed ban were implemented across the whole feed chain and at the border during import controls (all 11 consignments of fish meal were checked). Although the backyard farms are also foreseen for feed ban controls, the vast majority of checks are carried out in commercial farms which are considered as presenting a higher risk.
- According to the officials met, the national control programme on feed which also contains verification of the feed ban started at the end of third quarter of 2009. Depending on the county samples were taken either as the entire annual allocation or its proportion correlated with the number of months left. This resulted in discrepancies in the number of samples between the counties. In total 905 official samples were analysed in 2009 of which all were negative.
- The same officials stated that in 2010, financial arrangements for the examination of official samples changed. In brief, the feed operators had to pay for official samples and their analyses. This resulted in a drop in official samples taken and analysed; 674 such samples were analysed in 2010.
- According to NSVFSA the lower number of official samples should be compensated by an increase in the number of samples taken as part of plants' own-check programmes. However, in the feed mill visited, which produces feed for various species and uses fish meal, the own-check programmes for 2009 and 2010 did not contain any sample related to feed ban controls. On the competent authority request the operator planned one such sample in the programme for 2011.

Conclusions

Although the organisation of official controls takes into account some of the risk factors required by Article 3 of Regulation (EC) No 882/2004, the reliability of own-checks is not considered. Moreover, there has been an important reduction in the number of official analyses to verify compliance with the feed ban which is not justified. Therefore, there is a risk that controls on the implementation the feed ban are not prioritised appropriately. Therefore the relevant recommendation of the previous report is not satisfactorily addressed.

Requirements concerning physical checks on feed required by Annex IV to Regulation (EC) No 999/2001 are largely met, and inspection results are recorded; therefore the relevant recommendation of the previous report have been satisfactorily addressed.

5.7 LABORATORY NETWORK

5.7.1 Sampling and laboratory testing for BSE

Legal requirements

Article 19 (1) and Chapter A of Annex X to Regulation (EC) No 999/2001 set out functions and duties of national reference laboratories for BSE. Article 20 and Chapter C of Annex X to the said Regulation lay down requirements for sampling and laboratory testing for the presence of BSE.

Findings

According to NSVFSA there are 32 regional laboratories performing various BSE rapid tests. With the exception of three laboratories where accreditation is in progress all other laboratories are accredited for the rapid tests used. In January 2011 the NRL for BSE received renewal of its

accreditation for the rapid tests and the BSE confirmatory methods.

The following was observed:

- According to the NRL representative met, in 2009 and 2010 the NRL staff, each year, participated ten times in comparative tests organised by the CRL; in all cases with satisfactory results. In addition, in 2009 all but five regional laboratories participated in comparative tests organised by the NRL with satisfactory results. According to the NRL representative met, these five laboratories participated in the tests organised in 2010 but during this audit the assessment results were not available yet.
- The audit team verified the sampling records and checked tests results in the slaughterhouses visited and confirmed that both samples and laboratory results were delivered in a timely fashion; mostly within 24 hours.
- The NSVFSA representative met stated that almost all samples taken and sent for laboratory examination were suitable for testing; there were only a few cases when samples were rejected due to improper sampling at slaughterhouse. Wherever such situation was identified by the competent authority the staff responsible for sampling have been re-trained.
- The audit team noted that in one of the County Directorates visited one bovine suspected for BSE was not tested in accordance with the relevant procedures (see section 5.4) .

Conclusions

The requirements concerning sampling and laboratory testing for the presence of BSE laid down by Article 20 and Chapter C of Annex X to Regulation (EC) No 999/2001 are largely complied with.

The requirements concerning functions and duties of national reference laboratories for BSE laid down by Article 19 (1) and Chapter A of Annex X to Regulation (EC) No 999/2001 are satisfactorily complied with.

5.7.2 Testing for the determination of constituents of animal origin

Legal requirements

Directive 2003/126/EC sets out the analytical method for the determination of constituents of animal origin for the official control of feedingstuffs.

