FINAL REPORT
OF A MISSION
CARRIED OUT IN HUNGARY
FROM 4 TO 8 JULY CONCERNING
BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)
AND ANIMAL NUTRITION

Please note that factual errors in the draft report have been corrected. Clarifications provided by the Hungarian 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 Hungary, from 4 to 8 July 2005.

The overall objectives of the mission were to evaluate the implementation of certain EU rules:

− to protect against Bovine Spongiform Encephalopathy (BSE) and related issues; and
− to ensure the safety of feed, in particular the organisation of official controls and the arrangements for approval and registration of establishments and intermediaries operating in the animal feed sector.

Within its scope, the mission focused on the measures taken in response to the recommendations made following previous FVO missions addressing the above issues.

Overall, the report concludes that:

− Regarding BSE controls, the system of BSE controls and epidemio-surveillance is largely in place with minor shortcomings detected. Controls on the feed ban are in place but current levels of on-farm sampling for feed ban enforcement are insufficient to ensure no cross-feeding takes place. Controls on SRM are mostly satisfactory, some minor shortcomings were detected.

− Regarding controls in the field of Animal Nutrition, the system in place is largely in line with EU requirements with minor shortcomings detected.

The report makes a number of recommendations addressed to the Hungarian competent authorities, aimed at rectifying the shortcomings identified and further enhancing the implementing and control measures in place.
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Term</th>
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<tr>
<td>ABP</td>
<td>Animal by-products as defined in the ABP Regulation</td>
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<tr>
<td>Action plan</td>
<td>Plan provided by the Hungarian CA in order to address recommendations made by previous FVO missions carried out during the pre-accession period.</td>
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<tr>
<td>AHFCD</td>
<td>Animal Health and Food Control Department, (Állategészségügyi és Élelmiszer-ellenőrzési Főosztály)</td>
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<tr>
<td>BSE</td>
<td>Bovine Spongiform Encephalopathy</td>
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<td>CCA</td>
<td>Central Competent Authority - Animal Health and Food Control Department, (Állategészségügyi és Élelmiszer-ellenőrzési Főosztály) of the Ministry of Agriculture and Rural Development, (Földművelésügyi és vidékfejlesztési minisztérium)</td>
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<tr>
<td>CP</td>
<td>The Hungarian Contingency Plan for the control of TSEs</td>
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<td>CVI</td>
<td>Central Veterinary Institute</td>
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<td>CVO</td>
<td>Chief Veterinary Officer</td>
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<td>E/I</td>
<td>Establishments and intermediaries operating in the animal feed sector</td>
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<td>ENAR system</td>
<td>The national bovine identification and registration system</td>
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<td>FVO</td>
<td>Food and Veterinary Office</td>
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<td>MARD</td>
<td>Ministry of Agriculture and Rural Development, (Földművelésügyi és Vidékfejlesztési Minisztérium)</td>
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<tr>
<td>MAT</td>
<td>Microscopic analytical method for the determination of constituents of animal origin for the official control of feedingstuffs according to Commission Directive 2003/126/EC</td>
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<td>MBM</td>
<td>Meat and Bone meal</td>
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<td>NRL</td>
<td>National Reference Laboratory for feed controls (The Central Laboratory for the National Agricultural Qualifying Institute) - (Országos Mezőgazdasági Minősítő Intézet)</td>
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<td>OV</td>
<td>Official Veterinarian</td>
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<td>PAO</td>
<td>Products of animal origin, in the sense of Art. 7 of Regulation (EC) No 999/2001</td>
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<tr>
<td>SCIVBDF</td>
<td>State Control Institute for Veterinary Biologicals, Drugs and Feeds, (ÁGYTI, Állatgyógyászati Oltóanyag-, Gyógyszer- és Takarmányellenőrző Intézet)</td>
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<tr>
<td>SRM</td>
<td>Specified Risk Materials</td>
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<tr>
<td>Stations</td>
<td>County Animal Health and Food Control Stations. These are the regional authorities in charge of control in the animal health and animal nutrition sectors</td>
</tr>
<tr>
<td>Total feed ban</td>
<td>Prohibition of feeding PAO to farmed animals and exceptions applicable to this ban, as laid down in Regulation (EC) No 999/2001</td>
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<td>TSE</td>
<td>Transmissible Spongiform Encephalopathies</td>
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1. INTRODUCTION

The mission took place in Hungary from 4 to 8 July 2005.

The inspection team, which comprised 3 inspectors from the Food and Veterinary Office (FVO), was accompanied throughout the mission by a representative from the central competent authority (CCA), the Animal Health and Food Control Department, (Állategészségügyi és Élelmiszer-ellenőrzési Főosztály - AHFCD), of the Ministry of Agriculture and Rural Development, (Földművelésügyi és Vidékfejlesztési Minisztérium – MARD).

