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FINAL REPORT OF A MISSION

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FROM 15 TO 19 SEPTEMBER 2003

IN ORDER TO

EVALUATE THE IMPLEMENTATION OF EC MEASURES

IN THE FIELD OF ANIMAL NUTRITION REGARDING

THE OFFICIAL INSPECTIONS AND THE APPROVAL AND

REGISTRATION OF CERTAIN ESTABLISHMENTS AND INTERMEDIARIES

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Abbreviations & special terms used in this report

AGES	*Österreichische Agentur für Gesundheit und Erhährungssicherheit* (Austrian Agency for Health and Food Safety), the federal control body for feedingstuffs
BAE	*Bundesamt für Ernährung* (The Federal Office for Nutrition), the authority for the control of putting on the market of feedingstuffs and the approval of establishments
BH	District authorities (*Bezrikshauptmannschaft*), responsible authority for feed controls on farms
BMGF	*Bundesministerium für Gesundheit and Frauen* (The Federal Ministry for Health and Women), the central competent authority responsible for veterinary affairs
BMLFUW	*Bundesministerium für Landwirtschaft, Forsten, Umwelt und Wasserwirtschaft* (The Federal Ministry of Agriculture Forestry, Environment and Water-management), the central competent authority responsible in the field of animal nutrition
CCA	Central Competent Authority, the BMLFUW
CFS	Compound feedingstuffs
DVS	Veterinary Services at district level (*Bezrikshauptmannschaft*)
E/I	Establishments and intermediaries operating in the animal feed sector
Entry point	Point at which products are introduced in into the customs territory of the Community, as set out in Art 6 of Council Directive 95/53/EC
EU	European Union
FVO	Food and Veterinary Office
LH	Regional authorities (*Landeshauptmannschaft*), responsible authority on regional level for feed controls
MBM	Meat and Bone Meal
PAP	Processed Animal Protein
RASFF	Rapid Alert System for Food and Feed
Representatives	Representatives from establishments located in third countries, as set out in Art 6 of Commission Directive 98/51/EC

1. INTRODUCTION

The mission took place in Austria from 15 to 19 September 2003. The mission team comprised three inspectors from the Food and Veterinary Office (FVO).

The mission was undertaken as part of the FVO's planned mission programme and formed part of a series of missions to all Member States.

The inspection team was accompanied during the whole mission by a representative from the central competent authority (CCA), the Federal Ministry of Agriculture Forestry, Environment and Water-management *(Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft* - BMLFUW*).*

An opening meeting was held on 15 September 2003 with the CCA. At this meeting, the inspection team confirmed the objectives of, and itinerary for, the mission, and additional information required for the satisfactory completion of the mission was requested. In addition, the standard reporting and follow-up procedures were confirmed.

2. OBJECTIVES AND SCOPE OF THE MISSION

The overall **objective** of the mission was to evaluate the implementation of certain measures to ensure feed safety. In particular, it concerned the measures put in place, and their application, to give effect to:

1. Community rules fixing the principles governing the organization of official inspections in the field of animal nutrition, as laid down in Council Directive 95/53/EC[1], as amended to check compliance with provisions laid down in associated EU feed legislation;
2. Community rules laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector, as laid down in Council Directive 95/69/EC[2], as amended, and Commission Directive 98/51/EC[3].

In terms of **scope**, the mission was limited to the general elements of the official inspections and the approval and registration rules required by the above EU Directives. The mission covered all stages from production to the use of feeds for farmed animals.

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

COMPETENT AUTHORITY VISITS			**Comments**
Competent authorities	Central	√	Opening and closing (de-briefing) meetings
	Local	√	Local veterinary service responsible for the on-farm controls met during a visit to a farm
LABORATORY VISITS			
National Laboratory		**1**	One laboratory of the Austrian Agency for Health and Food Safety (AGES) carrying out official analyses in the feed sector

[1] OJ L 265, 8.11.1995, p. 17.
[2] OJ L 332, 30.12.1995, p. 15.
[3] OJ L 208, 24.7.98, p. 43.