Point F of Annex IV to Regulation (EC) No 999/2001 requires competent authorities to verify on a regular basis the competence of laboratories carrying out analyses for official controls on the total feed ban, in particular by evaluation the result of comparative tests.

Findings

Nine regional laboratories are involved in feedingstuffs analysis, in particular performing microscopic analytical testing. These laboratories analyse samples from self-control programmes by feed operators as well as official controls.

The Institute for Hygiene and Veterinary Public Health (IHVPH) is the NRL for feed.

According to NSVFSA there are nine regional laboratories accredited for examination for presence of constituents of animal origin; however, due to reconstruction in place, the activity and accreditation of one of the laboratories is suspended.

The following was observed:

- The NSVFSA representative met stated that every year IHVPH organises comparative tests and training sessions for all laboratories concerned. In 2009 and in 2010 there was one such test each year and all laboratories passed them with satisfactory results. The last training sessions took place in 2009 (one) and 2010 (one).
- The IHVPH staff every year participate in comparative tests as well as workshops organised by CRL for feed. According to the IHVPH representative a satisfactory result was obtained in 2009 but the final result of 2010 participation was not available during this audit.
- The audit team noted that results of the official analyses on processed animal proteins were delivered on average over one month after sampling; however, there had been samples waiting for examination approximately six months. According to the officials met in this County Directorate the delays were due to the specific financial arrangement (see section 5.6.2).

Conclusions

The requirements concerning verification of the competences of laboratories carrying out analyses for official controls on the total feed ban set out by Point F of Annex IV to Regulation (EC) No 999/2001 are satisfactorily complied with.

The requirements concerning the method used for the determination of constituents of animal origin for the official control of feedingstuffs set out by Directive 2003/126/EC are satisfactorily complied with.

6 OVERALL CONCLUSIONS

Overall, the report concludes that very limited progress has been made in order to address the recommendations of the previous FVO audit. In particular, BSE active epidemio-surveillance and compliance with SRM rules are significantly affected by the lack of arrangements for the collection of brain samples and SRM at backyard farms, where the majority of the bovine population is kept. There are also weaknesses concerning feed-ban controls.

7 CLOSING MEETING

A closing meeting was held on 25 February 2011 with the representatives of the competent authorities. At this meeting, the main findings and preliminary conclusions of the audit were presented by the audit team. The competent authorities did not indicate any major disagreement with these.

During the meeting additional information requested by the audit team was provided by the competent authorities met. Moreover NSVFSA representative stated that in 2011 examination of official samples should be paid from the state budget and actions will be taken in order to correct or eliminate the shortcomings identified during this audit.

8 RECOMMENDATIONS

The competent authorities of Romania are invited to provide details of the actions taken and planned, including deadlines for their completion, aimed at addressing the recommendations set out below, within 25 working days of receipt of this report.

N°.	Recommendation
1.	To continue to develop the cattle database, so that it can become a useful tool for monitoring the implementation of BSE epidemio-surveillance required by Annex III to Regulation (EC) No 999/2001.
2.	To ensure that all eligible bovine animals slaughtered at farm level are subject to BSE monitoring, in line with the provisions laid down in Annex III (Chapter A, point 2.1 and point 2.2) to Regulation (EC) No 999/2001.
3.	To ensure that fallen bovine animals are subject to BSE monitoring, in line with the provisions laid down in Annex III (Chapter A, point 3) to Regulation (EC) No 999/2001.
4.	To ensure that the measures taken following BSE suspicion are in line with the provisions laid down by Article 12 of Regulation (EC) No 999/2001.
5.	To ensure that SRM produced as a result of home slaughtering of bovine animals, are collected, transported and disposed of in compliance with requirements set out in Article 8.1 and Annex V to Regulation (EC) 999/2001.
6.	To take account of the reliability of the operators' own-checks for the organisation of the official controls concerning the feed ban, as required by Article 3 of Regulation (EC) No 882/2004.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/ap/ap_ro_2011-8950.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 999/2001	OJ L 147, 31.5.2001, p. 1-40	Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
Reg. 1774/2002	OJ L 273, 10.10.2002, p. 1-95	Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption
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. 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