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FINAL REPORT OF A MISSION  
CARRIED OUT IN  
PORTUGAL  
FROM 11 TO 20 MAY 2009

IN ORDER TO EVALUATE MEASURES CONCERNING BOVINE SPONGIFORM  
ENCEPHALOPATHY (BSE) AND ORGANIC FERTILIZERS AND SOIL IMPROVERS

*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 an endnote.*

## ***Executive Summary***

*This report describes the outcome of a Food and Veterinary Office (FVO) specific audit carried out from 11 to 20 May 2009, as part of the general audit of Portugal carried out under the provisions of Regulation (EC) No 882/2004 of the European Parliament and the Council.*

*The objective of the mission was to evaluate the implementation of certain protective measures against Bovine Spongiform Encephalopathy (BSE), as well as rules concerning organic fertilisers and soil improvers (OF/SI).*

*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 control measures in place to ensure the effectiveness of the total feed ban, in particular how the risks posed by the use of OF/SI are considered for the organisation of these controls. In addition and for OF/SI, it was assess the capability of the authorities to their correct production, flow and use. 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:*

- BSE monitoring was largely satisfactory, with the exception of fallen animals, an important number of which are still not sampled and tested. However, in two cases there were significant delays in the implementation of movement restrictions following the detection of suspects. SRM controls were largely satisfactory.*
- Progress has been made since the previous mission concerning feed ban controls and targets set by the control programme have been met; however, controls did not yet cover the entire country, and they were affected by deficiencies in the design and implementation of a risk based approach.*
- Progress has been also made concerning OF/SI, although there were some weakness in their production. Nevertheless, official controls on the use of OF/SI have been satisfactorily reinforced, although they did not cover yet the use of non-bulk OF/SI.*

*The report makes a number of recommendations addressed to the Portuguese 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**

<b>Abbreviation</b>	<b>Explanation</b>
ABP	Animal by-products
AV	Authorised veterinarian
BSE	Bovine Spongiform Encephalopathy
CA	Competent authority
CCA	Central competent authority, the DGV
CCP	Critical Control Point
DAA	Animal Feedingstuff Division
DGV	Veterinary General Directorate ( <i>Direcção Geral de Veterinária</i> )
DRAP	Regional Directorate for Agriculture and Fisheries
DSHPV	Directorate for Veterinary Public Health
DSVR	Regional Veterinary Directorate
Fallen stock	Dead on-farm bovines
FeBO	Feed Business Operator
FVO	Food and Veterinary Office
GTH	Glyceroltriheptanoate
IFAP	Financing Institute for Agriculture and Fisheries
LNIV	National Laboratory for Veterinary Research
MADRP	Ministry of Agriculture, Rural Affairs and Fisheries
MANCP	Multi-Annual National Control Plan

MAT	Microscopic analytical test
MBM	Meat and bone meal
MS	Member States
NFCP	National Feed Control Programme
NRL	National Reference Laboratory
OF/SI	Organic Fertilisers/Soil Improvers
OV	Official veterinarian
PAP	Processed animal protein
PDA	Proteins derived from animals
Report 2007/7246	Report of a mission carried out in Portugal from 17 to 27 April 2007 concerning BSE
Report 2008-7986	Report of a mission carried out in Portugal from 22 to 26 September 2008 in order to evaluate feed ban controls and compliance with requirements for OF/SI
SIRCA	Collection System for Fallen Stock
SNIRA	National System for Animal Identification and Registration
SRM	Specified risk material
Total feed ban	Prohibition of feeding PDA to farmed animals and exceptions applicable to this ban
TSEs	Transmissible Spongiform Encephalopathies

## 1 INTRODUCTION

The specific audit took place in Portugal from 11 to 20 May 2009. The audit team comprised two inspectors from the Food and Veterinary Office (FVO). The specific audit was undertaken as part of the general audit of Portugal carried out under the provisions of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

Representatives from the central competent authority (CCA), the *Direcção Geral de Veterinária* (General Directorate for Veterinary Services - DGV) accompanied the audit team for the duration of the audit. An opening meeting was held on 11 May 2009 with the CCA. At this meeting, the mission objectives, itinerary, and the standard reporting and follow-up procedures were confirmed, and additional information required for the satisfactory completion of the specific audit was requested.

## 2 OBJECTIVES OF THE MISSION

As part of the general audit, the objective of this mission was to verify that official controls are carried out in conformity with the Portuguese multi-annual national control plan drawn up in accordance with Article 41 of Regulation (EC) No 882/2004.

For this purpose, the mission team evaluated specifically the measures put in place to give effect to Regulation (EC) No 999/2001 of the European Parliament and of the Council, and Regulation (EC) No 1774/2002 of the European Parliament and of the Council, including implementing measures laid down by Commission Regulation (EC) No 181/2006.

In terms of scope, the mission focused 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 control measures in place in order to ensure the effectiveness of the prohibition of feeding products derived from animals (PDA) to farmed animals and exceptions applicable to this ban (hereafter: total feed ban); this concerned, in particular, how the risks posed by the use of organic fertilisers and soil improvers (OF/SI) are taken into consideration in the organisation of the said controls. Concerning OF/SI, the mission concentrated in the capability of the competent authorities (CAs) to ensure their correct production, flow and use.

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	3 Meetings in three regional directorates
	Local	√ Discussions held in the course of visits to premises
Laboratory visits		Comments

TSEs laboratory	√	Representative from the NRL for TSEs met during the opening and closing (de-briefing) meetings
<b>Establishments handling Animal by-products not for human consumption</b>		
Processing plant	7	Two Category 1, three Category 2 and three Category 3 processing plants
Technical plant	1	Technical plant using ABP for producing OF/SI
Animal feed processors / manufacturers	1	Feed mill authorised to use fishmeal, and producing feed for non-ruminants and for ruminants
On-farm mixer	1	On-farm mixer authorised to use derogated PDA
<b>Food processing establishments</b>		
Slaughterhouse	2	Establishment slaughtering cattle
<b>Other</b>		
Animal farm	2	Cattle holdings

### 3 LEGAL BASIS FOR THE MISSION

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

- Art. 21 of Regulation (EC) No 999/2001;
- Art. 45 of Regulation (EC) No 882/2004;

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

The previous mission concerning BSE in Portugal was carried out from 17 to 27 April 2007, the results of which are described in report DG(SANCO)/2007/7246 – MR Final (hereafter: report 2007/7246). In addition, a mission concerning feed ban controls and requirements for organic fertilizers and soil improvers was carried out from 22 to 26 September 2008, the results of which are described in report DG(SANCO)/2008-7986 (hereafter: report 2008-7986).

These reports are accessible at:

[http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm)

In response to reports 2007/7246 and 2008-7986, the CCA provided the FVO with the actions planned and/or undertaken to address the recommendations contained in the reports (hereafter: action plans). Where appropriate, relevant recommendations set out in these reports are indicated under the appropriate section headings in section 5 below. The corresponding actions as announced in the action plans are outlined thereafter.

Commission Decision 2008/908/EC authorised certain Member States (MS) to revise their annual BSE monitoring programme. Based on the said Decision, the CCA issued an administrative provision (Circular No 936 of 22 December 2008) introducing the new monitoring programme, which sets the age limit for testing at 48 months for healthy slaughtered animals, and 36 months for other sub-populations (fallen stock, emergency slaughter and sick at *ante-mortem*).

