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Directorate F - Food and Veterinary Office

DG(SANCO)/8069/2006 – MR Final

FINAL REPORT  
OF A MISSION  
CARRIED OUT IN SPAIN  
FROM 23 JANUARY TO 3 FEBRUARY 2006  
CONCERNING  
BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

*Please note that factual errors in the draft report have been corrected. Clarifications provided by the Spanish Authorities are given as footnotes, in bold, italic type, to the relevant part of the report.*



## **EXECUTIVE SUMMARY**

*This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in Spain, from 23 January to 3 February 2006.*

*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 from bovines, and the prohibition of feeding products of animal origin to farmed animals and exceptions applicable to this ban. The evaluation included measures taken in response to the recommendations made in a previous FVO missions regarding some of the afore-mentioned issues.*

*Overall, the report concludes that some progress was noted since the previous missions, but there are still some deficiencies that need to be addressed.*

*With respect to BSE epidemio-surveillance progress was noted with respect to eradication measures and testing of healthy animals slaughtered for human consumption, but some weaknesses still persist concerning an insufficiently harmonised approach in all the Autonomous Communities (AC) towards notification and ruling out of BSE clinical suspects, provision of guarantees on sampling of all fallen animals and inaccurate classification of animals tested in the other risk sub-populations referred to in Regulation (EC) No 999/2001.*

*In relation to the total feed ban, some progress was noted concerning organisation of the national control programme; however, implementation of targeted controls along the feed chain and prevention of cross-feeding at farm level still varies significantly in the different AC and insufficient controls were done on imported feed materials and on means of transport.*

*Concerning SRM insufficient measures in place can not ensure appropriate awareness of all operators and effective frequent official controls to avoid any contamination in places where SRM is removed.*

*In summary, the CCA were short of sufficient updated data to keep an informed overview of the level of compliance with the BSE monitoring programme as implemented by the AC and the control systems in place still lack an efficient and effective coordination between all CA that can demonstrate and ensure that the feed ban and the requirements on SRM are effectively enforced throughout Spain<sup>(\*)</sup>.*

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

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<sup>(\*)</sup> See footnote <sup>(16)</sup> in page 17 for comments of the CCA to the Overall Conclusion.

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## ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

ABP	Animal by-products not intended for human consumption as defined in Regulation (EC) No 1774/2002
AC	Autonomous Communities
Action plan	Actions announced/undertaken as submitted to the Commission services by the CCA in response to the recommendations made in mission reports 8631/2002 and 7041/2004
AESA	<i>Agencia Española de Seguridad Alimentaria</i> (Spanish Food Safety Agency). One of the CCA
BIPs	Border inspection posts
BSE	Bovine Spongiform Encephalopathy
CA	Competent authorities
CCA	Central competent authorities, the DGG and the AESA
Cross-feeding	Feeding of ruminants with feed intended for non-ruminants
DGG	<i>Dirección General de Ganadería</i> (Directorate General for Livestock). One of the CCA
Fallen stock	Dead on-farm bovines
FVO	Food and Veterinary Office
NRL	National Reference Laboratory, in the sense of Annex X to Regulation (EC) No 999/2001 and Art. 33 of Regulation (EC) No 882/2004
MAPA	Ministry of Agriculture, Fisheries and Food
MAT	Microscopic analytical method for the determination of constituents of animal origin for the official control of feedingstuffs according to Directive 2003/126/EC
PAO	Products of animal origin, in the sense of Art. 7 of Regulation (EC) No 999/2001
Report 8631/2002	Report of a mission carried out in Spain from 14 to 18 November 2002 concerning TSEs
Report 7041/2004	Report of a mission carried out in Spain from 26 to 30 April 2004 concerning the feed ban controls
SGSA	<i>Subdirección General de Sanidad Animal</i> (Sub-directorate General for Animal Health), within the DGG
SGMPG	<i>Subdirección General de Medios de Producción Ganadera</i> (Sub-directorate General for Means of Livestock Production), within the DGG
SRM	Specified risk material as defined in Art. 2 of Regulation (EC) No 1774/2002
Feed ban	Prohibition of feeding PAO to farmed animals and exceptions applicable to this ban, as laid down in Regulation (EC) No 999/2001
TSEs	Transmissible Spongiform Encephalopathies

## 1. INTRODUCTION

The mission took place in Spain from 23 January to 3 February 2006.

The inspection team, which comprised 2 inspectors from the Food and Veterinary Office (FVO), was accompanied throughout the mission by representatives from the two central competent authorities (CCA), the Directorate General for Livestock (*Dirección General de Ganadería* - DGG), from the Ministry of Agriculture, Fisheries and Food (MAPA); and the Spanish Food Safety Agency (*Agencia Española de Seguridad Alimentaria* - AESA) of the Ministry of Health and Consumer Affairs. In the four Autonomous Communities (AC) visited, the mission team was accompanied also by representatives of the two relevant competent authorities (CA), the Regional Ministries of Agriculture and Health.

An opening meeting was held on 23 January 2006 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 AND SCOPE 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<sup>(2,3)</sup>.

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: feed ban).

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

The mission itinerary included the following:

COMPETENT AUTHORITY VISITS			Comments
CA	Central	√	Opening and closing (de-briefing) meetings
	Regional	4	Meetings with the CA of the Autonomous Communities visited ( <i>Asturias, Castilla y León, Cataluña</i> and <i>Extremadura</i> )
	Local	2	Two meetings with two local veterinary authorities. Representatives of several other local veterinary authorities met during the visits to establishments

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(2) Legal acts quoted refer, where applicable, to the last amended version.

(3) 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; OJ L 147, 31.05.2001, p. 1.

<b>LABORATORY VISITS</b>		
TSEs laboratories	<b>5</b>	Meetings with staff responsible for the two NRL responsible for methods of analysis for TSEs and the feed ban and with staff from the relevant regional laboratories in the four Autonomous Communities visited
<b>ESTABLISHMENTS HANDLING ANIMAL BY-PRODUCTS NOT FOR HUMAN CONSUMPTION (ABP)</b>		
Plants processing ABP	<b>3</b>	Two Category 1 processing plants and one Category 3 processing plant producing blood products for use in feed
Animal feed	<b>2</b>	One intermediary for fishmeal and one double stream feed mill authorised to use PAO (fishmeal) producing feed for ruminants and non-ruminants
<b>FOOD PROCESSING ESTABLISHMENTS</b>		
Slaughterhouses	<b>3</b>	Three high-throughput establishments slaughtering cattle
Cutting plants	<b>2</b>	One stand alone and one attached to one slaughterhouse

### **3. LEGAL BASIS FOR THE MISSION AND OTHER RELEVANT LEGISLATION**

The mission 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 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<sup>(4)</sup>.