ESTABLISHMENTS AND INTERMEDIARIES		
Feed processors / manufactures	**4**	Three large or medium-scale feed mills approved according to Council Directive 95/69/EC and producing premixtures and compound feedingstuffs containing premixtures; one feed mill not covered by Council Directive 95/69/EC
On farm mixer / mobile mixer	**1**	One on-farm mixer registered for manufacturing feedingstuffs containing premixtures according to Article 7 (2d) of Council Directive 95/69/EC
Intermediary	**1**	One intermediary approved according to Council Directive 95/69/EC putting in circulation additives
PRODUCT CONTROL SITES		
Entry point	**1**	Customs authorities at a designated entry point whereby products used in animal nutrition are checked before imported into the EU

3. LEGAL BASIS FOR THE MISSION

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

1. Article 17a of Council Directive 95/53/EC of 25 October 1995 fixing the principles governing the organization of official inspections in the field of animal nutrition, as amended;
2. Commission Decision 98/139/EC[4] of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States.

4. BACKGROUND

4.1. PRODUCTION AND TRADE OF FEEDINGSTUFFS

According to the CCA, 121 commercial manufacturers produced some 1,020,000 tonnes of compound feedingstuffs (CFS) in 2001, of which 29% were intended for ruminants, 20% for pigs and 37% for poultry. In addition, some 50,000 tonnes of CFS were imported. About 25% of CFS used in the country come from commercial feed mills and 75% are produced on-farm, which reflects the high number of home-compounders (some 100,000 out of 117,000 animal holdings).

143 manufacturers (including producers of pet food, additives, straight and compound feedingstuffs) put into circulation some 3 Mio tonnes of straight feeding material (produced and imported) in 2001, 0.85 Mio tonnes for commercial manufacturing of CFS and 2.15 Mio tonnes for direct use on-farm.

Some of the commercial manufacturers have their distribution networks, in total some 179 outlets. In addition, there are some 900 traders and stores of feed materials and 14 intermediaries.

4.2. STRUCTURE OF THE FEED INDUSTRY

The feed industry comprises mainly small to medium size feed mills. The biggest company produces around 1/3 of the commercial CFS. All establishments and intermediaries operating in the feed sector (E/I) are members of the chamber of

[4] OJ L 38, 12.2.1998, p. 10.

commerce (*Wirtschaftskammer*). Most of them are organised in one of the national associations in the feed sector:

- the organisation of the feedingstuffs industry (*Fachverband der Futtermittelindustrie*), which is a member of the European Feed Manufacturers Federation;
- the guild of millers (*Bundesinnung der Müller*);
- the federal agriculture trade body (*Bundesgremium des Agrarhandels*) representing the traders of feed materials and feedingstuffs.

5. MAIN FINDINGS AND OBSERVATIONS

5.1. COMPETENT AUTHORITIES

5.1.1. Organisation and responsibilities

The BMLFUW is the CCA in the field of animal nutrition. The practical implementation of the controls is under the responsibility of

- the Federal Office for Food Safety (*Bundesamt für Ernährungssicherheit* – BAE) as regards approval and registration of establishments, the control over the production and placing on the market and the testing of feedingstuffs;
- the regional authorities (*Landeshauptmannschaft* - LH) as regards on-farm controls, which are entrusted to the district authorities (*Bezirkshauptmannschaft* - BH);
- the federal veterinary service and the customs as regards import controls.

For other than regulatory and enforcement tasks the BAE acts as the Austrian Agency for Health and Food Safety Ltd (*Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH* - AGES). The AGES with 5 locations, laboratories in Vienna and Linz and some 1,000 staff was created in July 2002, merging the former Federal Office for Agriculture, covering the regions in the eastern part of the country and the Federal Office for Agricultural Biology, covering the western part. Beside tasks in the feed control, the AGES carries out duties in the responsibility of the Federal Ministry of Health and Women (*Bundesministerium für Gesundheit und Frauen* – BMGF).

The mission team noted that:

- Through regular meetings, the BMLFUW informs operators in the animal feed sector about developments and requirements with regard to official controls.
- For some areas of the official control at federal level there are no clear guidelines or instructions (including documentation requirements) for the control staff (see section 5.2 and 5.3). The AGES did not deem detailed guidelines or instructions necessary, pointing to the advantage of a relatively small and centralised federal control body as regards the flow of information.
- The LH has a well defined task of supervising the BH, whereas responsibilities for the supervision at federal level are not clearly defined. The CCA stated that the LH and the different control bodies at federal level act on their own responsibilities and that to some extent, supervision is ensured by annual reports from the AGES to the BMLFUW.