Concerning the BSE situation, there were 14 confirmed cases in 2007 (incidence of 17.02 cases per million adult bovine), and 18 in 2008 (incidence of 20.52); in the latter year, the youngest animal had been born in 2001. In 2009, a case has been confirmed in an animal born in July 2002.

The results of the TSE testing programmes can be found at:

[http://ec.europa.eu/food/food/biosafety/bse/index\\_en.htm](http://ec.europa.eu/food/food/biosafety/bse/index_en.htm)

## 5 FINDINGS AND CONCLUSIONS

### 5.1 COMPETENT AUTHORITIES

#### 5.1.1 Organisation and responsibilities

##### ***Legal requirements***

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

##### ***Findings***

The organisation and distribution of responsibilities between and within CAs is explained in detail in reports 2007/7246 and 2008-7896 and description of the CAs can also be found in the country profile for Portugal, which is accessible at:

[http://ec.europa.eu/food/fvo/country\\_profiles/CP\\_portugal.pdf](http://ec.europa.eu/food/fvo/country_profiles/CP_portugal.pdf)

In summary the DGV, a section of the Ministry of Agriculture, Rural Affairs and Fisheries (MADRP) is responsible for BSE control measures which are implemented at local level through five regional veterinary inspection offices in mainland Portugal and in the autonomous regions of *Açores* and *Madeira*.

The relevant recommendation of report 2008-7986 concerned the allocation of responsibilities between CAs involved in implementing official controls of the feed ban and the use of OF/SI. In response to this recommendation, the CCA undertook to draft a ministerial order that would clarify that matter.

The mission team noted that:

- DGV is the only CA in charge of implementing feed ban controls. The Food and Economic Safety Authority, placed under the aegis of the Ministry for Economy and Innovation, is only



involved in cases where investigations linked to economic fraud are undertaken.

- A joint order by the MADRP and the Ministry of Environment, Land Use and Rural Development (MoE) was signed during the mission. This order stipulates that the Regional Directorates for Agriculture (DRAP) bear responsibility for official controls over the use of OF/SI while DGV is responsible for the approval of technical and processing plants from which such products originate. In the only region where meat and bone meal (MBM) was still being used as OF/SI, similar arrangements were already in place before this order was signed (see 5.7.3).
- According to the representatives of DGV met, the requirements of the above order will only be implemented for bulk OF/SI and MBM directly used as OF/SI. Therefore, no official controls are foreseen by the CCA over the use of packaged OF/SI, including those received in big-bags at farm level, in particular to ensure that animals can not access lands to which these products have been applied; this view was also shared by the DRAP representatives met.

### ***Conclusions***

The responsibilities for feed ban controls have been clarified and steps have been taken to designate the CAs in charge of official controls over the production and use of OF/SI. However, it is still unclear which CAs, if any, will be responsible for carrying out official controls over the use of packaged OF/SI. Therefore, the requirements of Art. 4.1 of Regulation (EC) No 882/2004 were not fully met.

#### *5.1.2 Cooperation and coordination*

### ***Legal requirements***

Art. 4.3 of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between CAs. Art. 4.5 of the said Regulation requires that, when, within a CA, 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***

Coordination and cooperation is performed by different communication channels. Activity of CAs, vertically subordinated to the CCA, is formalised by Official Circular letters. Between Directorates there is direct horizontal communication. In particular, the communication between regional directorates concerning the definition of the cohort of BSE confirmed cases is carried out through the DGV.

The relevant recommendations of report 2008-7986 concerned cooperation and coordination between and within CAs in charge of official controls of the feed ban and the use of OF/SI. In response to this recommendation, the CCA undertook to improve the exchange of information within and between CAs.

The mission team noted that:

- Numerous examples of vertical communication were seen: documents concerning the new epidemio-surveillance monitoring scheme for BSE, changes in the list of SRM, handling of SRM, head meat harvesting and requirements for using derogated product derived from animals (PDA).
- One of the Regional Veterinary Directorates (DSVRs) visited was notified by the CCA about the fact that two BSE cases had been born in their region (although they were found in other regions). However, the communications were made eight and 12 months following the

results of the BSE rapid tests.

- Two coordination meetings between DGV and its regional services took place in 2008 and 2009. In the minutes of these meetings, there was evidence of actions foreseen to improve the flow of information pertaining to feed controls activities between regions and central administration.
- Some information about the implementation of feed ban controls by DSVRs was sent to the Animal Feedingstuff Division (DAA), which in turn updated and circulated a number of documents aiming at facilitating the organisation of official controls at regional level. In addition, in several regions, the DAA was actively involved in sampling and inspections to feed business operators (FeBOs) in order to achieve the targets set in the national feed control programme (NFCP) for 2008. As a result, the DAA took 835 of the 2,444 official feed samples taken.
- Farms keeping ruminants and non-ruminants had been inspected as part as feed ban controls in some of the regions visited. However, no samples were collected during these inspections although such farms were considered as high priority in terms of sampling in the risk assessment of these regions (see 5.7.2). Representatives of one DSVR visited stated that such situations stemmed from the fact that the teams involved in inspections to farms were not the same as those responsible for sampling and that the priorities for sampling were not known by the teams in charge of inspections.
- Information about farms using MBM as organic fertilisers and those which had recently stopped using it, was detained by the Directorate of Public Veterinary Hygiene (DSHPV) and DRAP representatives met. However, they stated that this information had not been communicated to the DSVR concerned. As a result, none of these farms, some of which were keeping animals, were targeted or visited in the frame of feed ban controls (see 5.7.2).
- Approvals of processing plants are granted by the DSHPV, once the validation of the plant has been performed by the DSVR in charge of the operator. However, following a recent change in the processing method used, the approvals of a Category 1 and 3 processing plant visited were renewed although the validation procedure was not yet finalised, despite the fact that a favourable opinion from the concerned DSVR was not yet produced.

### ***Conclusions***

There are arrangements in place in order to ensure some coordination between central and regional services of DGV. However, there are still some gaps concerning timely exchange of information and imposing of measures in the case of BSE eradication. There is still also an incomplete coordination between DSHPV and DSVR and this affects the performance of official controls on the production and use of OF/SI. As regards feed ban controls, important information that could improve the targeting of official controls to farms is not exchanged between DRAP and DSVR, and in some cases, within DSVR. This does not ensure that the requirements of Art. 4.3 and 4.5 of Regulation (EC) 882/2004 are met.

#### *5.1.3 Resources and training*

### ***Legal requirements***

Art. 4 of Regulation (EC) No 882/2004 requires the CA 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. Art. 6 of the said Regulation requires CAs to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

### ***Findings***

The relevant recommendations of report 2007/7246 concerned training for officials responsible for SRM controls. In response to this recommendation, the CCA noted that training on SRM controls was planned for official veterinarians and health inspection assistants.

Several training sessions related to BSE aspects as epidemio-surveillance, total feed ban or SRM for Official Veterinarians (OVs), technicians and health inspectors from different levels have been organized in recent years: 15 in 2007 (309 participants), six in 2008 (76 participants) and four in the first quarter of 2009 (50 participants). Staff from DGV and all DSVRs also attended these trainings.

The mission team noted that:

- Most of OVs met had satisfactory knowledge of SRM requirements.
- In the DSVRs visited, the feed inspectors met confirmed that they had participated in training sessions on feed hygiene requirements. This was because staff from all DSVRs have attended a two-day training course organised by DAA in October 2008, given that feed inspections were a new task for them.
- In two Category 1 and one Category 3 processing plants visited, insufficient data were available to allow the validation, by official services, of the continuous processing method used. This had been overlooked by DSVR inspectors, who had not received training on that matter (see 5.5.1 and 5.7.1).

