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FINAL REPORT OF A MISSION CARRIED OUT IN BULGARIA FROM 16 FEBRUARY TO 20 FEBRUARY 2009 IN ORDER TO EVALUATE MEASURES CONCERNING BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

Executive Summary

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in Bulgaria, from 16 to 20 February 2009.

The objective of the mission was to evaluate the implementation of certain protective measures against Bovine Spongiform Encephalopathy (BSE).

In terms of scope, the mission 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 previous FVO missions regarding the afore-mentioned issues.

Overall, the report concludes that very little progress has been made since the previous mission concerning the monitoring of on-farm slaughtering, as a result of which requirements for epidemio-surveillance and SRM are not complied with at this level; moreover, testing of fallen animals is still limited and passive surveillance has not resulted in the declaration of any suspect so far. On the contrary, epidemio-surveillance and SRM controls at slaughterhouse level were largely satisfactory; the same applies to feed ban controls, although there were deficiencies in the organisation of controls in accordance with risks.

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

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
ABP	Animal by-products
BSE	Bovine Spongiform Encephalopathy
CA	Competent authorities
CCA	Central competent authority, the NVS
CDB	Cattle identification database
Fallen stock	Dead on-farm bovines
FVO	Food and Veterinary Office
MS	Member States
NGFS	National Grain and Feed Service (Национална служба по зърното и фуражите)
NRL	National Reference Laboratory
NVS	National Veterinary Service (Национална ветеринарномедицинска служба), the CCA
PAO	Products of animal origin
Report 7272/2007	Report of a mission carried out in Bulgaria from 2 to 10 October 2007 in order to evaluate the implementation of measures concerning official controls on feed and compliance with requirements for feed hygiene
Report 7728/2007	Report of a mission carried out in Bulgaria from 18 February to 22 February 2008 in order to evaluate control measures on BSE
Report 7736/2008	Report of a mission carried out in Bulgaria from 23 to 27 June 2008, in order to evaluate the implementation of health rules on ABP
RVS	Regional Veterinary Service
SRM	Specified risk material
Total feed ban	Prohibition of feeding PAO to farmed animals and exceptions applicable to this ban
TSEs	Transmissible Spongiform Encephalopathies

1 INTRODUCTION

The mission took place in Bulgaria from 16 to 20 February 2009.

The inspection team comprised 2 inspectors from the Food and Veterinary Office (FVO), and was accompanied throughout the mission by representatives from the central competent authority (CCA), the National Veterinary Service (Национална ветеринарномедицинска служба – NVS).

An opening meeting was held on 16 February 2009 with the CCA, during which the mission objectives, itinerary, and the standard reporting and follow-up procedures were confirmed, and additional information required for the satisfactory completion of the mission was requested.

2 OBJECTIVES OF THE MISSION

The overall objective of the mission was to evaluate the measures put in place to implement certain protective measures against 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 mission 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 products of animal origin (PAO) 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 mission which addressed the above issues.

The mission itinerary included the following visits:

Competent authorities visits			**Comments**
Competent authority	Central	√	Opening and closing (de-briefing) meetings
	Regional	**2**	Meetings in two Regions and staff from another one met on-site
	Local	√	Discussions held in the course of visits to premises
Establishments handling Animal by-products not for human consumption			
Animal feed processors / manufacturers		**1**	One feed mill authorised to use PAO (fishmeal) producing feed for non-ruminants and for ruminants
Processing plant		**1**	One Category 1 processing plant where samples are taken from fallen stock
Food processing establishments			
Slaughterhouse		**2**	Two middle size establishment slaughtering cattle (one harvesting head meat)
Other			
Animal farm		**2**	Two animal farms with cattle

		(one of them with an on-farm mixer)

3 LEGAL BASIS FOR THE MISSION

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

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

All legal references relevant for this mission are listed in Annex 1. Legal acts quoted refer, where applicable, to the last amended version.

4 BACKGROUND

Since the accession of Bulgaria to the EU, the FVO carried out a number of missions, in order to assess and monitor progress with the adoption of the relevant EU requirements.