5.1.2. Resources and training

At federal level there is a centre for official controls of BAE/AGES located in Linz, with some 14 staff responsible for controls of feed materials, fertilisers, pesticides, seeds and plant health. The AGES stated that some 6 members of the staff of the AGES are mainly engaged with feed controls. Their ongoing training is ensured by direct and regular contacts with specialists within the AGES. Some 8 further AGES staff can be deployed for official feed controls, if required.

In each of the 9 regions (LHs) there is at least one contact person for the BMLFUW as regards the feed controls. In most BHs the district veterinary service (DVS) is in charge of the on-farm feed controls, whereas in some others it is the agricultural department.

In 2001/2002, the federal control bodies provided training concerning official controls and sampling for veterinary staff at the DVS and Border Inspection Posts (BIPs) as well as for customs officers at designated entry points.

5.2. OFFICIAL INSPECTIONS IN THE FIELD OF ANIMAL NUTRITION

5.2.1. Legal situation and administrative provisions

5.2.1.1. Legal transposition

Council Directive 95/53/EC has been transposed in Austrian legislation by the Feed Act of 1999, BGBl. I Nr. 139, as last amended by the Amendment Act of 2003, BGBl. Nr. 78, and by the Feed Regulation of 2000, BGBl. II Nr. 93, as last amended by Amendment Regulation of 2003, BGBl. II Nr. 243, which also transposes Commission Directive 98/68/EC[5] laying down the standard document referred to in Article 9 (1) of Council Directive 95/53/EC. The national legislation includes provisions regarding labelling, packaging, approval, registration, official controls, use and authorisation of additives and premixtures, imports and fees.

Administrative guidelines on the controls, risk analysis and risk management in the field of animal nutrition are outlined in the "Action plan for feedingstuffs" (*Aktionsplan Futtermittel*) of the BMLFUW, which also provides for a contingency plan (see 5.2.3). In addition, it contains some general rules on official controls and their documentation, templates for rapid alert information, annual reports at federal and regional level and sampling and action protocols.

5.2.1.2. Official control plan

The CCA has drawn up a detailed annual control programme since 2001. The AGES stated that a formal system where the results of the control programme will be used as input for the design of the next one was only included this year, although this approach was already informally applied in the past.

The number of inspections to be carried out by the AGES at production and trade level is primarily calculated on the basis of the output of establishments. This number may be increased taking into account the results of previous inspections and emerging factors such as changes in production, new or unknown materials, facilities, etc. The official control programme establishes the number of visits to be made to a given type of premises, the total number of samples to be taken in each type of premises, and the total number of samples to be taken from each type of feedingstuffs.

[5] OJ L 261, 24.9.1998, p. 32.

At farm level the DVS inspects from 2 to 20% of the animal premises each year for general compliance purposes, including animal feeding practices. The samples to be taken at farms by the BHs are allocated on the basis of the livestock population in the regions. The subsequent distribution of samples is established following a risk-based approach which considers, among others, whether animal of different species are kept or not. This allocation is done either manually or by a computer programme (in three regions), although the latter will be adopted throughout the country in the near future, because of the cumbersome manual procedure.

As regards sampling, the official control programme for 2003 establishes that samples should be taken: – regularly and at random;
– in case of suspicion of irregularities;
– proportional to the desired objective;
– taking into account particular risks in each case.

Approximately 2,800 samples have to be taken annually. All inspections carried out by the AGES imply a sampling operation, but not all those carried out by the BH.

The mission team noted that:

- Establishments outside of the scope of Council Directive 95/69/EC are included in the official control programme. This is possible since all operators in the animal feed sector have to notify their activity to the competent authorities (see 5.3.1).
- Representatives of establishments located in third countries are included in the official control programme.
- The control programme for 2003 takes due account of the outcome of the analytical results of previous sampling, but does not consider other risks which could emerge at establishment level such as carry over, risk not covered by own control plans, type of additives used, feeds produced, etc.

5.2.2. Application and supervision in practice

5.2.2.1. Official on-the-spot inspections

In 2002, from 1,419 establishments and traders 1,287 were inspected by AGES and 2,466 samples were taken. During the same period the BHs inspected 8,504 farms and took 809 samples.