### ***Conclusions***

Training has been organised concerning SRM rules, and the relevant recommendation on this issue has been satisfactorily addressed. However, training courses for officials in charge of inspections and sampling do not cover validation of processing plants operating with continuous methods. Therefore, the requirements of Art. 6 of Regulation (EC) No 882/2004 were not fully met.

#### *5.1.4 Internal supervision*

### ***Legal requirements***

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

### ***Findings***

The relevant recommendation of report 2008-7986 concerned the internal supervision system. In response to this recommendation, the CCA stated that they undertook to take actions on this issue.

The Multi-Annual feed control programme sets out that the DAA should perform second-level controls in order to assess how official controls on feed are carried out by DSVRs; according to this programme these controls should cover 3% of the checks conducted by DSVR.

The mission team noted that:

- Each of the DSVRs visited has appointed a regional coordinator for the organisation of official controls on feed. These officials were in charge of allocating the overall number of samples and ensuring the collection of all inspection reports, which they monitored in order to identify the main shortcomings detected. This information, along with the nature and the number of samples taken, was forwarded to DAA. According to DAA, they also bear responsibility for verifying that these reports are correctly filled in.
- The DDA acknowledge that the information they receive is not routinely analysed in order to monitor the implementation or the targeting of official controls on feed. Moreover, no

actions were taken by the DAA following the absence of feed inspections in *Açores* or to correct the very limited number of samples taken on feed at entry points.

- In 2009, for the first time, the DAA established a planning in which it was foreseen that a week would be spent in each of the DSVRs to carry out joint inspections between the DAA and DSVRs feed inspectors. However, at the time of the mission only one joint inspection has been performed. No report on the assessment of the DSVR inspector concerned was yet available. According to the DAA, their participation in the NFCP left little time for these second-level controls.

- **Conclusions**

There are procedures in place for the implementation of an internal supervision system on feed controls. However, these provisions are not implemented as planned. Moreover, the existing flow of information between the DAA and DSVRs, which conveys some useful information on the way official controls are performed, is not used for the purpose of the verification of the effectiveness of these controls. This does not ensure that the requirements of Art. 8.3 of Regulation (EC) No 882/2004 are met.

## **5.2 BSE EPIDEMIO-SURVEILLANCE**

### *5.2.1 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 current system of animal identification and registration of bovine animals has been in place since January 2000. Information on all cattle is held on a single central database, the National System for Animal Identification and Registration (SNIRA –formerly known as SNIRB), which is managed by the Financing Institute for Agriculture and Fisheries (IFAP) of MADRP.

The mission team noted that:

- All bovines seen during the on-the-spot visits were correctly identified.
- The holding register on the farms visited was fully completed and awareness about obligation of timely notification to SNIRA has been confirmed by animal owners on both farms visited.
- In one of the regional offices visited, details of a number of animals were checked on the SNIRA database. It was possible to identify the current location of offspring of these animals using the database.
- Identification of cohorts of BSE cases is carried out using information on the cattle identification database and on-farm holding registers. The medical treatments records database is also used as an additional tool for animals born before the SNIRA started to be operational in 2000.
- The SNIRA is used to verify the eligibility of bovine animals for BSE sampling in slaughterhouses and rendering plants.
- In 2007, the target of holdings checked for animal identification and registration (5 %) was nearly met. However, only 3,85 % of holdings were checked in 2008.

#### **Conclusion**

The animal identification and registration system is able to support the BSE monitoring and control system required by Annex III and Annex VII Regulation (EC) 999/2001.

### 5.2.2 *Passive surveillance*

#### ***Legal requirements***

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

#### ***Findings***

There has been a decrease in the notification of reported suspect cases comparing with some years ago. Nevertheless, BSE suspect continue to be notified, especially in the regions with highest BSE incidence: ten and nine animals were notified in, respectively, 2007 and 2008, of which two animals turned to be positive in 2008.

According to the CCA this trend reflects the evolution of the BSE epidemiological situation, better knowledge of farmers due to the experience with BSE obtained in the past years and continuous training. The most frequent alternative diagnoses were Listeriosis, Streptococcosis or hypocalcemia.

The mission team noted that:

- There are procedures for official veterinarian at the DSVR how to confirm or exclude official suspect of BSE.
- In the holdings visited, awareness of BSE issues was confirmed.

#### ***Conclusions***

A satisfactory system of passive surveillance for BSE in line with Artt. 11 and 12 of Regulation (EC) No 999/2001 is in place.

### 5.2.3 *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 recommendation of report 2007/7246 concerned the testing of fallen stock, in particular in *Açores* and *Madeira*, and the classification of animals in the different sub-populations. In response to these recommendations, the CCA noted that several meetings had been organised in the concerned islands to improve the situation, and they expected to test around 75 % of fallen stock in 2007. Concerning the attribution of samples in the different sub-populations, a training was organised 2007.

In mainland, sampling of fallen stock is performed either in Category 1 processing plants (there is a System for Collection of Fallen Stock –SIRCA) or at farm level by veterinarians of the livestock producers organisations (OPP). In the islands, sampling of fallen stock is performed mainly by private veterinarians and, since the last BSE mission, several contracts have been signed with

private veterinarians for BSE monitoring; at this level, there is no organised system for the collection of fallen stock. The figures concerning the level of testing of fallen animals, in 2007 and 2008, are shown in the table below:

	Mainland 2007	Mainland 2008	Islands 2007	Islands 2008
255 Notification to SNIRA *	2,705	3,028	4,918	4,539
Notifications to SIRCA	27,444	35,266		
Total No of notified fallen animals	30,149	38,294	4,918	4,539
Tested animals	23,755	31,571	2,513	2,495
% of testing	78.79	82.45	51.09	54.96

\* Form No 255 is used for the notification of dead animals which are not collected for different reasons and where sampling is not possible.

The mission team noted that:

- The percentage of fallen stock has increased in relation to previous years, however there is still not satisfactory. According to the CCA, in the islands there were budgetary problems in the first semester of 2008; 70% of fallen stock was tested (727 animals out of 1,038) in the first quarter of 2009.
- According to the CCA the reasons for not collecting dead animals in mainland are that they are decomposed, not accessible, buried, that the holdings are under restriction for animal health reasons, or for other reasons. Although there is an obligation set up by DGV to collect fallen animals the day following their notification, this is not always the case, especially during weekends and holidays; moreover, in some case notifications are delayed by farmers due to the extensive system of cattle breeding. There are cases when the notification is not done at all and animals are buried on farm. All these situations are considered risk factors for deciding which farms will be checked the following year.
- The absence of notification of fallen stock from holdings with more than 25 heads of cattle and cases in which holdings reported fallen stock to the SIRCA but where the SIRCA was unable to collect the majority of the carcasses either because they had already been buried or because they were in advanced state of decay are considered other risk factors. The mission team was provided with a list of administrative measures taken to rectify this lack of notification.
- According to the CCA, the number of animals tested and notified to the national database are supposed to be cross-checked on a monthly basis. However, there were discrepancies between the figures concerning the number of animals slaughtered and tested in the different sub-populations, as shown in the table below (figures concerning 2008):

	No of animals	No of tests
Normal slaughter	60,481	55,685

Sick at ante-mortem	6,040	6,288
Emergency slaughter	2,301	1,748
Total	68,822	63,721