An opening meeting was held on 4 July 2005 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 objectives of the mission were to evaluate:

a) the implementation of certain protective measures against Bovine Spongiform Encephalopathy (BSE), in particular, the measures put in place to give effect to the requirements laid down in Regulation (EC) No 999/2001 (hereafter: the TSE Regulation)\(^{(1,2)}\);

b) to ensure the safety of feed, in particular, the measures put in place to give effect to:

- EC rules fixing the principles governing the organization of official inspections in the field of animal nutrition, as laid down in Directive 95/53/EC\(^{(3)}\) and associated EU feed legislation;

- EC rules laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector (E/I), as laid down in Directive 95/69/EC\(^{(4)}\) and Directive 98/51/EC\(^{(5)}\).

In terms of scope, the mission concentrated on:

a) active and passive BSE epidemi-surveillance in bovine animals, removal and handling of Specified Risk Materials (SRM), and the prohibition of feeding products of animal origin to farmed animals and exceptions applicable to this ban (hereafter: total feed ban);

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\(^{(1)}\) Legal acts quoted refer, where applicable, to the last amended version.


b) the general elements of the official controls and approval/registration arrangements required under Council Directive 95/69/EC. The mission covered all stages from production to the use of feed for farmed animals.

The evaluation specifically followed up on the actions taken and planned by the CCA in response to recommendations made in previous FVO missions which addressed the above issues.

In pursuit of the above objectives, the following were visited/meetings were held with:

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<th>FEED ESTABLISHMENTS</th>
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<td>Feed Mill</td>
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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:

1. Article 21 of the TSE Regulation.
3. Article 17(a) of Council Directive 95/53/EC.

Other legislation, including implementing measures was considered during the mission, in particular Regulation (EC) No 1774/2002 (7) (hereafter: the ABP Regulation).

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4. **BACKGROUND**

This mission was the first FVO mission concerning BSE and Animal Nutrition since the accession of Hungary to the EU. Prior to accession, the FVO carried out missions in the framework of the accession preparations of Hungary, in order to assist and monitor progress with the adoption of the relevant EU requirements.

5. **MAIN FINDINGS**

5.1. **BSE CONTROLS**

5.1.1. **Competent authorities**

The relevant recommendations made following pre-accession missions referred to:

- ensuring that there were sufficient staff to carry out BSE and other work;
- improving supervision of implementation of BSE controls.

In their action plan produced in response to previous FVO missions (hereafter: action plan), the CCA undertook:

- to organise use of staff efficiently so that several tasks could be carried out at the one farm visit;
- to carry out supervision in line with the national Contingency Plan for Transmissible Spongiform Encephalopathies (TSE).

The comprehensive Contingency Plan (CP) for the control of TSE was drawn up in 2003 in accordance with the provisions of Hungarian Decree 69/2003 on the prevention control and eradication of TSE. This plan is issued to all official veterinarians (OVs) involved in the control of TSE and contains detailed information on all aspects of TSE controls including the controls on SRM. The requirements for active surveillance for TSE are set out in an action guide which is annexed to the CP. The CP details the supervisory checks that must be carried out by the AHFCD to ensure that required TSE controls are implemented.

The mission team noted that:

- in the counties visited, farm visit check lists for veterinary staff covered many different work areas to be checked at the same farm visit;
- there were sufficient staff present to carry out on-farm inspections in the counties visited.

5.1.2. **Legislative provisions**

On accession the TSE Regulation became directly applicable in Hungary. However, Hungarian Decree 69/2003 which transposed the TSE Regulation before accession is still in force as an implementing rule. As the TSE Regulation has subsequently been amended there are some differences between the TSE Regulation and Decree 69/2003. The fact that the TSE Regulation has primacy over Decree 69/2003 has been published as a signed announcement by the Chief Veterinary Officer (CVO) in April 2004. Decree 69/2003 is currently being amended to bring it into line with the TSE Regulation.
5.1.3. Epidemio-surveillance in bovine animals

The relevant recommendations made following pre-accession missions referred to:

- supervision of the epidemic-surveillance system to ensure that all animals requiring to be tested for BSE are tested;
- distribution of samples between the National Reference laboratory and the regional veterinary institutes and ensuring uniform testing and reporting procedures throughout Hungary.

In their action plan, the CCA undertook to:

- supervise the County Animal Health and Food Control Stations (hereafter: Stations) in accordance with the requirements of the CP;
- increase the amount of samples tested by the regional laboratories and to supervise the testing of samples and reporting of results to ensure that procedures are in line with the action guide for implementation of rules for control of TSE (this is the annex to the CP referred to in section 5.1.1 above). In addition the CCA stated that both the regional veterinary laboratories that carry out BSE testing would be supervised by the Central Veterinary Institute during 2004.