The mission team noted that:

- The control programme was largely applied as described.
- The AGES plans the implementation of the official control programme on a monthly basis (or even more frequently if needed), when the visits and priorities of the inspectors are discussed and decided.
- The visits of the DVS to farms and sampling are based on the risk factors stated in the control programme.
- The AGES inspectors are allowed a considerable freedom to decide how many samples to take at individual premises, and where to sample. According to the AGES, this is because the inspectors are considered to be in the best possible situation to take the right decision. No guidelines are given on how to perform their inspection, including the targeting of the sampling in relation to the possible risks emerging at establishment level such as carry over.
- According to the explanations given by an AGES inspector:

  - Samples are taken considering the production sequence. However, this could not be demonstrated in practice. In one feed mill visited, no samples for the detection of coccidiostats in CFS for laying hens was taken during the last inspection, although such feed was produced following a batch containing coccidiostats and a flushing batch.
  - Although samples are taken in case of previous non-compliance, suspicion, irregularities (e.g. in the labelling) or when new practices or materials are found, most samples are taken at random with a view of fulfilling the numbers attributed in the control programme.

- Samples are taken in accordance with First Commission Directive 76/371/EEC[6] establishing Community methods of sampling for the official control of feedingstuffs and kept in triplicate for confirmation purposes, if needed. An AGES-inspector indicated that the official sampling procedure was difficult to apply in large closed containers, where this can be only done taking advantage of the loading/unloading process.
- No reports are produced upon the AGES inspections, apart from a sampling protocol accompanying the samples taken. Only in few occasions is stated in the sampling protocol for which reason the sample was chosen, even when not randomly chosen.
- Mobile mixers (the number of which could not be specified) are not subject to any type of control. According to the AGES, the reason behind this is the difficulty in supervising such operators directly, which are to a "certain extent" under "some" surveillance through the controls at farm level.
- As regards on-farm controls, the AGES issued comprehensive guidance and provided training for the BHs on how to perform their inspections on animal feed, including the targeting of the sampling, and protocols to be used.

5.2.2.2. Intra-community trade

The official inspections do not discriminate on the basis of the EU origin or destination of the products unless there is an alert notification.

5.2.2.3. Imports from third countries

The CCA have designated 25 entry points for the checks of feed materials of non-animal origin as laid down in Article 5 of Council Directive 95/53/EC. Products covered by veterinary import legislation are checked at the BIPs by the veterinary services. In co-operation with the BMLFUW, the Ministry of Finance issued a list of feedingstuffs (including straight materials) which have to undergo import controls. Based on the customs codes a computerised clearance system indicates whether a material is subject to such controls.

Pre-notification of imported feed materials is not deemed necessary. After a 100% documentary check and a 5% random identity check the customs issue the standard document as laid down in Commission Directive 98/68/EC, irrespective of whether the imported products will be marketed in Austria or in another Member State. A copy of the document is to be sent to the AGES headquarters, where it is used for their inspections. On the basis of the document provided by customs, the AGES decides on which of the imported consignments physical checks will be carried out.

[6] OJ L 102, 15.4.1976, p. 1.

at the point of destination (according to the control programme, on approximately 5% of the consignments).

The mission team noted that:

- When the destination of a consignment is unclear or there are doubts about its content or final use, the customs either consult with the AGES or carry out analytical examinations before releasing it into free circulation.
- The physical checks on imported consignments foreseen in the official inspection programme are carried out when this material has already been placed on the market. The AGES acknowledged that in some cases, imported feedingstuffs selected for physical checks had already been used before the checks could be carried out.
- The imported feedingstuffs released for another Member State are not subject to physical checks by the AGES. However, for each consignment the competent authorties of the Member State concerned is informed by the AGES since it is considered most efficient to carry out physical checks at the point of destination.

5.2.2.4. Laboratories

All samples taken on the basis of the annual control programme are brought directly to one of the two official AGES laboratories for feedingstuffs, at Vienna and Linz.

The responsibles for the laboratories (head or deputy head of AGES) decide what analyses will be carried out on a given sample. According to the AGES, input from the inspectors who took the samples is possible either by requesting an analysis on the accompanying documents or by direct contact.

The mission team noted that:

- The traceability system, as applied, appeared satisfactory.
- In some documents accompanying samples, inspectors gave indications which a specific analysis were required. In most cases, it was not documented how the decision on analyses took account of the risk-based or targeted approach of samples.
- For some substances, the laboratories use methods other than the official EU methods for screening purposes. In case of inconclusive or positive results in the screening, the samples are analysed by official methods. According to the staff in the laboratory in Vienna, comparative tests have been performed to ensure that the screening methods are at least as sensitive as the EU methods.
- The national legislation allow a certain tolerance (up to 40%) in the results of the analyses of additives for which maximum levels have been fixed, not taking into account Article 21 of Council Directive 70/524/EEC[7], as amended, concerning additives in feedingstuffs.