Other legislation, including implementing measures, was considered during the mission, in particular:

- Regulation (EC) No 1774/2002<sup>(5)</sup>;
- Regulation (EC) No 1760/2000<sup>(6)</sup>.

### **4. BACKGROUND**

The previous missions concerning BSE in Spain were carried out from 14 to 18 November 2002 and from 26 to 30 April 2004 (this, only on feed ban controls), the results of which are described in reports DG(SANCO)/8631/2002 – MR Final (hereafter: report 8631/2002) and DG(SANCO)/7041/2004 – MR Final (hereafter: report 7041/2004). These reports are accessible at

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

The reports made a number of recommendations to the CCA, which subsequently informed the Commission of actions that had been or would be taken aimed at

<sup>(4)</sup> OJ L 191, 28.05.2004, p. 1.

<sup>(5)</sup> 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; OJ L 273, 10.10.2002, p. 1.

<sup>(6)</sup> 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; OJ L 204, 11.08.2000, p. 1.

addressing the recommendations made (hereafter: action plan). Where appropriate, both the relevant recommendations and the action plan are outlined under the relevant parts of Section 5.

## 5. MAIN FINDINGS

### 5.1. COMPETENT AUTHORITIES

Under the Spanish Constitution, the 17 autonomous communities, and the two autonomous cities, have the principal responsibility for the operation of control systems in Spain. It attributes, however, the State the exclusive powers regarding establishing the bases and guarantee co-ordination of all the measures in the areas of public health and animal health. Responsibilities of the CCA are, therefore, the preparation of national legislation, the coordination of the activities of the AC and application of import controls, including those on feedingstuffs.

In summary, distribution of responsibilities at central level is as follows:

- With respect to epidemio-surveillance of BSE, the Sub-directorate General for Animal Health (*Subdirección General de Sanidad Animal - SGSA*), within the DGG, is responsible for drafting national legislation, providing financing for BSE testing and eradication measures and overall coordination of implementation by the AC of the annual BSE eradication and monitoring programme. The SGSA is the CA submitting to the Commission the annual report concerning the BSE testing and eradication programme in line with Art. 6(4) of Regulation (EC) No 999/2001.
- The Sub-directorate General for Means of Livestock Production (*Subdirección General de Medios de Producción Ganadera - SGMPG*), also within the DGG, is responsible for animal feed, including approval and agreement with the AC of the national control plan for the feed sector and of guidelines for its implementation. Among other things, it must coordinate execution of official feed ban controls by the AC and of import controls on feedingstuffs by staff of the DGG operating in the Border Inspection Posts (BIPs) <sup>(7)</sup>.
- The AESA is the CCA responsible for coordination of sampling by the AC of cattle at slaughterhouses and for controls on removal, staining and handling of SRM. One of its Sub-directorates co-ordinates the annual control programmes and control procedures of the AC, carries out training needs analyses and designs training programmes.

In the AC, implementation of BSE measures is organised through:

- Regional Ministries of Agriculture, which are the CA responsible for BSE eradication measures, passive surveillance, collection and sampling of fallen stock and controls on the feed ban. Direct implementation of these provisions is ensured by territorial veterinary service units subdivided into Local Offices (*Oficinas Comarcales*) or Local Veterinary Units.

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<sup>(7)</sup> *In their response to the Draft report the Spanish authorities noted that the SGMPG is responsible for controls in relation to the feed ban and for other products related to animal feeding and they clarify that responsibility for controls on imports of products of animal origin and intra-Community trade in PAP rests with the SGSA.*

- Regional Ministries of Health, which are the CA responsible for sampling of cattle at slaughterhouses and for controls on removal, staining and handling of SRM. Direct implementation of these provisions is ensured by territorial service units; under which management operate several local units.

To meet their responsibilities, the CCA have set up a number of coordination bodies over recent years to assist in ensuring compliance with EU law and to promote a harmonised and consistent application of EU law across the whole territory of Spain. The coordination bodies involved in control, prevention and eradication of BSE are:

- Concerning BSE epidemio-surveillance, the National Committee for a Veterinary Alert System and the National Committee for the coordinated control programme of TSEs, which convene several times per year representatives of the animal health services of the AC. Both committees have been established in national legislation since 2001 and 2000, respectively. The first one has as its main functions to coordinate and monitor the epidemiological situation of animal diseases and the animal health situation. The second one must monitor and coordinate the implementation of the national control programme of TSEs and propose and give advice to all CA involved on appropriate measures to improve its application.
- With regard to feed ban controls there is a National Coordinating Committee for Animal Feed, which convenes regularly representatives of the SGMPG and the AC. One of its aims is the preparation and approval of the national annual control plan for the feed sector. This Committee has not yet been established in national legislation on feed safety; nevertheless, a draft was presented to the mission team where its formal legal basis is set up and its main functions are defined. Apart from the approval of the national coordinated feed control plan, these will include monitoring and coordinating the implementation of the national feed ban control plan and propose and give advice to all CA involved on appropriate measures to improve its application.
- The National Commission for Animal By-products not for human consumption (ABP) includes, amongst others, representatives from both CCA and the CA in the AC, and it has been established in national legislation since 2003. Some of its functions are setting up proposals to achieve the objectives of legislation and co-ordination and follow-up of the implementation by the AC of provisions on SRM and fallen stock. Several working groups have been established pursuant to these aims, among which one has already prepared a reference document dealing with the handling of fallen stock at farm level and another one, coordinated by the AESA, has produced a draft document dealing with handling of ABP in slaughterhouses.

The mission team noted that:

- Little evidence of meetings carried out by the Committees mentioned above could be provided by the CCA. Minutes or any summary on the evaluations done by any of them demonstrating their regular involvement in the functions described in their legal provisions with respect to BSE control, prevention or eradication could only be seen for meetings of the coordination committee for the feed sector.
- National legislation on BSE, including the feed ban, and controls in the feed sector require that the AC inform regularly the CCA on the progress with the implementation of the BSE monitoring programme and the controls of the feed ban (official inspections and sampling carried out). Hardly any evidence for the



use of this regular feedback for any evaluation or verification of the progress of the respective programmes or of their effective and efficient application by the AC could be presented by any of the CCA or the National Committees mentioned above.