- The CCA explained the above discrepancies due to the way the figures are collected where animals could be counted twice in different sub-populations at the same time due to the entering of wrong codes for the animals; this was confirmed by the mission team. ([see Endnote](#)) They also noted that, at present, it would be necessary to check every single file concerning each animal to prove that data are correct. The DGV indicated that they would improve the software used for data collection before the end of this year.
- In the slaughterhouses visited, it was confirmed that all eligible animals were sampled.
- The level of testing of healthy slaughtered animals represents 7 % of the cattle adult population; this percentage is one of the lowest in the Community (the average was 18.5 % in 2007). According to the CCA the main reason for this is that a significant number of cattle is sent to other MS for slaughtering (for instance 26,878 were sent to Spain in 2007 – animals of all ages). However, the mission team noted during the visits to two slaughterhouses that animals from other MS were also being slaughtered.
- In the slaughterhouses visited, adequate sampling procedures were in place and all parts of carcasses were identified and kept under official control until the results of BSE tests were received. At this level, there were procedures in place to dispose of one carcass before and two carcasses after any carcass that might be identified as BSE positive.
- Although on-farm slaughtering is forbidden (unless there are animal welfare reasons and after the approval of a private veterinarian), the CAs admitted that it is quite common, in particular in one region; there is no indication that these animals are sampled. The DSVR in the concerned region follows this situation, and more than 350 administrative procedures in this respect were opened in 2007.

### ***Conclusions:***

Although progress in the sampling of fallen stock has been made, the percentage of cattle sampled in this sub-category remains unsatisfactory. Concerning animals slaughtered for human consumption, although there were no evidences to assume that sampling is not carried out in slaughterhouses, the available data did not allow confirming this. Therefore, the requirements for sampling laid down in Annex III to Regulation (EC) 999/2001 were not fully complied with.

## **5.3 MEASURES FOLLOWING SUSPICION/CONFIRMATION OF BSE**

### ***Legal requirements***

Artt. 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 following a positive or inconclusive result is found following a rapid test.

### ***Findings***

Instruction for dealing with suspect and positive BSE cases are included in the BSE eradication

plan. In the case of suspicion, an epidemiological inquiry has to be done in accordance with a special form. If the suspicion is confirmed a new epidemiological inquiry has to be done. The DGV is informed of the results of both epidemiological inquiries and confirms the cohort for a decision on its eradication being taken.

The mission team noted that:

- In one DSVR visited, there had been a case of BSE in a fallen animal in July 2008. The mission team were shown documentary evidence that movement restrictions were put in place, an epidemiological investigation carried out and risk bovines destroyed.
- In other DSVR visited, there had been two cases of BSE in animals born in this region (but bred and slaughtered in another region). Several months (eight and 12) elapsed between the positive result to the rapid tests and the notification of the cases by the DGV to the DSVR (at that moment, both cases had been confirmed); in the latter case, movement restrictions in the holding of origin were only put in place seven weeks after this notification. ([see Endnote](#))

### **Conclusions**

Movement restrictions following the detection of suspect animals have been significantly delayed in two cases, which does not ensure compliance with Art. 12 of Regulation (EC) No 999/2001.

## **5.4 SPECIFIED RISK MATERIAL**

### *5.4.1 Requirements*

#### **Legal requirements**

Art. 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 2007/7246 concerned the removal of SRM in *Açores*. In response to this recommendation, the CCA noted that the situation on *Açores* has been already improved.

SRM can be removed only in slaughterhouses, with the exception of vertebral columns which can be also removed in cutting plants specifically authorised for such activity. Harvesting of head meat from cattle over 12 months is authorised in five slaughterhouses and one cutting plant.

The mission team noted that:

- In the slaughterhouses visited, the requirements concerning SRM were satisfactorily met. In particular, procedures for head meat harvesting were in place, including sampling programme to check the absence of contamination with central nervous tissue. In 2008 and 2009, 576 and 199 samples had been taken for this purpose (all negative) in the entire country. However, in one slaughterhouse visited, head meat was harvested on the slaughterline before the heads were cut and prior to the *post-mortem* inspection.
- Given that on-farm slaughtering is forbidden, there are no arrangements for the collection of SRM generated.
- A percentage of fallen stock is still disposed by burial on-site (see 5.2.3).
- In the two Category 1 processing plants visited, there were insufficient data to confirm that the processing method used was one of those prescribed by Regulation (EC) No 1774/2002; while the operator stated that method 4 was used, there was no evidence that the required



time/temperature combinations were met. In addition, in one of the plants, the rate of extraction of processed ABP from the continuous cooker was not considered as a critical control point (CCP) and therefore not monitored (although this rate impacts the treatment time).

### **Conclusions**

Handling of SRM at slaughterhouses was largely satisfactory, except for the harvesting of head meat in one slaughterhouse, which was not in line with Annex V, 8.1.(a) of Regulation (EC) No 999/2001.

The processing methods laid down in Chapter III of Annex V to Regulation (EC) No 1774/2002 were not always complied with by Category 1 processing plants.

#### *5.4.2 Official controls*

### **Legal requirements**

Point 11 of Annex V to Regulation (EC) No 999/2001 requires CAs to carry frequent official controls to verify the correct application of this Annex. Artt. 8(1) and 9 of Regulation (EC) No 882/2004 introduce, respectively, requirements for the existence of documented procedures for official controls and for drawing up reports following their performance.

### **Findings**

Concerning the official controls on SRM, the DGV has issued a Manual of best practice for controls of animal by-products (ABP) in slaughterhouses, cutting and deboning plants; the manual foresees the production of different reports concerning SRM controls. If the reports note non-compliances, the DSHPV carries out a control in the slaughterhouse in question in order to verify, among other things, whether SRM and other ABP are correctly removed and handled; following this control, another report is drawn up.

The mission team noted that:

- In the slaughterhouses visited, official controls on SRM were satisfactory. Several examples of reports concerning SRM controls were seen.
- In 2009 two slaughterhouses have been inspected but reports were not drawn up yet.
- Cross-checks between the quantities of ABP received and the amounts of final products (MBM and fat) were not performed in one of the Category 1 processing plants visited. In one region, these checks had been initiated but they were inconclusive as the OV was not aware of the yield that could be expected for processed ABP. In the same plant, no verification was performed on the quantity of fat used in the thermal boiler of the operator.
- Although both Category 1 processing plants visited were approved, the (continuous) method used by them had not been validated in one case, and in the other, there were not enough elements to support the validation.
- Category 1 material was dispatched from one slaughterhouse to another MS. However, not all consignments were notified to the CA of the place of destination.

### **Conclusions**

The implementation of official controls on SRM in slaughterhouses was largely in line with the requirements of point 11 of Annex V to Regulation (EC) 999/2001. However, the official controls required by Art. 26 of Regulation (EC) No 1774/2002 were not always carried out satisfactorily at some Category 1 processing plants, notably concerning their validation and the monitoring of their operation; moreover, the notification of the dispatch of Category 1 material to other MS, which is

requested by Art. 8 of the said Regulation, was not always carried out.