5.2.2.5. Results of the control plan

The number of analyses performed in 2002 in response to Commission Recommendation 2002/214/EC[8] of 12 March 2002 on the co-ordinated inspection programmes in the field of animal nutrition for the year 2002 in accordance with

[7] OJ L 270, 14.12.1970, p. 1
[8] OJ L 70, 13.3.2002, p. 20

Council Directive 95/53/EC are presented in the following table (positive results or results exceeding maximum levels are indicated in brackets):

Undesirable substances					Forbidden antibiotics	Additives				*Salmonella* spp
Dioxins and PCBs	Heavy metals					Trace elements	Antibiotics and coccidiostats	Probi-otics	Vit. A and D	
	Pb	Cd	As	Hg						
668 (0)	472 (0)	467 (0)	296 (0)	198 (0)	1,091 (39)*	4,920 (104)	268 (39)	151 (31)	851 (39)	323 (15)

*: 337 positive samples were detected, most of them attributed to the presence of unspecific inhibitory effects The number given corresponds to non-compliance where official procedures were launched.

In total, 629 out of 2,466 samples analysed in 2002 revealed non-compliances.

5.2.2.6. Actions in case of infringements

Actions to be taken when non-compliance is found vary from oral or written communications to the operator to correct the situation, to administrative or legal procedures, depending on the seriousness of the offence. In the event of positive results, the operator is charged for the costs of the inspections and the analyses. According to the CCA the experience gained during the dioxins crisis showed that a corrective approach only based on legal actions was of limited value. Therefore, a new policy based on additional measures with a more deterrent effect is now in place. This includes public information of irregularities found, decontamination measures, blocking of material in premises and/or obligation for operators to recall it.

- The mission team noted that the system is operated as described by the CCA.

5.2.2.7. *Supervision*

See chapter 5.1.1.

5.2.3. Action in case of emergencies

A rapid alert system for food and feed (RASFF) in accordance with the requirements of Regulation (EC) No 178/2002[9] of the European Parliament and of the Council and Directive 2001/46/EC[10] of the European Parliament and of the Council amending Council Directive 95/53/EC has been established. This includes, *inter alia*, a risk evaluation unit at the AGES and a contingency plan. The mission team was presented with the relevant procedures and several examples on the operation of the system.

5.2.4. Disposal of meat and bone meal (MBM)

All animal waste is processed in 4 rendering plants and subsequently incinerated, the tallow at the sites and the MBM in 13 incinerators and cement plants. No MBM is in stock. The maximum annual incineration capacity for MBM amounts to 124,000 tonnes.

In total, some 90,800 tonnes and 90,100 tonnes of MBM were produced in 2001 and 2002, respectively, and sent directly under official control for incineration.

[9] Regulation (EC) No 178/2002 of 28 January 2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Agency and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1

[10] OJ L 234, 1.9.2001, p.55

5.3. APPROVAL AND REGISTRATION OF ESTABLISHMENTS AND INTERMEDIARIES

5.3.1. Legal situation and administrative provisions

5.3.1.1. Legal transposition

Council Directive 95/69/EC regarding approval and registration of E/I and Commission Directive 98/51/EC laying down certain measures for implementing Council Directive 95/69/EC were transposed in Austrian legislation by the Feed Act 1999 and the Feed Regulation 2000.

These statutory instruments include amongst others provisions for the approval and registration of certain E/I producing and/or placing on the market certain additives, premixtures or feedingstuffs. As regards the approval and registration requirements, the Feed Regulation of 2000 refers to the Annex of Council Directive 95/69/EC.

The mission team noted that:

- Under national legislation, E/I are required to notify the competent authorities when operating in the animal feed sector, even those outside the scope of Council Directive 95/69/EC. However, the CCA could not specify the number and activities of mobile mixers (see also chapter 5.2.2.1).
- Apart from the above notification, intermediaries putting additives, premixtures or feedingstuffs into circulation do not need to be approved or registered unless they are involved in international trade. Intermediaries only operating nationally were stated to be covered as outlets of approved or registered establishments.

5.3.1.2. Administrative provisions

As regards exchange of information between the CCA and operators, see section 5.1.