The previous mission concerning BSE in Bulgaria was carried out from 18 to 22 February 2008, the results of which are described in report DG(SANCO)/7728/2008 – MR Final (hereafter: report 7728/2008). There were two other missions whose results are of relevance for the objectives and scope of the present one; these missions assessed measures concerning:

- official controls on feed and compliance with requirements for feed hygiene, which was carried out from 2 to 10 October 2007, the results of which are described in report DG(SANCO)/7272/2007 – MR Final (hereafter: report 7272/2007)
- ABP not intended for human consumption, which was carried out from 23 to 27 June 2008, the results of which are described in report DG(SANCO)/7736/2008 – MR Final (hereafter: report 7736/2008),

All these reports are accessible at:

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

Report 7728/2008 made a number of recommendations to the CCA, which subsequently informed the European Commission of actions that had been or would be taken, aimed at addressing the recommendations made (hereafter: action plan). Where appropriate, both the relevant recommendations and the action plans are outlined under the relevant parts of Section 5.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

The main features of the organisation of the competent authorities (CAs) in the context of the scope of this mission are described in report 7728/2008. A description of the CAs can also be found in the country profile for Bulgaria, which is accessible at:

http://ec.europa.eu/food/fvo/country_profiles/CP_bulgaria.pdf

The Animal Health Directorate of NVS, is responsible for drafting the BSE monitoring programme, collecting and analysing data and reporting to the European Commission. Its regional offices are responsible for official controls on-the-spot and taking actions if irregularities are identified.

The Public Health Directorate of NVS and its regional offices are responsible for official control as regards the removal and disposal of SRM in slaughterhouses, cutting plants and in the retail sector. The control of on-farm slaughtering and sampling for BSE monitoring is responsibility of authorised veterinarians.

The total feed ban has been introduced since January 2006 based on national legislation.Two CAs are responsible for official controls in the feed sector: NVS and the National Grain and Feed Service (NGFS), which is responsible for the authorization of establishments in the feed sector. The identification and authorisation of compound feed producers as well as regular checks of the feedingstuffs produced is responsibility of NGFS, whereas Regional Veterinary Services (RVSs) of NVS are responsible for checks as regards the total feed ban. Each RVS is responsible for collecting data as regards number of bovines slaughtered as healthy, emergency or found sick at ante-mortem and fallen stock; this is done by the Animal Health and Public Health departments of RVSs.

The mission team noted that:

- The responsibilities with regards to monitoring of BSE and feed ban official control were clearly defined and understood at central and regional levels.
- The Public Health and Animal Health Directorates and departments of RVSs did not exchange information which could facilitate verification results of BSE monitoring (see section 5.2.1).
- According to the representatives of the RVSs visited, there is good cooperation between them and the NGFS at regional level. The information as regards new establishments authorized and results of inspections by any of mentioned services is exchanged by regular correspondence and during meetings.

5.2 BSE EPIDEMIO-SURVEILLANCE

BSE has never been recorded. The results of the Bulgarian TSE testing programmes can be found at:

http://ec.europa.eu/comm/food/food/biosafety/bse/annual_reps_en.htm

5.2.1 Identification and registration in bovine animals

The relevant recommendation of report 7728/2008 concerned the cattle identification database (CDB). In response to this recommendation, the CCA committed to grant access to CDB to authorised veterinarians and owners of animal holdings, with a view to facilitate the up-date of data.

The mission team noted that:

- There were no changes as regards functioning of CDB: authorised veterinarians and owners still do not have access.
- There were significant differences in the notification of events to CDB in the regions visited: in a region with a population of 49,000 bovines over 30 months only 58 animals have been notified as slaughtered from January to October 2008, whereas in other region with a population of less then 7,000 bovines over 30 months, 194 animals have been notified for the same reason during the same period.
- According to representatives of the CAs met at various levels, there are significant discrepancies between number of bovines held in CDB and the live bovine population; depending on the regions these discrepancies can vary from 50% to 100%. Two sets of figures concerning the bovine population were presented by the CCA: the extract from CDB shows a bovine population of 1,010,210 animals from January to December 2008, whereas the number of animals produced by the Animal Health Directorate and used for epidemiological purposes amounts to 584,468 bovines during the same period of time.
- There were discrepancies between data produced by the Animal Health and Public Health departments in the RVSs visited, as regards number of bovines slaughtered as healthy, emergency or found sick at ante-mortem. At central level, the overall data produced by the Public Health Directorate mirrored figures from the Public Health department of RVSs, whereas data produced by the Animal Health Directorate did not. The summarized figures provided by two directorates for period from January until December 2008, are showed in the table below.

Directorate	Healthy slaughter over 30 months	Emergency slaughter over 24 months	Found sick ante-mortem over 24 months
Public Health Directorate	11,061	10	19
Animal Health Directorate	12,900	2,857	19

- The Animal Health Directorate is relying on the information provided by laboratories performing BSE diagnostic tests for the purpose of BSE monitoring; these are the figures uses for reporting to the European Commission.

- Data obtained by the Animal Health departments from RVSs are not cross-checked against data from laboratories performing BSE diagnostic tests. Data provided by laboratories as regards the numbers of bovines in different monitoring sub-groups were different from the figures produced by RVSs.
- In one of the regions visited, during the routine checks of 10% herds for animal identification purposes, eight farms were identified where events (movements, slaughtering or deaths) had not been notified to CDB; corrective action had been taken following these checks. Moreover, according to the CCA, official veterinarians (OVs) will start in April 2009 a verification process to eliminate the overrepresentation of bovines in CDB.
- One of the farmers met declared that not all of the animals that die are entered as death in the farm register (the farm had around 500 animals).

5.2.2 Passive surveillance

The relevant recommendation of report 7728/2008 concerned the education and training programmes on BSE clinical suspects. In response to this recommendation the CCA stated that trainings have been provided.

According to the CCA, an awareness campaign concerning BSE clinical symptoms, eradication measures and compensation arrangements had taken place. Approximately 200,000 leaflets were distributed through OVs, authorised veterinarians and local authorities. In addition 294 OVs and 630 private veterinarians have participated in 113 training seminars where principles of BSE monitoring have been explained and DVDs with examples of clinically suspected animals have been provided.

The mission team noted that:

- A BSE suspect case has not been notified ever (not even as a consequence of a non-negative result of rapid tests). It was the view of all the CAs, veterinarians and operators met, that the reason for this lack of notification is that there is an extremely low risk of BSE in the country.
- In 2008 two cases of bovines have been notified to the CA which could have been considered as BSE suspects: one bovine suspected of rabies and one suspected of nitrates poisoning. In both cases the animals were tested for BSE by rapid tests as fallen animals due to their age (over 24 months).

5.2.3 Active surveillance

The relevant recommendation of report 7728/2008 concerned the sampling of bovines over 24 months in different sub-populations. In response to this recommendation, the CCA stated that corrective measures had been taken and all sub-populations of bovine animals, as it is required in Annex III to Regulation (EC) No 999/2001, are subject to laboratory examination; for this purpose, a modification of the sampling reporting form had been made and training for OVs had been organised.

Fallen animals are collected by vehicles belonging to the processing plants. The collection of fallen stock is free of charge but requires prior notification to the collectors.

The mission team noted that:

- Home slaughter of bovine animals is possible. Although previous reports indicated that up to 50% of bovine animals could be slaughtered on farms, but the CA still do not know how many animals are home-slaughtered; as a consequence, there are no figures showing how many animals have been sampled out of those that have been home-slaughtered.
- There is an obligation by owner to notify home slaughter activity to CDB by an owner, but the CCA stated that there is no mechanism to check if the requirement has been fulfilled. The authorized veterinarians are not responsible for verification if fallen or home slaughtered animals were notified to CDB.
- The figures concerning the sampling of healthy and emergency slaughter, and animals found sick at ante-mortem were as follows:

Source of data	Healthy slaughter over 30 months	Emergency slaughter over 24 months	Found sick ante-mortem over 24 months
Animal Health Directorate	12,900	2,857	19
Laboratory	12,896	2,861	19

- The OVs met could not explain the distinction between animals found sick at ante-mortem inspection and animals from emergency slaughter;for the majority of them, both groups are equal. According to the CA one of the regions visited, if on-farm slaughtering takes place, the animal's owner decides about classification as healthy or emergency slaughter.
- In one of the slaughterhouses visited, 12 animals were reported as emergency slaughtered. Only a copy of the documentation accompanying one sample could be presented to the mission team, but it referred that the sample has been taken from a healthy slaughtered animal.
- The number of bovines notified as fallen and sampled are showed in the table below (data from CDB):

Year	Population over 24 months	Fallen bovines sampled	Fallen bovines tested	Percentage of animals over 24 months tested
2008 (Jan-Oct)	793,283	1,638	1,549	0,19%

- Authorized veterinarians are responsible for sampling on-the-spot in case of farm slaughtering and fallen stock for which they receive a fixed fee from the

government. According to the CAs from the regions visited, in remote areas or in areas with low density of bovines, the sampling is not always profitable for authorized veterinarians what results in number of samples taken on-the-spot lower than expected.

- In two farm visited, the collection of fallen bovines had taken place. According to the CAs met at various levels,sometimes, collection of fallen stock is hampered by insufficient road infrastructure in particular in the mountains.
- In 2008, the percentage of fallen stock sampled amounted to 0.21% of the cattle population over 24 months. Neither the CCA nor the CAs met, carried out any verification on the possible under-notification of fallen stock or investigation as regards the reasons of differences between regions.
- According to the data presented by the CCA, the percentage of samples, from fallen animals, taken (0,21%) and sampled (0,19%) are quite close; however, the representatives of the CA met and the OV from the processing plant visited stated that season or remote location significantly affect the quality of samples. According to records presented in the processing plant visited, around 50% of the animals handled during summer and around 20% in other seasons cannot be sampled. The CCA have not cross-checked the number of fallen bovines collected against the number of bovines notified as fallen to CDB. Representatives of the CCA undertook to carry out this cross-check in the future.

5.3 MEASURES FOLLOWING SUSPICION/CONFIRMATION OF BSE

There is a BSE contingency plan in place, and the CCA stated that the requirements according to Art. 13 of Regulation (EC) No 999/2001 would be followed in the event of BSE being confirmed.

5.4 TOTAL FEED BAN

General information relating to the feed sector and the national programme for official controls in the field of feed safety can be found in report 7272/2007. The Annual National Control Plan prepared by the CCA contains the minimum number of inspections and samples which should be taken by OVs in a given year for official control over the total feed ban.

The mission team noted that:

- In the feed mill visited there were two production lines, one for compound feed for ruminants, and the other for non-ruminants. Both lines share the silos for feed material of plant origin and later divide in two separate production lines with separate mixers and silos for additives and feed material destined either for ruminants or non-ruminants. The storage facilities for products intended for ruminants and for non-ruminants (both for raw products and final products) were separated and identified. Although the establishment has been authorized for use derogated PAO (fishmeal) due to economical and practical reasons only proteins of plants origin were used.

- One of the bovine farms visited used their own on-farm mixer for feedingstuffs production. The owner was aware of the prohibition of use PAO in feed for ruminants. Before the on-farm mixer was authorized, the owner had to sign a declaration that PAO will not be use for feedingstuffs production destined for ruminants.
- Both the feed mill and the farm visited were regularly inspected and samples were taken during all visits. Inspections and samplings were documented. No irregularities have been detected.
- In two RVSs visited, the inspectors followed the Annual National Control Plan, but their approach for samplings and inspections was different; in one region each inspection was always combined with sampling (they took simply one sample), whereas in the other region the inspections were carried out without sampling or few samples were taken during one inspection. In both regions visited, the total amount of inspections and samples exceeded the minimum limits required by the Annual National Control Plan. The OVs met stated that risk base approach was the reason of increasing the number of inspections and samples; however, they were not able to explain what kind of risk has driven them to do so. Previous reports from establishments and farms where the frequency of inspections had been increased did not show any shortcomings which could justify such increase.
- The selection of establishments and farms for inspections by OVs should follow the risk factors and criteria mentioned in the instruction concerning the total feed ban official controls. However, the OVs met, did not follow rules for selection; according to them establishments and farms were chosen randomly without any particular reason.