The mission team noted that:

- the legal and administrative provisions with respect to the epidemic-surveillance system for BSE in bovine animals are in line with the requirements of Annex III of the TSE regulation;
- in 2004 four Stations have been supervised by staff from the AHFCD in accordance with the requirements of the CP. Documentary evidence of these supervisions was available for inspection;
- following a reorganisation the two regional veterinary laboratories are now considered to be an integral part of the Central Veterinary Institute (CVI). Staff in the regional laboratory visited stated that they were directly trained in the CVI. However the requirements of Annex X Chapter A of the TSE Regulation are not fully met e.g. no ring trial has been organised by the CVI to assess the reliability of BSE testing in the regional laboratories and no on-site supervision by the CVI of BSE testing in the regional laboratory visited had taken place.
- in 2004 there were 62 clinical BSE suspects. All tested negative for BSE;
- data from the ENAR system with respect to epidemic-surveillance presented to the mission team prior to the mission was inconsistent particularly in respect of the emergency slaughter category e.g. in two counties visited ENAR data provided showed that 80 and 295 bovines were recorded as having been sampled as in the emergency slaughter category while the figures provided during the mission by stations visited were 4 and 552;
- in 2004 3.83% (16,687) of the bovine population over 24 months (435,668) were recorded as having died on farm. However, 4,423 of these bovines were not tested for BSE. It is unclear how much of the shortfall is due to inaccuracies in the data and how much is due to actual failure to test dead bovines. In one of the Stations visited it was not possible to easily evaluate data on bovines having died on farm during the first quarter of 2005 using the bovine identification
database (ENAR system)(8). However, information was provided at the closing meeting that indicated the situation appears to be improving:

- bovines aged over 30 months slaughtered on farm for home consumption are not tested for BSE. Currently it is not a national legal requirement to officially notify such bovines for BSE sampling. The CCA stated that they have recently started to capture data on on-farm slaughtering in ENAR system and that national legislation would be changed to make notifications of bovines slaughtered on farm obligatory. This will enable BSE sampling of these animals to take place. Information provided at the closing meeting and after the mission showed that there were 148 over 30 month animals out of 599 animals slaughtered from January to May 2005;

- in the high throughput slaughterhouse visited normal slaughter bovines over 30 months old were sampled in accordance with the TSE Regulation. However, health marks were applied to carcases prior to negative BSE test results being available in contravention of the requirements of Annex III Chapter A I 6.1 of the TSE Regulation(9). In addition, evidence that all bovines slaughtered had been routinely subjected to ante-mortem inspection could not be provided and only 2 animals had been sampled in the “animals found sick at ante-mortem” category in 2005 until the date of the mission;

- review of documents and information provided by the OV and County staff responsible for a low throughput slaughterhouse indicated that bovines slaughtered in the emergency slaughter category were less urgent cases than would be covered by the definition of emergency slaughter in Directive 64/433/EEC(10). The mission team were informed by the CA that many bovines slaughtered as emergency slaughter cases were slaughtered for economic reasons rather than being true emergencies. Full reliance was placed on the information in the passport accompanying the animal. The data on one animal selected at random by the mission team was checked. It had been slaughtered as a 23 month old emergency slaughter case (not BSE tested). It was subsequently found on the ENAR system to have been older than 24 months of age at slaughter and, accordingly, should have been BSE tested;

- an examination of the ENAR system in one of the counties visited showed that it was potentially a useful tool for implementing BSE controls e.g. the progeny of one animal selected as a hypothetical BSE case could be identified on the ENAR system. However, a random check on traceability showed that there are gaps in the information e.g. some movements were not notified to the system.

5.1.4. Specified Risk Materials (SRM)
The relevant recommendations made following pre-accession missions referred to:

- ensuring that all SRM, including dead ruminants under 50kg, are disposed of in accordance with EU requirements;

(8) In their response to the Draft report the Hungarian authorities noted that the programme used for the query of dead bovines is based on internet and the time of the visit was during the busiest period of the day.

(9) In their response to the Draft report the Hungarian authorities noted that they will contact the authority responsible for classification of carcases to solve this problem which concerns carcases having to be health marked before they are classified.

ensuring that the system for removal and disposal of SRM is effectively supervised;

ensuring that the stores of processed SRM are safely disposed of.

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

- fully implement EU legislation including the ABP Regulation from the date of accession;
- supervise the system for removal and disposal of SRM in accordance with the provisions of the CP;
- procure funds to pay for the incineration of the stored backlog of Meat and Bone Meal (MBM) resulting from the processing of SRM.

An announcement issued by the CVO in April 2004 advising that EU legislation had primacy over national Hungarian legislation stated that the burial of ruminants is only allowed in remote areas as defined in the TSE Regulation. Five such remote areas have been notified to the Commission.

The mission team noted that:

- the legal and administrative provisions for dealing with SRM were in line with EU requirements;
- in 2004 four Stations were supervised by staff from the AHFCD in accordance with the requirements of the CP. These supervisions included checks on removal and disposal of SRM;
- with respect to the stored backlog of SRM MBM, in 2004 5425 tonnes of Category 1 MBM were exported to Slovakia for disposal. At present there is more than sufficient capacity for disposal of MBM within Hungary and, according to the CA, the backlog should be eliminated by mid-2006. All Category 1 MBM is co-incinerated in two plants (one cement kiln and one electricity power plant);
- in the slaughterhouse visited there was a good awareness of SRM issues;
- reconciliation of the amounts of SRM dispatched from the slaughterhouse with amounts arriving at the processing plant could not be easily carried out. Information received from the processing plant on consignments of animal by-products (ABP) was compiled by the environmental authorities but this information did not specify the ABP category of material received;
- in the area where BSE sampling took place edible offal was stored close to where the heads entered the area giving rise to a risk that the offal could be contaminated with SRM. The OV took immediate action to minimise this risk by moving the edible offal;
- sides and quarters of beef from over 12 month bovines were dispatched from the slaughterhouse with vertebral column (SRM) still in place. However, there was no indication on the accompanying commercial document (as required by Annex XI A 14 (b) of the TSE Regulation) advising that the vertebral column was SRM and would have to be removed. The OV stated that he would ensure that the wording as required by the TSE Regulation would be included in future commercial documents;
- blood resulting from bovine slaughter was dispatched to an ABP processing plant as Category 2 material (under the ABP Regulation) prior to negative BSE.
test results being received. Such blood is potentially ABP Category 1 material if blood from a BSE positive case is subsequently found to be included. The OV stated that, in future, bovine blood dispatched prior to results of BSE tests being received would be sent as Category 1 material.