The "Action plan for feedingstuffs" provides for general information on which E/I require approval and registration. In addition, the BAE provides applicant E/I with a leaflet summarising the requirements laid down in the Annex of Council Directive 95/69/EC. After receiving the application, the BAE provisionally approves or registers the applicant E/I while dealing with the file.

The E/I are subject to on-the spot inspections by AGES staff before the final approval can be granted by the BAE. E/I seeking registration can be visited before finally registered. All documents provided by the operators are kept by the BAE and available to the control staff carrying out on-the spot inspections. All approved or registered E/I are under the regularly supervision of the BAE.

The mission team noted that:

- Detailed specifications are in place for the requirements to be fulfilled by E/I regarding qualification of personnel and mixing homogeneity in production. Homogeneity tests are performed using, micro-tracers.
- The AGES inspectors have no instructions or guidelines in hand on other minimum requirements to be fulfilled by the operators, e.g. as regards technical and organisational procedures to avoid carry-over between batches and errors, quality control systems including own control plans, documentation and traceability or recall. The BAE considers that, due to the small and centralised control body, a uniform approach for approval and for the checks is ensured without the need for issuing detailed guidelines.
- With the exception of templates for sampling protocols and protocols on actions to be taken in case of a non-compliance, the AGES inspectors have no

instructions or guidelines on how and what to document during the regular on-the spot checks in order to demonstrate that E/I continue to fulfil the minimum requirements under which they were approved or registered.

5.3.2. Application and supervision in practice

5.3.2.1. Official on-the-spot verifications and checks

At the time of the mission 73 E/I were approved, 7 of which only provisionally. 80 establishments were registered, 12 of which only provisionally. The CCA registered 16 representatives of establishments located in third countries, importing certain products into the Community as required by Article 6 of Commission Directive 98/51/EC. According to the AGES, due to limited staff not all files could be processed, leaving some E/I provisionally approved and registered.

Out of the estimated 100,000 on-farm mixers, one required registration for using premixtures containing certain additives.

The mission team noted that:

- The procedures were largely applied as described by the CCA.
- All E/I visited kept comprehensive documentation regarding their activities. However, one feed mill visited was approved without a written own control plan having been requested by the BAE prior to authorisation. This was not deemed necessary for this feed mill by the control staff.
- At the establishments visited, the AGES was satisfied with the measures taken by the establishments to prevent carry over of certain additives to subsequent batches of compound feedingstuffs without requesting proof for the effectiveness of the measures or carrying out repeated targeted sampling.
- The AGES did not document the extent and outcome of their visits to the establishments to demonstrate what regular checks were carried out to ensure that the approval and registration requirements are still met.
- Most of the approved E/I have been authorised to add directly into CFS certain additives such as antibiotics, coccidiostats and other growth promoters and/or selenium, copper, vitamins A and D although it was not known if the additives have been authorised for direct mixing into CFS in accordance with Article 13 of Council Directive 70/524/EEC. However, none of the establishments visited made use of this possibility.
- The CCA keep up-dated lists of all approved and registered E/I, representatives of third country establishments and of all other establishments operating in the animal feed sector. However, although required under national legislation, the list of approved and registered E/I has not been published. According to the BAE, this list will be made available on their internet site within the next few weeks.
- There was no evidence that the federal control staff is supervised to ensure a uniform approach regarding approval and checks that the E/I still fulfil the conditions. According to the CCA, supervision of the BAE / AGES is achieved on the basis of the annual AGES reports.

5.3.2.2. Actions in case of non-compliance

According to the BAE, actions to be taken by them if an establishment fails to fulfil the requirements under which approval or registration was granted, has to be discussed on a case by case basis, when it occurs.

6. CONCLUSIONS

6.1. COMPETENT AUTHORITIES

1. The controls in the field of animal nutrition are carried out by a relatively small federal control body and as regards on-farm controls, mainly by the veterinary services. The responsibilities between the services are adequately defined. Staffing and training allow adequate controls.
2. In many areas of the feed controls the CCA and/or the AGES issued adequate guidelines or instructions. However, for the AGES inspectors adequate guidance is not in place as regards the official inspections including risk-based targeted sampling, checks for approval and registration, and the proper documentation of their activities to ensure a uniform application. This is deemed unnecessary by AGES given the short communication lines within the small and centralised federal control body.
3. The supervision within the different levels of the federal controls is not clearly defined.