5.5 LABORATORY NETWORK

5.5.1 BSE diagnosis

The main features of the organisation of laboratory network have not been changed since previous FVO mission.

The mission team noted that:

- None of the laboratories involved in BSE diagnostic have been accredited yet. According to the National Reference Laboratory (NRL) representative, the accreditation process for NRL for BSE should begin before the end of 2009. The dates for two BSE regional laboratories are not known.
- In 2008 the NRL has organised ring test for BSE regional laboratories. Both of them have achieved satisfactory results. The NRL themselves has participated in one ring test organised in 2008 by the Community Reference Laboratory for TSEs to verify compliance with expected performances for the use of rapid and confirmatory tests. According to the representative of the NRL, satisfactory results have been obtained; although, the certificate of this has not been received yet.

- According to representatives of the slaughterhouses visited, the arrangements for the collection of samples from slaughterhouses and distribution of examination results work effectively.
- The majority of samples from animals found sick at ante-mortem, emergency or healthy slaughtered bovines send for laboratory examination are suitable for examination: in 2008 (January to October), 0.34 % and 0.75 % of samples from healthy and emergency slaughtered bovines, respectively, have been rejected due to improper sampling.

As regards fallen bovines, the grading of samples is carried out either by the authorised vets or OVs responsible for sampling in processing plants, therefore samples of bad quality should be refused at this stage. However, 5.4% of samples were rejected and not tested for their bad quality. It is noted that the rapid test used (BioRad *TeSeE*® test) can still be applied to autolytic samples as it is considered to be very sensitive in such cases.

5.5.2 Analyses for the control of the total feed ban

The main features of the organisation of laboratory network have been described in report 7272/2007. Basically, the National Diagnostic and Research Veterinary Institute acts as NRL, and most of the testing is carried out by a network of nine regional laboratories.

The mission team noted that:

- None of the regional laboratories are accredited yet; plans for accreditation are on-going since 2007, although not much progress has been made in this respect.
- For 2008 in total 1,641 samples have been analysed for presence of PAO. In all cases results of analysis were negative. The place of sampling and number of samples are showed in the table below:

Place		Combined feeds	
	Feeding stuff	For ruminants	For non-ruminants
Feed mills	48	88	152
Intermediate / stores	16	38	22
Farms	218	798	232
Border Inspection Points	29	0	0
Total:	311	924	406

5.6 SPECIFIED RISK MATERIAL

The relevant recommendations of report 7728/2008 concerned:

- the harvesting of bovine head meat,
- controls and disposal of SRM produced during home slaughtering of cattle, and
- controls and disposal of Category 1 MBM.

In response to the above recommendations, the CCA undertook to:

- issue an instruction concerning the harvesting of bovine head meat,
- launch an awareness campaign concerning disposal of SRM produced during home slaughtering,
- ensure the proper disposal of all remaining category 1 MBM, either by incineration in a cement factory or by landfilling;

According to the CCA, removal of vertebral columns considered SRM is not allowed in places other than slaughterhouses or cutting plants; these establishments are approved for that purpose, for which provisions were in place. The CCA has developed check lists and protocols where control of removal of vertebral column is identified as one of the points to be checked during inspections.