5.1.5. **Total feed ban**

The relevant recommendations made following pre-accession missions referred to:

- *ensuring that the national legislation is fully in line with the TSE Regulation*;
- *improving co-ordination between the units involved in official feed-ban controls*;
- *increasing the risk based controls of the total feed ban in non-ruminant farmed animals to demonstrate that cross-contamination does not occur*;
- *bringing the testing methods for official samples in line with EU requirements*.

In response to the above recommendations, the CCA stated that:

- from the date of accession Hungary would be directly under the effect of the TSE Regulation, thus Hungarian provisions on the feed ban would not diverge from those of the EU;
- an internal instruction of the Chief Veterinary Officer No 31363/2004 on implementation of the feed ban was prepared jointly by the two divisions involved. It was issued on 14 May 2004;
- in case of feeding stuffs for non-ruminant livestock, they would increase the number of checks and inspections in order to exclude the risks of cross-contamination. The CCA confirmed in June 2004 that the increased risk-based controls of the total feed ban in non-ruminant livestock had already been started;
- from May 2004, the microscopic examination (MAT) is used compulsorily for the analysis of official samples to detect the presence of forbidden or derogated products of animal origin (PAO) and the ELISA test is carried out only additionally.

Since 2003 it is possible to apply in Hungary all derogations as laid down in Annex IV to the TSE Regulation. In practice only those concerning use of fishmeal for non-ruminants and the use of blood meal and other blood products for fish are applied. In the first case, Stations must issue a license upon request by the establishment wishing to incorporate fishmeal in feeding stuffs produced for non-ruminants. These establishments are not allowed to produce feeding stuffs for ruminants unless provisions in line with those laid down in the TSE Regulation are complied with. In addition, these establishments must draw samples every two weeks from feed for ruminants in order to demonstrate the absence of cross-contamination with fishmeal or other PAO. For these analyses, MAT or ELISA can be used by the National Reference Laboratory for feed controls (NRL) or by any of the other 8 laboratories accredited to do so.

Provisions in internal instruction No 31363/2004 include the frequency of controls to be applied on establishments and intermediaries operating in the animal feed sector (E/I), which is at least once a year in the case of plants producing only for ruminants or non-ruminants and twice a year in case of plants producing for both. Additional controls must be carried out whenever the feed inspector or the OV consider it appropriate following their risk analysis of the relevant E/I.
Additional provisions refer to compliance with the feed ban at farm level, which include that large-scale cattle farms shall be checked at least twice a year and small-scale cattle farms once a year. Similar provisions apply to farms where small ruminants are kept and farms keeping non-ruminants shall be visited at least once per year. Some 26,000 cattle farms are registered in Hungary, out of which some 25,000 are considered small farms with less than 50 animals.

Other requirements in place prescribe that all imported consignments of fishmeal shall be checked for the presence of other PAO and every tenth consignment of the same feed material that has been checked in another MS before its release in the EU shall be checked again upon arrival in the E/I of destination in Hungary. In this case, national provisions allow the use of ELISA for the analyses. Furthermore, in accordance with additional provisions samples shall be taken from other feed materials at random or when any suspicion of cross-contamination is raised by the feed inspector or OV.

The mission team noted that:

- more than 100 feed mills were using fishmeal to produce feeding stuffs for non-ruminants only. Four feed mills were using fishmeal to produce feeding stuffs for non-ruminants and also producing, in a separate building, feeding stuffs for ruminants. In this latter case the E/I had been categorised by the feed inspector with the maximum risk in relation to feed ban controls. Feed inspectors met were knowledgeable about and familiar with the criteria used for this categorisation;

- all CA representatives met confirmed that in Hungary priority for feed ban controls had been given to prevention of risks for cross-contamination of feeding stuffs at feed mills rather than checks on risks for cross-feeding at farm level.