- Both CCA have started preparing for the introduction of audit systems and are participating together with a view to ensuring a global approach to audit. AESA has concluded an agreement with the Regional Ministries of Health of the 17 AC to establish an external audit procedure and prepare and implement a Single Integrated Multi-annual National Control Plan. The DGG has created an internal working group to establish a common audit strategy. A preliminary document was sent to the AC, and the DGG was awaiting their comments. No additional information could be provided on how BSE issues will be audited or if this area will be part of the general audit approach anticipated.

## 5.2. BSE EPIDEMIO-SURVEILLANCE

### 5.2.1. *Passive surveillance*

The mission team noted that:

- General procedures for handling of BSE clinical suspects had been widely circulated from the SGSA in a manual on TSEs surveillance, control and eradication produced several years ago where detailed information was included on their notification, the clinical signs expected for an animal to be considered a BSE clinical suspect, actions to be taken following suspicion and which kind of samples had to be submitted to the relevant laboratory. Many AC had followed suit and had prepared similar manuals for their officials and the veterinary practitioners.
- Representatives of the animal health services in all the AC visited described different approaches towards notification of clinical suspects whereby animals where BSE can not be ruled out are not always considered as such and notified as official suspects or they were not always able to demonstrate how the ruling out of BSE had been applied in practice in such cases. In fact, several cases where BSE could not be excluded had not been considered as clinical suspects, nor were their brains sent to the relevant laboratory to perform *post mortem* examination as part of the system to establish an alternative diagnosis to BSE or to submit them to methods and protocols described in Annex X to Regulation (EC) No 999/2001 for BSE suspects. All these cases had been submitted to BSE rapid tests with a negative result and had been closed without a clear alternative diagnosis (see also 5.5.1).
- A summary of the final diagnoses obtained for bovine animals considered official clinical suspects during 2005 until December (49 with 16 cases confirmed) was provided by representatives of the National Reference Laboratory (NRL) and the authorised laboratories in two of the AC, where evidence was provided on how alternative diagnoses to BSE had been established in those cases where BSE was not confirmed.

### 5.2.2. *Active surveillance*

The mission team noted that:

- Under national legislation notification of dead animals must be done by the owners of the animals within 7 days of these events happening and the central database of the cattle identification and registration system is regularly updated

with input from the regional ones. Data present in the central database as of January 2006 were provided by the CCA with updated figures in relation to notification of dead animals in all AC during 2005. The CCA advised the mission team that reliable data could be only provided later in the year to acknowledge possible delays in notification and the update of the central database with all data from the regional ones. In addition, the CCA stated that it is up to the AC to check that these notifications are done within the legal deadlines.

- Since 2002, 14 out of the 17 AC have in place an insurance scheme to cover the collection and process of fallen ruminants; the percentages of animals under the scheme show a steady increase, and now around 90% of the bovines are covered.
- No summary could be provided by the CCA on the level of existing under-notification of dead cattle in all AC, nor on the percentage of notified animals that had not been sampled or tested; nevertheless, detailed data were provided by the four AC visited <sup>(8)</sup>. In two of them levels of sampling during 2004 had been over 80% of the number of notified animals and in the other two these levels were roughly of 50 and 65%. In three of the AC this problem had been tackled to a major extent during 2005 mainly by imposing severe fines in case of no notification. As a consequence, a higher rate of fallen stock had been sampled and tested for BSE during 2005. Percentages of testing in the two with lower levels in 2004 had risen to around 75 and 80%, respectively. In the other two percentages for 2005 were roughly of 90%.
- Data checked on animals tested in other AC during 2004 as compared with the number of animals notified to the database during 2005 show that, insofar as these data are comparable, in half of them percentages of non-sampled animals in 2004 would range from 20 to 50%. No further evidence was provided to verify that this was not the case during 2005.
- Reasons for not sampling of fallen stock were explained by representatives of the AC visited and were, in general, related to areas where collection and sampling of the animals was difficult due to the orography and weather conditions during winter or to delays in notification during the summer, respectively. Some of them pointed out that some of these areas should have been classified as remote areas in the sense of Annex III to Regulation (EC) No 999/2001, but no agreement was reached with the CCA to present this option to the Commission <sup>(9)</sup>.
- National provisions require that all cattle older than 24 months slaughtered for human consumption are tested for BSE. No evidence was found that any of these slaughtered cattle were not tested for BSE purposes. However, significant discrepancies were observed on how OV in different AC classify sampled animals in line with the sub-populations described in part 1, Chapter A of Annex III to Regulation (EC) No 999/2001. Definitions of animals slaughtered as an emergency and animals found sick at *ante-mortem* inspection, as well as the

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<sup>(8)</sup> *In their response to the Draft report the Spanish authorities reiterated the comments provided to the executive summary and the overall conclusion in relation to the availability of data on the BSE monitoring programme. See footnote <sup>(16)</sup> in page 17.*

<sup>(9)</sup> *In their response to the Draft report the Spanish authorities noted that an explanation was given to the mission team of the constitution of and progress of work by the National Commission for ABP. The work of the ABP Commission's "carcass collection subgroup" currently includes the production of guidelines for coordination by the AC on the designation of remote areas.*

numbers sampled in different AC, were very different and in many cases did not comply with EU requirements mentioned above <sup>(10)</sup>.

### 5.2.3. Supervision

The relevant recommendation of report 8631/2002 concerned the setting up of an effective monitoring system to ensure implementation of the BSE surveillance programme. A review of the procedures in place to carry out this monitoring at both national and AC level was considered necessary in order to enable uniform application and adequate corrective action, where required.

In response to the above recommendations, the CA advised the Commission that the National Committee for the coordinated control programme of TSEs had convened at the end of 2002 and that a manual on TSEs surveillance, control and eradication had been produced, which included information on the monitoring of the surveillance programme.