The mission team noted that:

- In January 2009 an amendment of the instruction concerning removal of SRM has been issued. Among others, the amended instruction mentions the age for removal of vertebral columns and the obligation to mark bovine carcasses with blue stripe label. However, some of the OVs and authorised veterinarians had a limited awareness concerning new SRM requirements: the representative of the CA met at regional level (who was responsible for the supervision of OVs at slaughterhouses and cutting plants) did not know that the definition of SRM has been changed; in one of the farms visited, both the authorized veterinarian responsible for the farm (including sampling for BSE and SRM from home slaughter) and the OV responsible for official controls were not aware that the SRM instruction has been changed and they thought that the intestines and mesentery were considered as SRM only from animals over 12 months not of all ages.
- In all slaughterhouses visited, splitting of carcases resulted in tunnelling, with the presence of spinal cord inside. In both slaughterhouses, OVs took appropriate actions to correct this and affected parts of vertebral columns were immediately removed.
- There were no reports or check lists which could demonstrate that during official controls in butcher shops, OVs checked if removal and handling of vertebral column are in accordance with Regulation (EC) 999/2001 and Regulation (EC) 1774/2002.
- SRM generated during on-farm slaughtering is not collected or dyed. According to the OVs and one of the animals owner met, SRM is buried and bones are fed to dogs. The representatives of the CA met were aware of such practice; however, no corrective actions have been taken in this respect.

- An instruction for OVs concerning requirements to prevent the possible contamination of head meat harvested with central nervous tissue has been issued. A controls system to ensure the prevention of cross-contamination was in place in the slaughterhouses visited; however, none of the operators had a sampling plan using appropriate laboratory test to verify that the measures were properly implemented.
- The old stock of MBM has been incinerated.
- In November 2008, the incineration of MBM was suspended due to technical problems in the cement factory; as a consequence, around 2,000 tons of Category 1 MBM are temporally stored in the processing plants. According to the CCA, the cement factory will re-start the incineration in March 2009.

6 OVERALL CONCLUSION

6.1 COMPETENT AUTHORITIES

1. The CCA and the CAs responsible for official control as regards BSE and implementation of total feed ban have been designated and their roles were clearly understood. Communication between the CA responsible for feed ban controls was satisfactory; however, as regards BSE epidemio-surveillance, efficient and effective cooperation and coordination, as required by Art. 4 of Regulation (EC) No 882/2004 were very limited, what affects the reliability of the data used for BSE monitoring.

6.2 BSE EPIDEMIO-SURVEILLANCE

1. Limited progress has been made to address the relevant recommendation in the previous report. The information contained in the cattle database is still not sufficiently reliable to be used to oversee the implementation of the BSE epidemio-surveillance as laid down by Annex III to Regulation (EC) No 999/2001.
2. The education programmes requested by Art. 10 of Regulation (EC) No 999/20001 have been organised, and the level of awareness concerning BSE symptoms was largely satisfactory; however, no suspect cases have been ever reported, which casts some doubts on whether the procedures on notification of suspects, as set out in Art. 11, are effectively implemented.
3. Sampling and testing was largely satisfactory at slaughterhouse level, although there was some confusion concerning the categorisation of animals in the sub-populations of sick at the ante-mortem and emergency slaughter. However, it could not be ensured that all animals slaughtered on-farm are sampled and tested, given that the weak monitoring of on-farm slaughtering means that there are not reliable figures on BSE surveillance at this level. Therefore, limited progress has been made in order to address the relevant recommendation in the previous report, and the situation is still

not in line with provisions laid down in Annex III (Chapter A, point 2.1) to Regulation (EC) No 999/2001.

4. The percentage of fallen animals notified remains quite low in comparison with what should be expected; even within the animals that are notified, there is no cross-check in order to ensure that all of them are sampled and tested. Therefore, limited progress has been made in order to address the relevant recommendation in the previous report, and the testing in this sub-population, as required by Annex III (Chapter A, point 3) to Regulation (EC) No 999/2001 cannot be ensured.

6.3 TOTAL FEED BAN

1. The implementation of the total feed ban was largely in line with the requirements of Annex IV to Regulation (EC) No 999/2001. However, the organisation of official controls in accordance with risks, as laid down in Art. 3 of Regulation (EC) 882/2004, was not fully satisfactory, in particular concerning the selection of premises to be inspected and the rationale behind sampling activities.