## **5.5 TOTAL FEED BAN**

### *5.5.1 Requirements along the chain*

#### ***Legal requirements***

Art. 7 of Regulation (EC) No 999/2001 prohibits the feeding to farmed animals of PDA, 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***

Following the last FVO mission, several actions were taken by the DAA in order to update the list of users of derogated PDA. In September 2008, a circular was sent to all intermediaries approved for placing derogated PDA on the market, in order to identify their clients and subsequently cross check this information with the lists held by the DAA. On the basis on the information collected, in January 2009, all feed manufacturers (industrial and own-producers) identified as users of derogated PDA were contacted and asked to apply for an authorisation or to submit some updated information for this purpose. In addition, in April 2009, the DAA informed all feed manufacturers and intermediaries, as well as national associations in that sector, about the obligation to submit monthly information on the use of milk substitutes containing fishmeal intended for young farmed ruminants.

The mission team noted:

- All FeBOs visited which were using derogated PDA had been authorised by the DAA and were meeting the requirements of Annex IV to Regulation (EC) 999/2001, in terms of production facilities and record keeping. Labelling of feedingstuffs containing fishmeal was in line with the requirements of the said Regulation.
- In all DSVRs visited, lists of authorised users were present and there was evidence of regular updates of these lists by the DAA. Users of animal fat, hydrolysed proteins and gelatine derived from non-ruminants were also listed although there is no legal Community or national requirements for them to be authorised. Concerning milk replacers containing fishmeal (for which there are no manufacturers), very few replies had been received and potential users of such products were not yet known.
- There was evidence of microscopy testing on imported consignments of fishmeal before they were released for free circulation.
- Processed animal proteins (PAP) derived from poultry and pig materials were exported from a Category 3 processing plant visited. An agreement with the third country of destination was in place but it did not contain an undertaking not to re-export these PAP.
- In 2005, samples were taken to check for the presence of constituents of animal origin in sugar beet pellets from the only active sugar beet factory. As the presence of bones spicules in root crops or tubers has never been detected, no risk assessment to authorise the use as feed of such material was carried out. Since 2005, the DAA stated that root crops or tubers were not specifically targeted by official samples.

#### ***Conclusions***

The FeBOs visited were largely compliant with the requirements of Annex IV of Regulation (EC) No 999/2001. Updated lists of authorised users are kept by the CCA. However, the CCA has not yet drafted the list of farms where milk replacers containing fishmeal are used and which is required by point II(BA)(g) of Annex IV to Regulation (EC) No 999/2001.

### 5.5.2 *Official controls*

#### ***Legal requirements***

Art. 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. Artt. 8(1) and 9 of the said Regulation introduce, respectively, requirements for the existence of documented procedures for official controls and for drawing up reports following their performance.

Point F of Annex IV to Regulation (EC) No 999/2001 requires CAs 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 2008/7986 concerned the risk-based strategy supporting feed ban controls, inspections to farms and the achievement of targets set for sampling. In response to these recommendations, the CCA undertook to update the feed control programme.

Official controls on the total feed ban are organised as part of feed controls and remain largely as described in report 2008/7986. Almost all feed samples taken are analysed for the presence of constituents of animal origin and feed inspections include a section for the verification of feed ban requirements. Therefore, the same risk prioritisation, documented procedures and report templates are used for feed and feed ban controls.

For the purpose of the NFCP for 2008 which started in September 2008 and ended in April 2009, the DAA circulated a number of documents and instructions aiming at facilitating the identification of FeBOs to be inspected or sampled by DRSVs. In terms of sampling, these documents comprised a list of FeBOs authorised for the use of derogated PDA and a list of FeBOs, other than farms, in which samples should be taken.

As regards farms, DSVRs are only given the overall number of samples to be taken and, in principle, they are responsible for setting up their own prioritisation criteria. Nevertheless, the DAA brought some modifications to the NFCP in October 2008 and introduced priority factors for sampling activities at farm level; according to these changes, holdings keeping ruminants and non-ruminants as well as holdings using mobile mixers should be targeted in priority. DSVRs have also the possibility to include additional factors which take account of their specificities. In addition, lists of farms in which samples should be taken on a compulsory basis were also circulated by the DAA to three regions which had not communicated their risk prioritisation.

In terms of inspections, following the modifications introduced in October 2008, the frequency of inspections to producers of compound feedingstuffs, premixtures and additives, were increased from 20% to 50% per year. For FeBOs authorised for the use or storage of derogated PDA, the frequency remained unchanged at 100% per year. For inspections at farm level, the decision was taken to carry out feed ban controls in farms which were selected for cross-compliance checks; for this purpose, the DGV communicated to IFAPa set of criteria to be used for the selection of such farms.

Checklists to be used during feed ban controls, whether at farm level or in other FeBOs, have also been circulated by DAA.

The mission team noted that:

- In the frame of the NFCP, an overall number of 2,444 samples were taken, representing 95% of the initial target. The implementation of inspections, which had been interrupted since 2007, has resumed and a total of 1,168 were performed at farm level and 105 in other FeBOs. However, no inspections were carried out in the Algarve and Açores regions and a very limited number in the Lisbon region (53); altogether, these regions account for 30% of the national bovine population.
- Feed inspections to farms were carried out at the same time as cross-compliance checks. The criteria that were chosen by the DGV for selecting the farms to be inspected were related to TSE (e.g. regions with highest TSE incidence or with animals born after the total feed ban), notification of fallen stock and international trade of animals. Therefore, farms keeping ruminants and non ruminants, farms using OF/SI, farms using bulk feed or feed containing derogated PDA were not targeted.
- Feed inspections to FeBOs (farms or feed mills) authorised for the use of derogated PDA were not performed in all cases. In one region visited, one double stream feed mill using fishmeal and blood products, 11 feed mills and 15 on-farm mixers using fishmeal were not inspected. However, the DAA had regularly communicated to all DSVRs updated lists of such authorised users.
- The quantity of feed or the species for which feed was produced were not considered when selecting the feed mills to be inspected. Inspections are carried out at random and up to the percentage required by the NFCP. In one DSVR visited, this percentage was still fixed at 20% for feed mills while it had been increased to 50% in the last version of the NFCP.
- According to the DAA, only one DSVR has requested a password to access the national database for feed controls. In this database, information concerning the main characteristics of FeBOs are present. In addition, files of approved FeBOs, including inspection reports, are kept at central level and therefore no historical data concerning the compliance of such FeBOs was available at regional level.
- All DSVR visited had identified risk factors for the sampling at farms. Among these criteria, the presence of ruminants and non-ruminants was considered as a major one. However, in the most important region in terms of livestock production, none of the farms sampled were mixed holdings. In the other regions visited, the few mixed holdings that had been visited were not sampled. According to the representatives of the DSVRs met, the current organisation of the different livestock databases does not allow the identification of these holdings; As a result, none of the DSVR visited was aware of their number.
- The lists of farms to be sampled which have been prepared by the DAA for three of the DSVR were based on criteria related to BSE or non-compliant results from previous feed or residues control plans. These criteria were different from those introduced in the last modification of the feed control programme for 2008 as, for instance, they did not target mixed holdings or farms with mobile mixers. As a result, and although these lists were distributed well after the implementation of the feed programme started, some of the DSVR visited readjusted their sampling activities to take account of them.
- The presence of an on-farm mobile mixer was another important risk factor identified by the DAA for the sampling strategy at farm level and, according to the risk prioritisation of all the DSVRs visited, 100% of these farms should have been sampled. However, in one region visited none of them were sampled and in the others, they were only partially visited. According to the DAA, this was because the lists of registered mobile mixers were circulated to DSVRs well after the implementation of the NFCP started. The representative

of the DAA further stated that the registration of farms using mobile mixers was still very incomplete. There are currently around a hundred of them that have been identified and listed. Although the total number of such farms is difficult to estimate, in one DSVR visited they were thought to be several hundreds.