The mission team noted that:

- For the activities of the coordination committees, please refer to point 5.1.
- Monthly figures of all animals slaughtered and tested for BSE broken down per sub-population are collected by the AC and provided to the AESA, which send then on to the SGSA to prepare the monthly figures provided to the Commission. However, no verification of the reliability of these data was carried out by any of the AC visited or any of the CCA with regards to the appropriate categorisation of animals sent to slaughterhouses that had eventually not been considered healthy and would have fit into any of the risk sub-populations of emergency slaughter, animals found sick at *ante-mortem* inspection or even fallen stock. Representatives of the AESA advised the mission team that efforts will be made to clarify and harmonise this area.
- Insufficient supervision was in place at central level to ensure that all fallen stock are sampled and tested, and cross-checks between animals notified as dead to the central database and those actually tested and notified from the AC were not yet carried out or, if ever done, no indication had been given to any AC on the need to take measures to solve the discrepancies found. Representatives of the SGSA advised the mission team that a new database available for notification from the AC of data on surveillance of animal infectious diseases was already in place and will enhance their options for a better monitoring of the situation.
- The lack of verification underlined above casts doubts on the reliability of data submitted by the SGSA to the Commission in the annual report concerning the BSE testing and eradication programme in line with Art. 6(4) of Regulation (EC) No 999/2001.

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<sup>(10)</sup> *In their response to the Draft report the CA of one of the AC visited provided further clarification and information on classification of the subpopulations of animals slaughtered for human consumption and subjected to BSE testing. They added that OV will be reminded that they must continue to perform the classification in accordance with Regulation (EC) No 999/2001. Furthermore, the CA underline that all bovines aged over 24 months must be slaughtered in authorised abattoirs in this AC, where such slaughter operations are restricted to specific days of the week. In this way, by restricting the slaughter of animals aged over 24 months to specific establishments and specific dates, and by registering these animals in a database, it is possible to guarantee that all bovines aged over 24 months intended to be slaughtered for human consumption are tested. The CA of two other AC visited responsible for this issue noted that all observations made in this respect will be taken into account in the various official control programmes.*

- All CA agreed that the different levels of their services have, in general, enough data available to identify areas suggesting that not all eligible animals are sampled or correctly classified, though their regular and formal use needs additional coordination and organisation <sup>(11)</sup>.

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

The mission team noted that:

- Measures taken following suspicion of BSE were in line with EU requirements.
- The extent and depth of the inquiries made in accordance with Annex VII to Regulation (EC) No 999/2001 seemed to be satisfactory to provide information on the members of the progeny and cohort of the confirmed BSE case.
- Placing under official control of holdings where a BSE case had been confirmed and application therein of eradication measures, including provisions for compensation of the owners, is done in line with provisions laid down in Art. 13 of Regulation (EC) No 999/2001.

### **5.4. TOTAL FEED BAN**

#### *5.4.1. Legal and administrative provisions*

The relevant recommendation of report 7041/2004 concerned improving the way the annual control plan is drawn up in order to allow verification of how the risks and experience are taken into account.

In response to the above recommendations, the CA undertook to a number of actions to enable risks and experience to be taken into account in the design of the control plan for 2005.

The CCA advised the mission team that the AC are requested to draw up a summary of data and assess and justify the results obtained in the previous year's plan. This summary and the conclusions made by each AC while implementing the plan would allow the CCA to make a general assessment of the findings and modify accordingly inspection and sampling procedures for the following year. A preliminary evaluation of these proposals offered the following weaknesses:

- Importantly, it should be noted that the relevant conclusion in report 7041/2004 stated that the way the plan is drawn up at central level does not allow evaluating how the risks are taken into account. The actions proposed by the CCA were more aimed at refining the risk based approach rather than presenting the control plan in such a way that it is clear how the risks and experience have been taken into account.
- The assessment done to substantiate how these new actions and the information available translated into new provisions included in the control plan for 2005 was not auditable or sufficiently detailed to enable any judgement of the reasons behind or their likely effectiveness.

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<sup>(11)</sup> *In their response to the Draft report the CA of one of the AC visited noted that the wording of the bullet points and the heading lead to the conclusion that activities performed by the AC must be supervised at central level. This CA reiterated that the different administrations of the Spanish State are not bound by a hierarchical or supervisory relationship, but only a relationship of coordination and, at the same time, that existing Community requirements do not require there to be a central supervisory mechanism in the MS.*

- The same actions were proposed by the CCA for an analysis of the results of the 2003 plan as a basis for the design of the 2004 plan – the shortcomings noted in report 7041/2004 suggested that application of these actions had not been sufficient to improve the effectiveness of the control plan proposed for 2004.
- Nevertheless, the mission team acknowledges that account had been taken in the preparation of the national control plan for the feed ban of many of the recommendations of the Commission on the co-ordinated inspection programme in the field of animal nutrition for 2005<sup>(12)</sup>.

A list of establishments availing of derogations for storage or use of derogated products of animal origin (PAO) as laid down in Annex IV to Regulation (EC) No 999/2001 was provided to the mission team by the SGMPG.

In addition, the mission team noted that:

- A database is available to all CA carrying out official controls in the feed sector where information on all establishments authorised and registered in this area is included. One of the objectives of this initiative was to improve the level of coordination between all CA concerning planning and implementation of official controls in the feed sector. No specific example of how this information was used in the regular organisation of feed ban controls could be described by any CA and limited use of it by OV met was seen in the AC, whether they were responsible for planning or implementation of these controls in their territories.
- The national control plan for the feed sector assigns each of the AC a minimum number of inspections and samples to be performed in relation to feed ban controls. These totals may be increased further within the AC to take account of the local situation. Another specific programme describes in a similar way the basis and number of import controls and sampling activities to be carried out by staff at the BIPs.
- Organisation of control plans by the AC was done following the guidance of the national plan agreed with the SGMPG, but precise account of how criteria included therein had been weighted and how particular risks present in each region had been taken into account was not formalised in all of them. Again, the plans organised by the AC assign each of the local veterinary units or each of the OV responsible for these controls a minimum number of inspections and samples to be performed.
- Distribution of responsibilities concerning these official feed ban controls in the AC varied between them; in some AC a dedicated team of OV was responsible for their implementation and, in general, they have received specific training on the feed sector and could explain to some extent how to distribute their inspection and sampling activities following a risk-based approach; however, this has not been formalised in any document accounting for the planning and risk-targeting done.
- In other AC, and particularly as regards feed controls carried out at farm level, OV deployed in the local veterinary units add to their daily official controls those on the feed sector and, in particular, inspections and sampling for the feed ban. In

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(12) Commission recommendation 2005/187/EC on the coordinated inspection programme in the field of animal nutrition for 2005 in accordance with Council Directive 95/53/EC; OJ L 62, 9.3.2005, p. 22.

these cases the level of training was, in general, not enough to guarantee targeting of risks related to cross-contamination or cross-feeding.

- Some of the AC expressed their concerns in relation to the usual delays occurring before the annual control plan is agreed upon and circulated for its implementation because when this normally happens is often too late to reorganise their already ongoing own control plans.