6.4 LABORATORY NETWORK

1. Satisfactory arrangements for the collection of samples and the distribution of results are in place, as well as an appropriately functioning laboratory network regularly supervised by the NRL. However, weaknesses were found in relation to the limitation of analyses only to good quality samples, although the test used is able to detect the BSE agent in liquefied samples. This is not in accordance with the recommendations of the Community Reference Laboratory guidance document on TSE-related sampling issues as referred to in Annex X (Chapter C, point 1) to Regulation (EC) No 999/2001.
2. Most of the laboratories carrying out official analyses for the total feed ban have not been accredited yet. However, this is still allowed under the transitional arrangements laid down by Commission Regulation (EC) No 2076/2005.

6.5 SPECIFIED RISK MATERIAL

1. The requirements for the removal and disposal of SRM as set out in Annex V to Regulation (EC) 999/2001 were respected by operators in the slaughterhouses visited; however, the weak monitoring of on-farm slaughtering resulted in a lack of compliance with the above mentioned requirements. In addition, there were no records which could demonstrate that the official controls required by Annex V (point 11.1) to Regulation (EC) 999/2001 were organised.
2. The relevant recommendation in the previous report has been partially addressed,

since although control systems were implemented to ensure the prevention of possible cross-contamination of head meat with central nervous system tissue, sampling plans required by Annex V (point 8) to Regulation (EC) No 999/2001 to verify their proper implementation were not in place.

3. The relevant recommendation in the previous report concerning the disposal of Category 1 MBM has been satisfactorily addressed.

6.6 OVERALL CONCLUSION

The report concludes that very little progress has been made since the previous mission concerning the monitoring of on-farm slaughtering, as a result of which requirements for epidemio-surveillance and SRM are not complied with at this level; moreover, testing of fallen animals is still limited and passive surveillance has not resulted in the declaration of any suspect so far. On the contrary, epidemio-surveillance and SRM controls at slaughterhouse level were largely satisfactory; the same applies to feed ban controls, although there were deficiencies in the organisation of controls in accordance with risks.

7 CLOSING MEETING

A closing meeting was held on 20 February 2009 with the representatives of the CCA. At this meeting, main findings and preliminary conclusions of the mission were presented by the inspection team. The CCA did not indicate any major disagreement with these, they acknowledged the need for additional co-ordination and verification of the official controls carried out by the different units of the CCA and undertook to put measures in place to address the shortcomings identified with respect to SRM obtain during home slaughter as well as with respect to head meat harvesting. During the meeting, additional information requested by the mission team was provided by the CCA.

8 RECOMMENDATIONS

The CAs are invited to provide details of the actions taken and planned, including deadlines for their completion within 25 working days following the receipt of the report.

No.	Recommendation
1	To ensure that efficient and effective coordination and cooperation between different units of the CCA as well as between the CCA and the CAs at regional and local levels is established, as required by Art. 4 of Regulation (EC) No 882/2004.
2	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.
3	To reinforce the system of notification of BSE suspects, in order to guarantee

No.	Recommendation
	compliance with requirements of Art. 11 of Regulation (EC) No 999/2001.
4	To verify that 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) to Regulation (EC) No 999/2001.
5	To verify sampling bovine fallen 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.
6	To take into account the criteria listed in Art. 3 of Regulation (EC) No 882/2004 for the organisation of official control of total feed ban.
7	To follow the recommendations of the Community Reference Laboratory, in particular in the case of samples from fallen stock, to comply with requirements laid down in Annex X (Chapter C, point 1) to Regulation (EC) No 999/2001.
8	To ensure that SRM produced as a result of home slaughtering of bovine animals, are collected, transported and disposed of in compliance with requirements laid down in Annex V to Regulation (EC) 999/2001.
9	To put in place the sampling plans required by Annex V (point 8) to Regulation (EC) No 999/2001.

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

http://ec.europa.eu/food/fvo/ap/ap_bulgaria_8110_2009.pdf

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Decision 98/139/EC	OJ L 38, 12.2.1998, p. 10–13	98/139/EC: Commission Decision of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 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