- The use of bulk feed or feed containing derogated PDA was not considered in the risk prioritisation of DSVRs. One feed mill visited was selling feed containing fishmeal directly to several farms. This information had not been used for the purpose of feed ban controls at farm level.
- The import of feed with high protein content is not a risk factor which is taken into account for the prioritisation of inspections to FeBOs. In addition, while the NFCP foresaw that, at entry points, 112 samples should be taken on imported consignments of feed materials, only 18 were taken by the two main border inspections posts for bulk feed materials. However, as the representative of the DAA stated, Portugal is highly dependent on imports for sourcing the vegetable proteins used in feed.
- The use OF/SI (including the direct use of MBM) is not considered as a risk factor for targeting feed ban controls, and the farms where such products are used are not known by DSVRs. In addition, during feed inspections to farms, the presence or use of OF/SI are not checked.
- Bulk OF/SI containing Category 2 MBM was picked up from one technical plant by farmers, using their own means of transport. This practice, which poses a risk of cross-contamination, had been overlooked during official controls (which ones?) and was not considered for feed ban controls.

## **Conclusions**

Official controls on the total feed ban are carried out in accordance with documented procedures and reports are drafted following inspections. Quantitative objectives set for sampling have been met, except on imported feed. However, the risk prioritisation that has been designed to target sampling does not take account of some important identified risks. Moreover, this risk prioritisation is not followed in practice. As a result, samples are not taken in all places bearing the highest risks of cross-feeding or cross-contamination.

Inspections have resumed after an interruption of 18 months. However, they are still not carried out in regions where a significant part of the bovine population is present. In terms of prioritisation, inspections performed at farm level are based on criteria that do not match those usually retained for feed ban controls. The target of yearly inspections set up by the NFCP for FeBOs using derogated PDA is not met; moreover, other FeBOs (not using PDA) are inspected at random.

Therefore, official controls (inspections and sampling) are not fully performed on the risk-basis required by Art. 3 of Regulation (EC) No 882/2004. Moreover, there are regions where the adequate control activities required by Point F of Annex IV to Regulation (EC) No 999/2001, in particular inspections, are still not in place.

## **5.6 LABORATORY NETWORK**

### *5.6.1 Sampling and laboratory testing for BSE*

#### **Legal requirements**

Art. 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. Art. 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***

There are ten laboratories performing BSE rapid test (six official and four private, attached to slaughterhouses), all of them using the Bio-Rad TeSeE rapid test. The National Laboratory for Veterinary Investigation (LNIV), which is the national reference laboratory (NRL), is the only laboratory accredited (since 16 January 2009); this accreditation covers rapid tests, histopathology, immunohistochemistry and Western blot. Private laboratories are authorised by the NRL, after the concerned staff is trained; OVs of the slaughterhouses are responsible for overseeing the result of rapid tests.

The mission team noted that:

- The NRL organised ring proficiency tests in 2007 and in April 2009 (the results of the latter test were not yet available). In 2007 one private laboratory did not pass the ring test (only one weak positive sample); staff from this laboratory were further training and succeeded in the second round of the ring test.
- Private laboratories are supposed to be audited by the NRL every year, however in 2008 only one of these laboratories was audited by the NRL; the CAs note that this was due to the workload derived from the routine testing and accreditation activities.
- According to the CCA, if the result of a rapid test carried out in one laboratory is positive or inconclusive, the sample has to be sent to the NRL for repetition of the rapid test (this is independent of the confirmation of the rapid test). Moreover the NRL repeats, every year, ten samples randomly taken from each of the laboratories.

## ***Conclusions***

The requirements laid down by Artt. 19 and 20 and Annex X to Regulation (EC) No 999/2001 were satisfactorily met.

### *5.6.2 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 CAs 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 ring trials.

#### ***Findings***

Two laboratories perform microscopic analysis for the detection of constituents of animal origin in feed: the LNIV, which has also been designated as NRL, and the Regional Veterinary Laboratory Angra in *Açores*.

The mission team noted that:

- According to the CCA, both laboratories use the Community method referred to in Directive 2003/126/EC. However, none of them have yet received accreditation for this method.
- The LNIV has participated in a ring proficiency test organised by the Community Reference Laboratory in 2008 and in two inter-laboratory proficiency tests organised in 2006 and 2007. Overall, a very good level of performance was reported, including a faultless set of answers for all blind samples received in the frame of the 2008 proficiency test.

- RVLA participated in one proficiency test organised by LNIV in 2008 and in two other tests organised by the Danish plant directorate and the Dutch NRL in 2007 and 2008. All tests were passed with faultless results for all samples analysed.

### **Conclusions**

The arrangements required by Point F of Annex IV to Regulation (EC) No 999/2001 are in place and there is evidence that laboratories carrying out analyses for official controls on the total feed ban perform their tasks competently.

## **5.7 ORGANIC FERTILISERS AND SOIL IMPROVERS**

### *5.7.1 Production*

#### **Legal requirements**

Regulation (EC) No 181/2006 lays down a number of requirements for the production of OF/SI.

Art. 19 of Regulation (EC) No 1774/2002 lays down that processed animal proteins (which are defined in Annex I (No 42) as proteins derived entirely from Category 3 material which have been treated in accordance with Chapter II of Annex VII so as to render them suitable for various purposes, including their use in OF/SI) have to be processed in accordance with its Annex VII; in particular, point A.1 of Chapter II of Annex VII prescribes the application of processing method 1 to mammalian processed animal proteins. Moreover, points 10 to 13 of Chapter I of Annex VI lay down procedures for the marking of Category 2 processed products.

#### **Findings**

The relevant recommendations of report 2008/7986 concerned the processing method used for the production of OF/SI as well as the marking of processed ABP used in such products. In response to these recommendations, the CCA stated that official controls would be performed to verify compliance.

There are 11 Category 2 processing and five Category 3 processing plants involved in the production of processed ABP that are subsequently used as OF/SI. Twelve of them process ABP of poultry origin and the remaining ones process mixed material, including material of ruminant origin in some cases.

In 2008, the overall quantity of OF/SI produced was estimated at 45,759 tonnes, 15,979 of which were exported to third countries.

The mission team noted:

- The layout, infrastructure and equipment of the approved processing and technical plants visited were largely in line with the requirements of Regulation (EC) No 1774/2002.
- The marking of Category 2 ABP with Glyceroltriheptanoate (GTH) was in place in all the processing plants visited. However, most of them had not performed, by means of analysis, a determination of the concentration of GTH effectively achieved in all processed products.
- Own-controls performed by operators included the verification of compliance with microbiological standards referred to in Regulation (EC) 181/2006 and Regulation (EC) No 1774/2002. However, the analysis of five samples per batch was not always performed. In some cases, this shortcoming had been identified during official controls.
- In the processing plants visited, the tests carried to verify the absence of *Clostridium perfringens*, whether for the validation of method 7 or for the purpose of own-controls, were expressed as a count (<10 ufc/g) and not as absence/presence as required by Regulation

(EC) No 1774/2002. This issue had only been recently identified by one DSVR during the implementation of official controls.