- in line with criteria for the official controls of the feed ban included in the annual recommendations of the Commission on the co-ordinated inspection programme in the field of animal nutrition, the CCA had given priority to sampling of supplementary feeding stuffs with high protein content, other than fishmeal;

- confusing data were provided by the CCA on the number of official analyses carried out in 2004 for detection of other PAO in fishmeal. Some data indicated that some 332 of the 458 samples taken from feed materials had been drawn from consignments of fishmeal whereas the number of reported analyses done with MAT in the same feed material had been 192. Most of the other samples seem to have been analysed using the non-official ELISA test. The same applied to a much lesser extent to the number of official analyses carried out in compound feeding stuffs for ruminants and non-ruminants. No sample had been taken in 2005 the time of the Mission from any other feed material;

- both the CCA and staff of the NRL for feed controls advised the mission team that all official analyses for controls of the feed ban in 2005 were only done with MAT. A minimum of 661 determinations of the presence of PAO had been planned for 2005. The NRL had participated with satisfactory results in ring tests organised at Community level to evaluate the performance of MAT in European feed laboratories;

- in the feed mill visited, which was using fishmeal for producing feeding stuffs for non-ruminants, 8 consignments of this feed material had been received so
far. None had been sampled by July 2005 since only when the tenth consignment arrives the first sample will be taken. Consignments were said to come from France, but no confirmation was given about their origin, whether imported into France or other MS, or produced in France or other MS\(^{(11)}\). Two non-official samples had been taken by the feed inspector for the feed mill as part of the own-control checks;

- managerial staff of the Stations visited advised the mission team that staff at the Districts had lists of home mixers using fishmeal and confirmed that these establishments were not allowed to keep ruminants on their farms. However, no data were available on how many farms using compound feeding stuffs that could contain fishmeal could keep together ruminants and non-ruminants\(^{(12)}\);

- several OVs met in the three counties visited explained that they were responsible for feed ban controls at farm level. Apart from this area, their inspections cover a broad range of issues like animal identification, tuberculin testing or milk quality. Each Station had prepared its own inspection checklist for the OVs with questions on these areas including some for animal nutrition. As far as compliance with the feed ban was concerned in one Station the checklist was very detailed whereas in the other two this area was covered only superficially;

- in 2004 1,311 farms keeping ruminants and 189 keeping non-ruminants had been inspected in relation to the feed ban, numbers that are below the figures expected taking into account the number of farms in Hungary and national provisions on this area described above. In the same period there were 113 home mixers and mobile mixers inspected for the same purpose;

- all OVs met advised the mission team that when visiting farms, samples could be taken only in the case where there was evidence of contravention of the feed ban. They added that the costs of taking samples and their analyses must be covered by the farmer and since many of them were small farmers this would be an excessive cost for them. Some of the OVs met confirmed that this was deterring them from considering sampling as an option during their farm inspections;

- no samples have been taken so far in 2005 in any of the three Stations in any farm, whether large of small or whether keeping ruminants or not, except from some acting as home mixers. The three feed inspectors met confirmed that these were the only farms under the responsibility of their inspections for feed controls and samples had been drawn in some home-mixers producing feeding stuffs for ruminants. In 2004 36 samples had been taken from compound feeding stuffs in this kind of establishments and 1 turned out to be positive. No sample was taken during the same period in farms keeping other species of animals;

- the CCA accepted some of the shortcomings noted regarding controls at farm level adding that they will strengthen this area of feed ban controls and additional instructions thereon will be prepared for the OVs and feed inspectors.

\(^{(11)}\) In their response to the Draft report the Hungarian authorities noted that all consignments of fishmeal did originate in France.

\(^{(12)}\) In their response to the Draft report the Hungarian authorities noted that according to point 2.15. of the Annex 3 Decree No 69/2003.(VI.25) FVM it is banned to use fishmeal and other derogated animal proteins for feeding of non-ruminants as well in farms where ruminants are also kept.
Nevertheless, they emphasised that there were financial constraints on increasing the number of samples to be taken in farms during 2005.

5.2. CONTROLS IN THE FIELD OF ANIMAL NUTRITION

5.2.1. Competent Authorities

One Division of the AHFCD deals with the control of animal nutrition and feeding stuffs and one official therein is responsible for the overall strategy, legal background and management of the annual control programme for the feed sector. The State Control Institute for Veterinary Biologicals, Drugs and Feeds (SCIVBDF) has 2 members of its staff involved in the preparation of the annual control programme, including setting up of a sampling plan, and its operational management and co-ordination. Finally, feed inspectors and OVs allocated to the 20 Stations carry out the official inspections and draw samples in E/I or farms, and apply sanctions when necessary. In addition, the CCA advised the mission team that staff of the AHFCD placed in Border Inspection Posts (BIPs) are responsible for import controls including documentary, identity and physical checks in line with provisions of Directive 95/53/EC.

The mission team noted that:

- the organisation and co-operation of the CA involved in the feed sector has improved and a common strategy and planning of feed safety controls had been introduced;
- all CA meet regularly during the year to exchange information on the feed sector. CCA use these meetings to inform feed inspectors about new instructions and provisions that apply to feed controls and to receive feedback from them on their implementation. However, during the on-the-spot visits several differences were observed in the way the annual control programme was perceived by feed inspectors and in the level of implementation of these controls by the Stations;
- all staff of all CA met during the mission were familiar with provisions included in the annual recommendations of the Commission on the co-ordinated inspection programmes in the field of animal nutrition for 2004 and 2005(13);
- the CCA had informed the Customs Authorities about their involvement in import controls in the feed sector and had provided them with details of the feed materials and feeding stuffs that shall be brought to the attention of the AHFCD officials at the BIPs.

5.2.2. Legislation

The relevant recommendation made following pre-accession missions referred to:

- bringing the national legislation fully in line with Directive 98/51/EC.