#### 5.4.2. *Implementation of official controls and supervision*

The relevant recommendations of report 7041/2004 concerned compliance with provisions laid down in Annex IV to Regulation (EC) No 999/2001 on adoption of a systematic approach to ensure compliance with the controls on cross-feeding and on authorization of all relevant mobile mixers availing of derogations contained therein.

In response to the above recommendations, the CCA advised the Commission that there were no mobile mixers in Spain availing of any derogation for the use of derogated PAO. The CCA added that in order to tighten the level of control, they had introduced a requirement for the AC to supply quarterly data from inspections and controls carried out on holdings and to ensure that those data are expressed in terms of the specific criteria of the coordinated programme of animal feed controls.

The mission team noted that:

- Derogations on blood derivatives and blood meal as set out in Annex IV to Regulation (EC) No 999/2001 are being already applied in some AC without ensuring in all cases compliance with requirements on dedication of establishments producing and processing blood and feed mills using these products. Examples of the weaknesses found were:
  - A slaughterhouse that slaughtered several species including ruminants that was supplying pig blood to a processing plant producing blood products and which has not been approved and listed for such activity,
  - A feed mill using blood products and producing in a separate line feedingstuffs for ruminants, which had not yet been authorised or listed for that purpose, but only for the use of fishmeal,
  - Another feed mill which had been authorised to start using blood products without having been visited by the CA to verify that legal requirements to prevent risks of cross-contamination had been observed.
- Controls to ensure that all general implementing conditions laid down in part III of Annex IV to Regulation 999/2001 are complied with concerning dedication and cleaning of storing facilities and prevention of cross-contamination in means of transport were very rare in the AC visited. Only in one of the AC there was an initiative to be introduced shortly during 2006 that will increase significantly the level of control imposed on means of transport participating in the feed sector.
- Confuse data were provided by the CCA on how many samples had been drawn during 2005 from consignments of fishmeal before they had been released for free circulation in the Community. These data indicate that not all consignments of fishmeal have been sampled as required by provisions laid down in Annex IV to Regulation (EC) No 999/2001.
- Plans drawn up for controls to be carried out during 2005 on imported feed materials had not been implemented accordingly by the BIPs. No flow of information on imported consignments of feed materials of non-animal origin and

the import checks carried out on them was observed between the CA involved in feed ban controls. Few data on physical checks carried out on these consignments were available for evaluation by the mission team and they show that for all imported consignments of feed materials, only five samples had been taken at the BIPs during 2005. Representatives of the SGMPG advised the mission team that more samples had been taken, but they had not been notified from the BIPs.

- Implementation of the planned number of official inspections and sampling activities varied between AC. An overall summary provided by the SGMPG shows that data sent from the AC on the number of inspections carried out would be much higher than the minimum targets allocated; however, many of them had been done in farms as part of other controls and, as checked in the AC visited, their actual focus on feed ban issues was very difficult to verify. Only in two of the AC visited some targeting had been done in relation to farms keeping ruminants. Minimum targets for inspections in establishments had not been achieved and, again, the content and nature of these controls were not verifiable in all cases.
- Concerning implementation of sampling, data show that targets have not been achieved for establishments in some of the regions and taking of samples in farms had mostly not been decided upon following any risk-targeting to visit farms where cross-feeding could be at stake.
- Some of the AC visited could not demonstrate that home compounders storing/using fishmeal or other PAO that had not been specifically authorised for that purpose do not keep ruminants or produce feedingstuffs for use only in the same holding. In addition, lack of information available on the presence on then of ruminants did not allow the AC to identify which farms posed the greatest risk as far as cross-feeding was concerned to target feed ban controls. In addition this targeting was not considered a priority in all AC and in one AC not all these farms are registered.
- No data were available to the SGMPG or in any AC on how many farms using compound feeding stuffs that could contain derogated PAO could keep together ruminants and non-ruminants. As a consequence, not enough guarantees could be provided on systematic controls ensuring that these farms have satisfactory procedures in place to prevent cross feeding.
- In several AC, circulation of fresh Category 3 ABP containing ruminant material and rendered fats produced in processing plants receiving it, which are destined for use as feed material, were not accompanied with commercial documentation that complies with provisions laid down in Chapter III of Annex II to Regulation (EC) No 1774/2002 on specification of the species of origin of the material. Moreover, verification that these fats had been purified with official testing of the level of remaining total insoluble impurities present in these rendered fats or its regular check within the own-control programmes in the processing plants were not often applied or not done at all.

## **5.5. LABORATORY NETWORK**

### *5.5.1. BSE diagnosis*

The relevant recommendation of report 8631/2002 concerned the urgent review of the system for authorisation of the laboratories involved in BSE epidemio-surveillance to ensure that minimum requirements for their performance were met. This review should include consideration of provisions prepared by the Community Reference Laboratory as the basis for the adoption of a general procedure of

approval and verification of these laboratories in Spain. In addition, the NRL should organise ring tests to verify the performance of confirmatory tests by all laboratories approved for the diagnosis of suspects of BSE.

In response to the above recommendations, the CCA advised the Commission that initial consideration had been given to the possibility for the NRL to carry out visits to evaluate the capability of the other laboratories authorised to deal with BSE suspect cases, but this was finally not implemented. Nevertheless, staff of the four other laboratories carrying out histopathology, immunocytochemistry or immunoblotting had been trained by experienced staff from the NRL.

Since January 2006 the former NRL for rapid tests became the only NRL for TSEs in the sense of Annex X to Regulation (EC) No 999/2001.