- According to the information provided by the CCA, all processed ABP used for the production of OF/SI are either subject to method 1 or, in the case of Category 3 material of poultry origin, method 7. However, in one of the Category 3 processing plant visited, PAP produced from mammalian ABP were subject, according the operator, to method 4 and subsequently exported as OF/SI to third countries; it is noted that Regulation (EC) 1774/2002 requires the use of method 1 for the production of PAP of mammalian origin.
- Although the operator of the above processing plant stated that method 4 was used in this establishment, it could not be demonstrated that the appropriate time-temperature combinations were effectively met (the temperature profile in the continuous cooker had not been verified and the residence time was measured in conditions different to the normal operating conditions). Moreover, a test performed by the operator with manganese oxide resulted in a residence time of 23 min while a minimum of 40 min is required for method 4. This problem had been overlooked during official controls.
- PAP of mammalian origin produced during the validation process of a Category 3 processing plant using method 7 was sent, for a limited period of time, to a technical plant for the production of OF/SI. This situation had been overlooked during official controls.
- In all processing plants visited, there was evidence of corrective action taken when processing parameters were not met. In one of them, reprocessing of Category 2 ABP was occurring on a daily basis. This was due to the fact that some of the cookers using method 1 were not airtight and therefore it could take up to three cooking cycles before an absolute pressure of 3 bars was reached for 20 min. Although there was evidence of reprocessing of batches, there was no evidence of corrective actions taken as regards the equipment. No maintenance programme was present in the Hazard Analysis and Critical Control Points (HACCP) plan.

### ***Conclusions***

There are some requirements for the production of ABP used in OF/SI, as laid down in Regulation (EC) No 1774/2002, that were not met: a) the monitoring and recording system for GTH required by point 11 of Chapter I of Annex VI was not implemented; b) the verification of compliance with the microbiological standards for processed products laid down in point D.10 of Chapter I of Annex VII and in Chapter III of Annex V (method 7) was not always performed; and c) not all PAP from mammalian origin intended to be used as OF/SI was subject to method 1 as it is required by point A.1 of Chapter II of Annex VII.

In addition, in some plants it could not be demonstrated that the processing method used was one of those laid down in Chapter III of Annex V to the said Regulation.

#### *5.7.2 Placing on the market and use*

### ***Legal requirements***

Regulation (EC) No 181/2006 lays down a number of requirement for the placing on the market, export and transit, and use of OF/SI. In particular, Art. 6(1) establishes that the special grazing restrictions set out in part IV of its Annex shall apply where OF/SI are applied to land, and Art. 6(2) lays down that processed products derived from the processing of ABP shall not be applied as such directly to land where farmed animals might have access.

Chapter 10 of Annex II to Regulation (EC) No 1774/2002 lays down requirements for the commercial documents to be used during transportation of processed ABP, including those which



might be used for the production of OF/SI.

### ***Findings***

The relevant recommendations of report 2008/7986 concerned the commercial documents used for OF/SI, and the measures to ensure that OF/SI can not be used on land where animals might have access. In response to these recommendations, the CCA stated that provisions would be put in place.

Only one company has been given by the DGV an authorisation to act as an intermediary for the supply of MBM to farms. At the time of the mission, there were six farms (all located in the same region) which were still receiving bulk MBM to be used as OF/SI (there were around 100 such farms in 2008); one of the farms also keeps animals. Before being spread, MBM had to be mixed with manure; according to representatives of this company, there are plans for building a technical plant that would ensure the mixing of MBM with manure before its delivery to farms.

A joint ministerial order (see 5.7.3) introducing some requirement for the use of OF/SI was signed during the mission. In March 2009, a meeting between the CAs and representatives of the company involved in the supply of MBM to farms took place and anticipated the requirements set in the joint ministerial order, in particular that the MBM had to be completely spread on the day of delivery, once it had been mixed with manure, with the obligation made to the supplier to witness the application before being allowed to leave the premises.

The mission team noted that:

- In October 2008, the DGV issued a circular letter prohibiting the direct supply of Category 2 or 3 MBM to be used as OF/SI to individuals, including farmers. All the processing plants visited were aware of this prohibition and had complied with it.
- OF/SI containing Category 2 and 3 processed ABP are made of a mixture of ingredients which varies but always comprises manure. In most cases, a composting process is involved in the production of OF/SI.
- Documents accompanying OF/SI included the statement required by Regulation (EC) 181/2006 as regards the grazing restrictions. Commercial documents accompanying MBM used as OF/SI indicated the farms of destination. However, the nature and the methods of the treatment applied were not mentioned; this information is not included in the national template for ABP commercial documents.

### ***Conclusions***

There are provisions in place to ensure that derived products from the processing of ABP are not applied as such on land to which animals might have access. Placing on the market is performed in compliance with the requirements of the Annex to Regulation (EC) No 181/2006. However, the commercial documents accompanying processed ABP do not contain all the information required in Chapter X of Annex II to Regulation (EC) 1774/2002.

#### *5.7.3 Official controls*

### ***Legal requirements***

Art. 26 of Regulation (EC) No 1774/2002 requires CAs to carry out official controls at regular intervals at approved ABP plants. Art. 9(1) of Regulation (EC) No 181/2006 lays down that the CAs shall take the necessary measures to ensure compliance with the said Regulation; in particular, Art. 9(2) requires CAs to carry out controls at regular intervals to land where organic fertilisers and soil improvers are applied and to which farmed animals might have access. Artt. 8(1) and 9 of Regulation (EC) No 882/2004 introduce, respectively, requirements for the existence of

documented procedures for official controls and for drawing up reports following their performance.

### ***Findings***

The relevant recommendations of report 2008/7986 concerned the implementation of official controls on the use of OF/SI. In response to this recommendation, the CCA stated that official controls would be performed.

In March 2009, the DSHPV circulated an instruction requesting the DSVR to perform a round of inspections to all approved processing plants with a particular emphasis on the destination of Category 2 and 3 MBM placed on the market; a checklist was attached. Another instruction issued by the DSHPV provided for official samples to be taken by the DSVR on processed ABP. This was requested as part as the validation of processing plants, following a recommendation made by the internal audit unit. In the meantime, the DSHPV announced that it would perform inspections to all technical plants producing OF/SI.

As regards official controls over the use of OF/SI at farm level, a joint ministerial order was signed during the mission according to which the DRAP should bear this responsibility. In March 2009, a coordination meeting between the DGV, MADRP and representatives of the company involved in the supply of MBM to farms took place and anticipated the requirements set in the joint ministerial order. According to this agreement:

- A prior authorisation to use MBM as OF/SI must be issued by the DRAP in charge of the farms of destination; the authorisation is based on an application that contains, in particular, information about the number of animals kept, if any.
- A notification to the DRAP of destination is required 48 hours before the delivery of MBM to farms.
- The DRAP must perform inspections to witness the conditions of application of the MBM received and to verify that animals can not access the land on which the spreading took place.

The mission team noted that:

- Concerning official controls on the production of MBM used in OF/SI, see 5.7.1.
- OVs in charge of the slaughterhouses visited were also performing controls on the attached processing plants. In most cases, they could demonstrate that regular checks were performed on processing parameters, hygienic conditions, documentation and results of operators' own-checks.
- Evidence of official controls performed by the DSVR, following the request from DSHPV, was available for all processing plants supplying MBM for the production of OF/SI. In addition, the DSVR had performed regular inspections as part of their official control plan.
- The DPVH has carried out a round of inspections to all approved technical plants involved in the production of OF/SI. As part of these inspections, some information was collected on the suppliers of MBM, the clients for OF/SI, the types of packaging and the technology (including ingredients) used for their manufacture. The presence of registers, commercial documents and appropriate labelling was checked.
- Validation of all approved processing plants visited was being performed by DSVR. There was evidence of official samples taken and analysed for the verification of microbiological standards of processed ABP.
- During the mission, it was confirmed that the requirements agreed between the DGV and DGRAP for the use of MBM as OF/SI were implemented. The DRAP has requested similar arrangements for the supply of bulk OF/SI containing MBM that were dispatched from an approved technical plant to two farms.