In their action plan, the CCA stated that:

- the harmonisation of Hungarian legislation with provisions laid down in Directive 98/51/EC has been carried out by 27 February 2004.

In addition to addressing the above mentioned recommendation, other national provisions on undesirable substances and feed additives had been also brought in

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line with EU requirements before accession with several Ministerial Decrees passed in 2003 and 2004\(^{(14)}\).

The mission team noted that:

- the CCA had a list of representatives of E/I situated in third countries that can import feeding stuffs into the EU. The representatives had provided the CCA with written declarations stating that the E/I they represented were operating in line with applicable provisions as laid down in Directive 95/69/EC. However, no specific control measures were in place to ensure the regular verification of the actual compliance with EU requirements of feeding stuffs imported under this regime.

5.2.3. **Official inspections**

The relevant recommendations made following pre-accession missions referred to:

- ensuring that the national annual programme covers all stages of the feed chain;
- bringing the list of authorised feed additives in line with EU rules and take appropriate measures to ensure that the use of prohibited additives is prevented.

In response to the above recommendations, the CCA stated that:

- by accession, inspections would cover all links of the feed chain. This requirement was already included in the annual control programme in the field of animal nutrition for 2004. The control of animal farms and import controls will be primary tasks in this programme;
- From 1 May 2004 the list of additives is fully in line with EU requirements.

The CCA advised the mission team that the control programme for the feed sector is prepared annually on the basis of the experience gained the year before and a risk analysis carried out at central level by all CA involved in the feed sector. The CCA explained that this programme is planned following the annual recommendations of the Commission on the co-ordinated inspection programme in the field of animal nutrition. They added that sufficient information on the operators along the feed chain and the amounts of feed materials and feeding stuffs used and produced in Hungary was available to them and staff at the Stations for the preparation and implementation of the programme.

Official inspections in E/I as defined in Article 2 of Directive 95/53/EC are carried out by feed inspectors though OVs can also perform such inspections when they visit E/I to check other issues related with animal health risks. Farm inspections are carried out by OVs.

The CCA outlined that feed inspectors had been provided, in 2004, with a manual prepared at central level, which explained how to categorise all E/I in terms of risk with regard to feed safety and whereby feed inspectors can set priorities for feed controls in their Station including the number of official inspections to carry out, number of samples to take or substances to be checked for in the different E/I under their responsibility.

\(^{(14)}\) In their response to the Draft report the Hungarian authorities noted that since May 2005 the control of feedstuff import is laid down in common Regulation 52/2005 (IV.26.) of MARD and the Ministry of Financial affairs on the import of foodstuffs.
The mission team noted that:

- the annual control programme for 2005 had been recently communicated to the feed inspectors during a meeting held in June. The programme consisted of two tables indicating the number of inspections and analyses for different substances to be done in all Counties during 2005. There was no indication for checks at farm level unless the farm acts as a home mixer or for checks as part of import controls;

- the CCA advised the mission team that these tables were only an indication of the minimum number of inspections and analyses to be done and that the actual implementation of the annual programme depends on staff at each Station who must elaborate their own risk analysis and further decide the reasons why, how often and for what and E/I will be inspected and sampled;

- the CCA had prepared a checklist for the official inspections of the annual control programme, but they advised the mission team that its use by feed inspectors was only advisory and not mandatory\(^{(15)}\). This was confirmed on-the-spot as two of the feed inspectors had modified the template and had adapted it to their experience and to the type of E/I under their responsibility. In another Station the feed inspector had been using a totally different checklist and he had started to use the template only recently;

- some feed inspectors considered the number of samples to be drawn as indicated in the tables provided for the annual control programme as a fixed or minimum target depending on the substance whereas other feed inspectors used the tables received only as guidance for their planning at County level. As a result, the implementation of the control programme was not harmonised and varied depending on the different levels of expertise noted among the three feed inspectors and the OVs met, who explained their different approaches on how to prioritise establishments for controls and on how to decide for which substances they will analyse the samples drawn;

- in the feed mill visited, the mission team was informed that in relation to analyses for several Mycotoxins, a scientific advisory body had prepared in 2003 a set of recommended limit values to be used for the acceptance or rejection of feeding stuffs. One of the limits considered by staff of the feed mill for Aflatoxin B1 for their own-control checks was higher than the one included in EU (2002/32/EC\(^{(16)}\))and national provisions for this substance. The CCA undertook to immediately solve this misunderstanding by issuing appropriate instructions;

- the CCA had not yet designated specific entry points for imports of feeding stuffs and they explained that these controls were done at BIPs. When asked about how often physical checks were carried out, the CCA explained that these controls were only done at the BIPs in case of sampling of fishmeal, but they added that no consignment had been imported since 1 May 2004. In addition, when any suspicion is raised concerning any other feed stuff, staff at the BIPs request these checks to be carried out by feed inspectors at the place of destination of the consignment. None of the feed inspectors met in three

\(^{(15)}\) In their response to the Draft report the Hungarian authorities noted that the use of a checklist is mandatory.