The mission team noted that:

- Ring tests had been organised for the past years including different rapid tests and including the participation of all the laboratories responsible for the use of rapid tests from the AC. No mayor problem had been found. In addition, supervision of the performance of the four other laboratories carrying out histopathology, immunocytochemistry or immuno-blotting had been done by the former NRL for confirmatory tests without any mayor problem found with the sensitivity of their diagnoses.
- The NRL has participated with success in several ring tests organised by the Community Reference Laboratory for TSEs to evaluate the performance of rapid tests in the NRL of the Member States.
- Appropriate deadlines had been established for the results of the rapid tests to be transmitted to the parties interested and no major problem was found in any AC with this issue.
- The NRL is not accredited yet for the performance of BSE diagnosis. Accreditation had been requested in January 2006 and its granting is anticipated for early 2007. Some of the laboratories in the AC had been accredited for the performance of BSE rapid tests and some other had their accreditation files in process of being evaluated.
- The NRL did not have much information on the quality of the samples received and analysed with rapid tests by the laboratories in the AC. No harmonised approach was seen concerning the level of quality acceptable in relation to the presence or not of the brain stem in the samples submitted to rapid tests and no initiative had been introduced in any laboratory, including the NRL, to evaluate the possible lost of sensitivity that this could imply. Nevertheless, in some of the laboratories information was kept on the number of samples not analysed due to their bad quality. The mission team learnt that this could be of significance for samples taken from fallen stock during the summer in the AC more to the South of Spain. Representatives of the NRL acknowledged this problem and advised the mission team that verification of the quality of the samples entering BSE testing will be introduced shortly.
- Despite the existence of a specific manual prepared by the SGSA and the NRL describing how to deal with the flow of samples in order to ensure the proper confirmation of any BSE suspect, several different interpretations were seen in the AC visited; in particular concerning:
  - The type of material collected in case of BSE clinical suspects (hardly if ever the whole brain),



- The use of rapid tests to exclude the presence of BSE in a clinical suspect,
  - Inconclusive results of rapid tests not sent for confirmation to the NRL as requested by the manual or,
  - Not using histopathology as a test of reference for the confirmation of a BSE suspect when the sample was not autolytic.
- Representatives of the NRL advised the mission team that a new manual was about to be sent to all the laboratories and that a coordinating meeting had just been held with them to explain the new procedures to be followed by the new NRL.

#### 5.5.2. *Analyses for the control of the total feed ban*

The relevant recommendations of report 7041/2004 concerned:

- Taking appropriate actions to ensure that the repetition of the microscopic analytical method for the determination of constituents of animal origin for the official control of feedingstuffs (MAT) strictly follows EU provisions and no confirmatory test is necessary once any presence of forbidden PAO is detected.
- To take measures to ensure that the outcome of the ring-tests of MAT are effectively communicated to the relevant CA in the AC in order to ensure that the performance of the laboratories is taken into account when assessing the results of the control plan and when designating the feed laboratories.

In response to the above recommendations, the CCA undertook to amend national provisions on the evaluation of MAT results to bring them totally in line with EU requirements and to communicate the results of the ring tests performed by the NRL for MAT to the relevant CA in the AC.

The mission team noted that:

- Both recommendations have been appropriately addressed. The legal basis for the change of interpretation of MAT was about to be published and all CA had been informed of this change, which had been already adopted and implemented by all of them.
- Regular ring tests are organised annually by the NRL for feed controls with the participation of all laboratories performing MAT in the AC. No significant problem had been found for the last two years.
- Appropriate deadlines had been established for MAT results to be transmitted to the parties interested and no major problem was seen in any AC with this issue.
- Accreditation of the laboratories with respect to MAT is ongoing in all AC, but no specific deadline could be provided for their final granting.

## 5.6. **SPECIFIED RISK MATERIAL**

The relevant recommendation of report 8631/2002 concerned making the overall control on SRM more efficient, ensuring adequate staff and a more systematic recourse to the reconciliation exercise in the whole chain of control.

In response to the above recommendation, the CA undertook to deal with these issues in the framework of national legislation and implementing initiatives introduced to comply with Regulation (EC) No 1774/2002.

Additional information can be found in reports DG(SANCO)/7248/2004 – MR Final and DG(SANCO)/8088/2006 – MR Final, which evaluate implementation of health rules on ABP. These reports are accessible at

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

Additional administrative provisions had been taken in view of the recent changes in Annex XI to Regulation (EC) No 999/2001 concerning removal of vertebral column from animals older than 24 months.

The mission team noted that:

- Limited awareness was still found among many operators and OV concerning management of the specific hazards and risks associated with the inadequate removal of SRM and the possible contamination with nervous tissue of head meat harvested for human consumption.
- Some deficiencies were still found in several of the slaughterhouses visited concerning removal of spinal cord and verification that remnants of this tissue were not present in carcasses of animals older than 12 but younger than 24 months. Stamping of several carcasses released for human consumption from animals of this age range did not guarantee that all SRM had been removed.
- Appropriate authorisation and listing had been carried out in the AC visited of establishments other than slaughterhouses where SRM is removed or head meat harvested; however, limited progress have been made in all AC to ensure that operation instructions and sampling programmes ensure compliance with requirements on harvesting of head meat from bovines older than 12 months. Only in one of the slaughterhouses visited the operator had carried out, on his own initiative, some trials to evaluate the level of contamination with nervous tissue that this practice could imply.
- In all establishments visited the low frequency and very superficial implementation of official controls to verify compliance with provisions on SRM and harvesting of head meat were insufficient to guarantee that measures put in place by the operators and their application were effective to prevent contamination of edible material with SRM.
- Verification of the amounts of SRM produced and dispatched for destruction was, in general, hardly ever seen to be done by OV in the establishments or by other officials responsible for further verification of their daily controls and supervision of the flow of SRM downstream in the ABP chain.
- Several AC advised the mission team that plans for the introduction of verification audits including controls on SRM were in place, but still waiting for further guidance from the National Commission for ABP before their operation starts.

## 6. CONCLUSIONS

### 6.1. COMPETENT AUTHORITIES

1. Sufficient administrative and organisational resources were in place for the CCA to bring together all CA involved in control, prevention and eradication of BSE, but their utilization was inadequate to guarantee their efficient and effective coordination <sup>(13)</sup>.
2. Insufficient procedures were in place to verify compliance with the BSE monitoring programme as implemented by the AC and the effectiveness of official control systems in place to demonstrate and ensure that restrictions and general obligations related to the feed ban and the requirements on SRM are enforced <sup>(14)</sup>.