- The use of OF/SI dispatched to farms in bags or big-bags was not subject to any official controls, in particular to ensure that animals can not access the land on which OF/SI have been spread.

### ***Conclusions***

There are regular official controls performed at processing plants producing MBM subsequently used at OF/SI. These controls now include sampling of processed ABP. However, the official controls required by Art 26 of Regulation (EC) No 1774/2002 overlooked a number of significant requirements in some cases.

As regards the use of OF/SI, a workable system has been devised for checking that animals can not have access to the land on which this MBM mixed with manure is applied. However, this system does not cover the use of OF/SI in big-bags or bags. This is not in line with the provisions of Art. 9 of Regulation (EC) No 181/2006.

## **5.8 ACTIONS TAKEN IN CASE OF NON-COMPLIANCE**

### ***Legal requirements***

Art. 54 of Regulation (EC) No 884/2002 requires CA, when non-compliance is identified, to take action to ensure that the operator remedies the situation. Art. 55 of the said Regulation establishes that rules on sanctions applicable to infringements shall be laid down and implemented; these rules must be effective, proportionate and dissuasive.

### ***Findings***

The relevant recommendations of report 2008/7986 concerned the legal basis to enable the CA to take actions when requirements for the use of OF/SI are not met. In response to this recommendation, the CCA stated that legal provisions would be introduced shortly.

The mission team noted:

- The joint ministerial order signed during the mission provides a legal basis for imposing corrective actions and sanctions in case of non-compliance with the requirements laid down for the use of OF/SI.
- Corrective actions had been requested following the detection of non-conformities in processing plants visited. In one case, on the grounds that recording devices for processing parameters could be faulty, restrictions were imposed on the placing on the market of processed products. However, in one region, important delays were noted between the inspections and the notifications to the operators of the outcome of the inspections (five weeks on average). According to the head of the DSVR, this situation arose from the procedures followed for drafting and signing letters.

### ***Conclusions***

Legal basis are in place for requesting corrective actions and imposing sanctions in case of non-compliance with the rules applicable to the production and use of OF/SI, and examples exist where these rules have been used. Therefore, the requirements of Artt. 54 and 55 of Regulation (EC) No 882/2004 were largely complied with.

## **6 OVERALL CONCLUSIONS**

BSE monitoring was largely satisfactory, with the exception of fallen animals, an important number

of which are still not sampled and tested. However, in two cases there were significant delays in the implementation of movement restrictions following the detection of suspects. SRM controls were largely satisfactory.

Progress has been made since the previous mission concerning feed ban controls and targets set by the control programme have been met; however, controls did not yet cover the entire country, and they were affected by deficiencies in the design and implementation of a risk based approach.

Progress has been also made concerning OF/SI, although there were some weakness in their production. Nevertheless, official controls on the use of OF/SI have been satisfactorily reinforced, although they did not cover yet the use of non-bulk OF/SI.

## 7 CLOSING MEETING

A closing meeting was held on 20 May 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, and noted the following:

- Measures would be put in place to address the shortcomings identified with respect to head meat harvesting.
- Measures would be taking for the identification of holdings keeping ruminants and non-ruminants.
- They intend to improve the database supporting the sampling of animals slaughtered for human consumption.
- Controls over the use of packed OF/SI could be performed during feed ban controls at farms and DSHPVs and the DAA will liaise about farms using MBM as OF/SI.
- Actions will be taken to validate the methods used in the Category 1 processing plants
- The cases where the imposition of movement restrictions was delayed were exceptional.

During the meeting, additional information requested by the mission team was provided by the CCA.

## 8 RECOMMENDATIONS

N°.	Recommendation
1.	To clarify the responsibilities for official controls over packaged OF/SI, as laid down by Art. 4.1 of Regulation (EC) No 882/2004, and to ensure that the official controls required by Art. 9 of Regulation (EC) No 181/2006 are organised, as appropriate, at this level.
2.	To ensure that the requirements laid down by Art. 4.3 and 4.5 of Regulation (EC) No 882/2004 for coordination and cooperation are complied with, notably concerning BSE eradication, official controls on OF/SI and feed ban controls.

N°.	Recommendation
3.	To include the validation of processing plants operating continuously in the organisation of training required by Art. 6 of Regulation (EC) No 882/2004.
4.	To ensure the undertaking of the internal supervision of official controls on the total feed ban, as required by Art. 8.3 of Regulation (EC) No 882/2004.
5.	To make progress in the sampling of fallen animals, in order to meet the requirements of Annex III to Regulation (EC) No 999/2001.
6.	To ensure that the available data can support that the sampling of animals slaughtered for human consumption is carried out as requested by Annex III to Regulation (EC) No 999/2001.
7.	To take action to ensure that the movement restrictions required by Art. 12 of Regulation (EC) No 999/2001 following the detection of BSE suspects are implemented in a timely fashion.
8.	To draft the list of farms using milk replacers containing fishmeal as required by point II(BA)(g) of Annex IV to Regulation (EC) No 999/2001.
9.	To take account of all identified risks for the organisation of feed ban controls as laid down in Art. 3 of Regulation (EC) No 882/2004.
10.	To ensure that the checks referred to in point F of Annex IV to Regulation (EC) No 999/2001, in particular inspections, are performed in all regions of Portugal.
11.	To ensure that the CAs of the place of destination of consignments of Category 1 material are informed of this dispatch as required by Art. 8 of Regulation (EC) No 1774/2002.
12.	To ensure that the official controls required by Art. 26 of Regulation (EC) 1774/2002 at processing plants are reinforced, notably concerning their validation and monitoring of operation.
13.	To ensure that processing plants use the processing methods laid down by Chapter III of Annex V to Regulation (EC) No 1774/2002.
14.	To ensure that processing plants involved in the OF/SI chain carry the verification of compliance with the microbiological standards laid down for processed products as laid down in point D.10 of Chapter I of Annex VII and in Chapter III of Annex V (method 7) to Regulation (EC) 1774/2002.

N°.	Recommendation
15.	To ensure that all PAP from mammalian origin intended to be used as OF/SI are subject to Method 1 as prescribed by point A.1 of Chapter II of Annex VII to Regulation (EC) No 1774/2002.
16.	To ensure that Category 2 processing plants involved in the OF/SI chain implement the monitoring and recording system for GTH required by point 11 of Chapter I of Annex VI to Regulation (EC) No 1774/2002, in particular by performing determinations of GTH concentration in processed products.
17.	To ensure that the commercial documents accompanying processed ABP contain all the information required in Chapter X of Annex II to Regulation (EC) 1774/2002, in particular the nature and the methods of the treatment.

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

[http://ec.europa.eu/food/fvo/ap/ap\\_pt\\_2009-8090.pdf](http://ec.europa.eu/food/fvo/ap/ap_pt_2009-8090.pdf)

## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dec. 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
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. 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. 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
Reg. 181/2006	OJ L 29, 2.2.2006, p. 31-34	Commission Regulation (EC) No 181/2006 of 1 February 2006 implementing Regulation (EC) No 1774/2002 as regards organic fertilisers and soil improvers other than manure and amending that Regulation