Counties had ever received any request to check any imported consignment and, in addition, they indicated that they were not necessarily informed about imported consignments destined to any E/I situated in their Counties. The CCA advised the mission team that new legislation provides for the designation of entry points and lays down new provisions for import controls to guarantee feed safety. They undertook to implement these provisions shortly;

- there was no contingency plan drawn up in line with Article 4a of Directive 95/53/EC, but staff met at central level and in the feed mill and Stations visited demonstrated experience in handling situations which could undermine feed safety. The CCA added that a plan will be prepared shortly since national provisions in place on feed safety already included a clear attribution of responsibilities to act in such cases;

- apart from the meetings mentioned in point 5.2.1, the Stations must send regularly reports explaining their activities in relation to controls in the feed sector, but no regular on-the-spot supervision was done by the CCA in order to evaluate how the annual control programme is actually implemented by the Stations;

5.2.4. Approval and registration of E/I

Staff of the SCIVBDF is involved in pre-approval on-the-spot verifications of compliance of E/I with requirements of national provisions transposing Directive 95/69/EC. After all verifications, the CA issues a report that is sent to the relevant Station recommending when appropriate the approval or registration of the E/I visited. The Stations have therefore the mandate from MARD to grant or withdraw approvals or registration of E/I. Renewal of approvals or registration shall be done every 5 years except for the manufacturers of pre-mixtures, which shall be done every 3 years. The national list of approved and registered E/I is kept by the SCIVBDF.

The mission team noted that:

- national provisions on implementation of EU requirements contained in Directive 95/69/EC were issued in 2003. In the feed mill visited, documentation issued for its approval was available and it dated back to 2001. Contradictory views were expressed by the three feed inspectors representing three different Stations in relation to the need for an update of the approvals and registration of E/I that had been issued before 2003. The CCA added that the current conditions of operation for all E/I, which are the reference for their official inspection, had been updated by the reports issued after regular verification visits done together by staff of the SCIVBDF and the feed inspector who carries out the annual official inspections in the establishment. Nonetheless, the CCA agreed that for the sake of administrative harmonisation all E/I shall be approved or registered in line with applicable provisions of national legislation now in force;

- during pre-approval or registration on-the-spot visits staff of the SCIVBDF are normally accompanied by the relevant feed inspector that will be responsible for the regular official inspection of the establishment. Examination of homogeneity, capacity and carry-over and cross-contamination checks are regularly carried out during those visits;
E/I out of the scope of Directive 95/69/EC had been granted a specific registration format under national legislation and had been included in feed safety control activities carried out by feed inspectors or OV;

checks on traceability and recall of feeding stuffs had been carried out with success in several feed mills in cases of detection of forbidden substances in food stuffs, e.g. cloramphenicol in duck and goose meat; or upon requests from customers downstream in the feed or food chain.

6. CONCLUSIONS

6.1. BSE CONTROLS

6.1.1. Competent authorities

1. The CA involved in BSE controls are able to deliver a satisfactory standard of BSE controls.

6.1.2. Legal framework and administrative provisions

2. The legal and administrative provisions in place to implement BSE controls are sufficient to deliver a satisfactory standard of official control.

6.1.3. Epidemi-surveillance in Bovine Animals

3. The passive surveillance system in place should be sufficient to detect clinical cases of BSE.

4. The system for active surveillance is in place but there are some gaps, in particular, over 30 month bovines slaughtered on-farm for home consumption are not sampled and it cannot be confirmed that all over 24 month bovines found dead on farm are sampled.

5. Information provided from the ENAR system to demonstrate the effectiveness of epidemi-surveillance cannot be considered to be fully reliable due to missing or incorrect data. Gaps in the data also undermine the usefulness of ENAR in identifying cohorts of possible BSE cases.

6.1.4. Specified Risk Materials (SRM)

6. The legislation in place and controls on SRM are generally satisfactory but there were some minor deficiencies detected in the slaughterhouse visited with a lack of awareness of some of the more detailed SRM requirements.

7. There is currently sufficient co-incineration capacity to dispose of all SRM MBM produced in Hungary and to deal with the backlog of SRM MBM in store.

6.1.5. Total Feed Ban

8. The system in place for controls on the feed ban is largely satisfactory as far as risks of cross-contamination of cattle feed with PAO is concerned, but still not sufficient to prevent in farms all risks related with feeding or cross-feeding of ruminants with feeding stuffs containing respectively forbidden or derogated PAO.

6.2. CONTROLS IN THE FIELD OF ANIMAL NUTRITION

6.2.1. Competent authorities

9. Improvements were noted as regards organisation and co-operation of all CA involved in the feed sector and all of them seemed to be aware of their responsibilities.
6.2.2. **Official inspections**

10. The CCA had introduced measures to improve the planning of the annual control programme for the feed sector; however, significant delays were observed with its preparation and communication to the CA responsible for its implementation.

11. Limited evidence was seen of the criteria used by the CCA to draw up the annual control programme and further elaboration by the Stations in the light of their perception of risks and their experience gained locally was considered necessary before its implementation.

12. Some useful tools had been prepared by the CCA to help the Stations with the implementation of the annual control programme, but more efforts are needed to better harmonise their approaches towards official inspections and sampling, otherwise, this limited supervision by the CCA can not always guarantee a uniform level of control throughout the feed chain.