### 6.2. BSE EPIDEMIO-SURVEILLANCE

3. Some progress was noted from the previous mission, in particular with respect to compliance with eradication measures and testing of healthy animals slaughtered for human consumption.
4. General instructions and operational procedures are in place as regards BSE passive surveillance, but some weaknesses still persist concerning an insufficiently harmonised approach in all the AC towards notification and ruling out of BSE clinical suspects in line with provisions laid down in Articles 3(h) and 12(2) of Regulation (EC) No 999/2001.
5. Insufficient use of data available on notification, sampling and testing of all fallen stock in all AC during 2004 and 2005 prevent verification by the CCA of the appropriate enforcement of all provisions laid down in point 3, Chapter A of Annex III to Regulation (EC) No 999/2001 and do not yet allow for a reliable picture of the BSE active surveillance to be drawn <sup>(15)</sup>.
6. Classification in the appropriate sub-populations of animals slaughtered for human consumption tested for BSE was not harmonised throughout Spain as laid down in point 2, Chapter A of Annex III to Regulation (EC) No 999/2001, which

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<sup>(13)</sup> *In their response to the Draft report the Spanish authorities noted that coordination is sufficiently effective; although there is certainly room for improvement and that they are therefore constantly working towards this. As evidence of this the CCA cited the new epidemio-surveillance manuals, the designation of a single national reference laboratory for TSEs and the implementation and monitoring of the new computerised application to monitor epidemio-surveillance and notification of outbreaks of infectious diseases.*

<sup>(14)</sup> *In their response to the Draft report the Spanish authorities noted that the Spanish Constitution clearly states that the AC are competent in the area of animal health and that coordination is the responsibility of the CCA. In this connection, the monthly submission of epidemiological data and the comparison of these with the previously defined objectives provide an indication of the degree of implementation of the programme.*

<sup>(15)</sup> *In their response to the Draft report the Spanish authorities noted that sampling performed on the subpopulation of fallen stock – some 100 000 animals in 2005, with an increase of nearly 10% on the previous year – allows them to state that surveillance on this subpopulation (without risk to public health) continues to improve year on year. The CCA added that from an epidemiological standpoint the data are more than significant and sufficient, as the Community Reference Laboratory has repeatedly stated in reports. It must also be noted that both the OIE Code and the imminent amendment to Regulation (EC) No 999/2001 indicate that there is no need to check 100% of the members of all of the subpopulations to ensure effective epidemio-surveillance, currently opting for surveillance based on epidemiological models that weight the quantitative value of the sample in accordance with earlier data and the risk analysis.*

prevents an accurate account of the number of animals tested in these risk sub-populations and biases the information submitted to the Commission in the annual report concerning the BSE testing programme in line with Art. 6(4) of Regulation (EC) No 999/2001.

### **6.3. TOTAL FEED BAN**

7. Some progress was noted concerning the addressing of recommendations of the previous mission and the organisation of the national control plan on the feed ban; however, it was still unclear and not auditable how the risks identified and experience gained during implementation of the previous control plan had been taken into account in drawing up the plan for 2005.
8. Sufficient guarantees that all general implementing conditions as laid down in part III of Annex IV to Regulation 999/2001 are complied with could not be provided by the CA, in particular with respect to up-to-date listing of all relevant establishments and dedication and cleaning of storing facilities and means of transport.
9. Implementation of targeted controls along the feed chain and prevention of cross-feeding at farm level can not be considered sufficient to manage the risks identified in the planning stage and still varies significantly in the different AC. In addition, insufficient controls had been done on imported feed materials, on means of transport and on rendered fats used in the feed sector. As a consequence, the CA are not in a position to verify that restrictions on the use of feed materials of animal origin in feedingstuffs are effectively enforced.

### **6.4. LABORATORY NETWORK**

10. An appropriate laboratory network supervised by the NRL was in place; however, some weaknesses still exist with respect to the harmonised handling of BSE diagnosis in clinical suspects, evaluation of the impact that the quality of samples taken could have on the sensitivity of rapid tests used for monitoring BSE in fallen stock and accreditation of all designated laboratories in relation to the tests they perform.
11. Significant progress was done with regard to the reliability and quality operation of the laboratory network set up to perform analyses in the framework of feed ban controls, but accreditation of most of the participating laboratories is still outstanding.

### **6.5. SPECIFIED RISK MATERIAL**

12. Instructions issued and training provided to ensure compliance with all requirements on SRM laid down in Annex XI to Regulation (EC) No 999/2001 are not sufficient to guarantee appropriate awareness of the operators and effective official controls throughout Spain in order to avoid any contamination in places where SRM is removed.
13. Insufficient measures in place concerning coordination and verification of the effective implementation of frequent official controls as regards removal, handling and dispatch of SRM can not guarantee effective enforcement throughout Spain of all requirements laid down in Annex XI to Regulation (EC) No 999/2001.

## 6.6. OVERALL CONCLUSION

Overall, the report concludes that some progress was noted since the previous missions, but there are still some deficiencies that need to be addressed.

In summary, the CCA were not using data sufficiently to keep an informed overview of the level of compliance with the BSE monitoring programme as implemented by the Autonomous Communities and the control systems in place still lack an efficient and effective coordination between all CA that can demonstrate and ensure that monitoring of BSE, restrictions and general obligations on the feed ban and the requirements on SRM are effectively enforced throughout Spain<sup>(16)</sup>.

## 7. CLOSING MEETING

A closing meeting was held on 3 February 2006 with the representatives of the CCA and the AC visited. 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, but they expressed some reservations concerning the overall conclusion, in particular as regards the limited impact, in their view, that the weaknesses identified in relation to BSE epidemio-surveillance and removal of SRM could bear on food safety. During the meeting, additional information requested by the mission team was provided by the CCA.

## 8. RECOMMENDATIONS

The CA are invited to provide details of the actions taken and planned, including deadlines for their completion within 20 working days following the receipt of the translated final report.

### With regard to the CA

1. To further enhance efficiency and effectiveness of coordination between all CA involved in control, prevention and eradication of BSE to ensure compliance with Art. 4(3) of Regulation (EC) No 882/2004.
2. To introduce procedures in line with Art. 8(3) of Regulation (EC) No 882/2004 to verify compliance with the BSE monitoring programme as implemented by the AC and implementation of efficient official controls to demonstrate and ensure that restrictions and general obligations on the feed ban and the requirements on SRM are effectively enforced.

### With regard to BSE epidemio-surveillance

3. To ensure that all cattle displaying symptoms compatible with BSE and for which no alternative diagnosis can be established are considered as official clinical suspects and notified accordingly as required by Art. 3(h) and 12 (2) of Regulation (EC) No 999/2001.