13. Despite efforts made to increase controls on feeding stuffs before their importation in the EU, the insufficient implementation of physical checks means that the CA cannot ensure prevention of all potential risks coming from outside the EU.

14. The CCA had not yet drawn up a contingency plan for the feed sector in line with provisions laid down in Article 4a of Directive 95/53/EC.

6.2.3. **Approval and registration of E/I**

15. The system in place is largely satisfactory; however, a harmonised administrative update is necessary for all approvals of E/I that were granted before national legislation was fully in line with the provisions laid down in 95/69 to bring their current conditions of operation definitively under its legal scope.

6.3. **OVERALL CONCLUSION**

Regarding BSE controls, the system of BSE controls and epidemic-surveillance is largely in place with minor shortcomings detected. Controls on the feed ban are in place but current levels of on-farm sampling for feed ban enforcement are insufficient to ensure no cross-feeding takes place. Controls on SRM are mostly satisfactory, some minor shortcomings were detected.

Regarding controls in the field of Animal Nutrition, the system in place is largely in line with EU requirements with minor shortcomings detected.

7. **CLOSING MEETING**

A closing meeting was held on 8 July 2005 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. During the meeting, additional information as requested by the mission team was provided by the CCA.
8. RECOMMENDATIONS

To the competent authorities of Hungary

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

With regard to BSE epidemi-surveillance

1. To ensure that all fallen bovine animals over 24 months and all bovine animals over 30 months and slaughtered on-farm for own consumption are tested for BSE in line with the requirements of Annex III Chapter A, I the TSE Regulation.

2. To ensure the correct categorisation of bovine animals tested in the “emergency slaughtered” and “found sick at ante-mortem inspection” categories in line with Annex III Chapter A, I, 2.1 of the TSE Regulation.

3. To ensure that the information held on the ENAR system is up to date and accurate in order to allow effective supervision and monitoring of the epidemi-surveillance system and tracing of progeny and cohorts of any possible future BSE cases.

With regard to SRM

4. To ensure that all staff are fully aware of all the detailed requirements of SRM controls as specified in Annex XI of the TSE Regulation and to supervise the implementation of these controls effectively.

With regard to the total feed ban

5. To ensure that official inspections and sampling for the official control of the feed ban can exclude the risks of feeding or cross-feeding of cattle with PAO.

With regard to official inspections in the field of animal nutrition

6. To ensure the timely preparation and communication of the annual control programme for the feed sector to the CA responsible for its implementation.

7. To bring the criteria used to draw up the annual control programme for the feed sector and its additional elaboration done by the Stations more transparent in order to render its implementation more auditable.

8. To consider improving the supervision of the implementation of official inspections and sampling by the Stations in order to guarantee a uniform level of control throughout the feed chain.

9. To ensure that sufficient physical checks are carried out on imported products in line with Article 7 of Directive 95/53/EC in order to ensure a satisfactory prevention of all potential risks coming from outside the EU.

10. To draw up a contingency plan for the feed sector in line with provisions laid down in Article 4a of Directive 95/53/EC

With regard to approval and registration of E/I

11. To ensure that all operators in the feed chain are approved or registered as appropriate in compliance with applicable provisions as laid down in Directive 95/69/EC.
ADDENDUM
RESPONSE OF THE COMPETENT AUTHORITIES TO THE RECOMMENDATIONS

Comments from the Hungarian CCA on the draft report were received on 21 September 2005, and included an outline of the actions planned and/or undertaken to address certain recommendations contained in the report. These may be summarised as follows:

With regard to BSE epidemi-surveillance
1. The new ministerial decree for executing of Regulation (EC) No 999/2001 will contain the compulsory notification of slaughter of home consumption in case of bovine animals over 30 months as well as some additional measures to ensure that all fallen stock bovine animals over 24 months are tested.
2. An internal instruction on the categorisation of bovine animals tested will be issued to help the veterinarians working in the field and during training organised by the stations the issue will be emphasised.
3. Two types of on farm inspections (for bovine identification rules and checks based on TSE Contingency Plan) will correct the system step by step. Furthermore we are planning to modify the system so that it contains up to date data, for example in case of emergency slaughter. Finally it is planned to establish a special working group for animal identification.

With regard to SRM
4. Please see point 2.

With regard to the total feed ban
5. The new ministerial decree for executing of Regulation (EC) No 999/2001 will contain specific rules for preventing of cross-feeding as well. However it is very important that according to the current Hungarian rules it is banned to use fishmeal and other derogated animal proteins for feeding of non-ruminants as well in farms where ruminants are also kept.

With regard to official inspections in the field of animal nutrition
6. The uniformity in the controls and in implementation of the sampling plan can be reached by improving the guiding, control and coordinative rule of SCIVBDF which is a central directing establishment. For the sake of harmonized control activity the coordinative role of SCIVBDF is going to be stressed in the future.
7. The rules in the field of feedstuff controls have been communicated to the inspectors.

With regard to approval and registration
8. The provisions of the directive 95/69/EC are already complied with. In this respect further emphasis is to be put for complying with Article 18 of 183/2005/EC regulation of the European Parliament and of the Council.