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<sup>(16)</sup> *In their response to the Draft report the Spanish authorities noted that the mission took place in January 2006 and collection of up-to-date information on the BSE monitoring programme up until December 2005 was not possible at this time. They stress that Art. 6(4) of Regulation (EC) No 999/2001 sets the date of 31 March for the submission of epidemiological data from the previous year. The CCA add that the mission team was advised about a Web application (<http://www.rasve.es>) developed and put into place to enable the CA to monitor, in real time, the level of compliance with the BSE surveillance programme, using data supplied by the AC. Finally, the CCA indicate that epidemiological data from 2005 have been available for consultation on [www.eeb.es](http://www.eeb.es) since April 2006.*

4. To ensure monitoring and testing of all fallen stock in line with provisions laid down in point 3, Chapter A of Annex III to Regulation (EC) No 999/2001.
5. To ensure a harmonised approach throughout Spain as regards classification in the appropriate sub-populations of animals slaughtered for human consumption tested for BSE in line with provisions laid down in point 2, Chapter A of Annex III to Regulation (EC) No 999/2001.
6. To enhance the coordination and regular verification of the BSE epidemiological surveillance in order to ensure full compliance with all provisions laid down in Regulation (EC) No 999/2001 to guarantee submission to the Commission of reliable data in the annual report concerning the BSE testing and eradication programme in line with Art. 6(4) of Regulation (EC) No 999/2001.

#### With regard to the total feed ban

7. To provide sufficient guarantees that all general implementing conditions as laid down in part III of Annex IV to Regulation 999/2001 are complied with, in particular with respect to up-to-date listing of all relevant establishments and dedication and cleaning of storing facilities and means of transport.
8. To further enhance the risk-based strategy used to draw up the national plan for controls of the feed ban to bring it more in line with general obligations laid down in Art. 3 of Regulation (EC) No 882/2004 and to render the use of criteria to set priorities and the planned arrangements to be implemented more auditable.
9. To ensure that circulation of Category 3 ABP containing ruminant material whose rendered fats could be destined for use as feed material is accompanied with commercial documentation that complies with provisions laid down in Chapter III of Annex II to Regulation (EC) No 1774/2002 on specification of the species of origin of the material.
10. To have efficient measures in place to verify that implementation of targeted controls along the feed chain, including imported feedingstuffs, means of transport, rendered fats used as feed material and prevention of cross-feeding at farm level can ensure that restrictions on the use of feed materials of animal origin in feedingstuffs are effectively enforced in compliance with Regulation (EC) No 999/2001.

#### With regard to the laboratory network

11. To ensure a harmonised handling of BSE diagnosis in clinical suspects in line with methods and protocols laid down in Chapter C of Annex X to Regulation (EC) No 999/2001.
12. To introduce measures to verify that the quality of samples taken has no significant impact on the sensitivity of rapid tests used for monitoring BSE in fallen stock.
13. To ensure accreditation of all designated laboratories in relation to the tests they perform, whether for BSE testing or feed ban controls, in line with Art. 12 of Regulation (EC) No 882/2004.

#### With regard to SRM

14. To ensure that sufficient instructions are issued and training provided to guarantee appropriate awareness of the operators and effective official controls throughout Spain to avoid any contamination in places where SRM is removed

and to ensure compliance with all other requirements on SRM laid down in Annex XI to Regulation (EC) No 999/2001.

15. To put measures in place to ensure coordination and verification of the effective implementation of frequent official controls as regards removal, handling and dispatch of SRM in order to guarantee effective enforcement throughout Spain of all requirements laid down in Annex XI to Regulation (EC) No 999/2001.
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## ADDENDUM

### RESPONSE OF THE COMPETENT AUTHORITIES TO THE RECOMMENDATIONS

Comments from the Spanish CA on the draft report were received on 31 May 2006, and included additional clarification and an outline of some actions planned and/or undertaken to address certain recommendations contained in the report. These may be summarised as follows:

#### With regard to the CA

1. The CCA advise the Commission that in their opinion all appropriate measures are being taken to attain the objective of effective and efficient coordination in the maintenance of the ban on the use of processed animal proteins.
2. The CCA advise the Commission that the SGMPG has within its programme the tools to be able to make corrections to the programme of controls of the feed ban on the basis of the data obtained, the justification for the controls by the AC, and the risk analyses prescribed as part of the coordinated programme of controls on animal feed.

#### With regard to the total feed ban

8. The CCA advise the Commission that the strategy based on the risks used in the development of the national programme of controls on animal feed for the maintenance of the ban is based on the Commission Recommendation published each year, which has not been amended for 2005 or 2006 in respect of processed animal proteins. This Unit will keep on taking into consideration the data obtained through the rapid alert system at both national and Community level. In order to be able to evaluate whether the programme is being implemented and to take the appropriate corrective action, the list of establishments and holdings required under Regulation (EC) No 1292/2005 has been updated and each AC provides justification for its control programme.
9. The CCA advise the Commission that the commercial document used for the transport of category 3 ABP is in line with Community requirements and that it is also incorporated into the programme of controls on animal feed for the year 2005 and earlier. Nonetheless, the National Commission on ABP is working on a commercial document that is more practical at national level.
10. The CCA advise the Commission that all of the specific comments on aspects detected in the establishments visited by the inspectors have been taken into account so that they can be rectified. In addition, the CCA stress the fact that specific criteria laid down in the national coordinated programme of controls on animal feed specifically identify the holdings where controls in respect of cross-contamination need to be stepped up. Specific justifications provided by the AC to explain the implementation of official controls of the feed ban are being evaluated and will be submitted to the Commission shortly.

#### With regard to the laboratory network

11. The CCA advise the Commission that Regulation (EC) No 1974/2005 establishes the Central Veterinary Laboratory in Algete as the only NRL for TSEs in Spain from 1 January 2006. Since this date the NRL has systematically carried out the three confirmation tests referred to in



Regulation (EC) No 999/2001: histology, IHC and immuno-blotting (Western Blotting).

12. The CCA advise the Commission that a handbook for the collection and submission of samples under the National Programme for the Surveillance and Control of TSEs has been drafted by the NRL and the SGSA in order to improve coordination between the various parties involved in implementing the epidemiological surveillance programme and to establish uniform criteria for collecting samples and sending them to laboratories. In order to improve the quality of samples, a procedure was also established for registration and communication of any irregularities in the samples received at the NRL, so that the competent authorities of the AC could subsequently be informed.

With regard to SRM

14. The CA of one of the AC visited advise the Commission that instructions have been provided to continue carrying out official controls in order to ensure compliance with the requirements in respect of SRM laid down in Regulation (EC) No 999/2001. Regarding the information provided to economic operators, from the start of the implementation of control measures in respect of SRM the main associations of slaughterhouses and cutting rooms have been informed of the instructions and measures adopted to enforce the Regulation. The CA of two other AC visited responsible for this issue advise the Commission that all aspects made in the report will be taken into account in the various official control programmes.
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