6.2. OFFICIAL INSPECTIONS IN THE FIELD OF ANIMAL NUTRITION

1. The official controls are largely applied as required by Council Directive 95/53/EC and in line with Commission Recommendations 2002/214/EC and 2003/91/EC[11] on the co-ordinated inspection programmes in the field of animal nutrition for the year 2002 and 2003, respectively, covering all stages in the feed chain; however, mobile mixers are not specifically included.
2. The control programme drawn up for 2003 takes comprehensive account of risks identified by previous inspections and sampling. However, other risks, especially at the level of establishments, are not clearly accommodated and therefore the programme covers only a part of the criteria set out in Article 4 of Council Directive 95/53/EC. In practice, it could not always be demonstrated that the inspections and the sampling are sufficiently risk based. This is mainly due to a lack of guidance and documentation for the federal controls.
3. Arrangements for the import controls of feed materials provide for a close supervision of such products, although the physical checks are not in line with Article 7 of Council Directive 95/53/EC, in particular when products are marketed in the territory of another Member State. The system in place to inform the AGES, and if applicable the competent authorities in another Member State, about all relevant consignments released for free circulation is well documented and exceeds EU requirements.
4. The laboratory network meets the requirements set out in Article 18(2)-(3) of Council Directive 95/53/EC. However, the decisions on analyses to be carried out are most times not documented to reflect the risk-based and targeted approach, and tolerances for additives are accepted which is not in line with the procedure set out in Article 21 of Council Directive 70/524/EEC.
5. The provisions for a response to emergencies are clear, transparent and sufficiently detailed.

[11] Commission Recommendation 2002/214/EC of 10 February 2003 on the co-ordinated inspection programmes in the field of animal nutrition for the year 2003 in accordance with Council Directive 95/53/EC, OJ L 34, 11.2.2003, p.20

6. Actions in case of infringements are in line with Article 19 of Council Directive 95/53/EC, the deterrent effect of which has been reinforced taking into account previous experience on this issue.

6.3. APPROVAL AND REGISTRATION OF ESTABLISHMENTS AND INTERMEDIARIES

1. National legislative provisions exceed EU requirements and allow in general a good overview on the operators in this sector. However, it does not ensure adequate information on mobile mixers.

   The national provisions for approval and registration of certain E/I are largely in line with the EU requirements, with the exception of requirements for intermediaries operating only nationally and the authorisation for approved establishments to add certain additives directly into CFS.

2. The application in practice largely fulfils the EU requirements. The system in place to keep the industry regularly informed as regards the requirements in the animal feed sector is satisfactory. However, for some establishments the decision on the final approval has not yet been taken due to the limited number of staff at the BAE.

3. It was not ensured that all approved establishments had put in place all necessary requirements. The checks carried out by the AGES in order to be satisfied with the operators' measures and to ensure that E/I still meet the requirements under which they were approved or registered could not be demonstrated. This may be due to a lack of sufficiently detailed guidance for the federal control staff
   - on some of the minimum requirements to be fulfilled for approval (e.g. quality controls, documentation, traceability), and
   - regarding documentation of their controls,

   which both compromise a uniform approach of the procedures and their supervision.

4. The list of approved E/I has not yet been published as laid down in Article 6 of Council Directive 95/69/EC.

6.4. OVERALL CONCLUSION

A largely satisfactory control system is in place. However, certain shortcomings with regard to guidance and documentation at federal level hamper its uniform application.

7. CLOSING MEETING

A closing meeting was held on 19 September 2003 with the representatives of the BMLFUW. At this meeting, main findings and preliminary conclusions of the mission were presented by the inspection team. The representatives of the CCA disagreed upon most of the conclusions provided by the mission team, stating that:

- The usefulness of the risk based approach for controls and sampling is questionable;
- Additional documentation requirements would only lead to increased paperwork for inspectors;
- In general, the different control bodies in Austrian work autonomously rather than being supervised by their superior levels.

In addition, they expressed reservations about certain aspects of the way in which the mission was carried out.

During the meeting, additional information as requested by the mission team was provided by the competent authorities.

8. RECOMMENDATIONS

8.1. TO THE COMPETENT AUTHORITIES OF AUSTRIA

The competent authorities of Austria are invited to provide, within 25 working days of receipt of the final translated report, details of the actions taken and planned, including deadlines for their completion, to address the following recommendations:

With regard to the performance of the competent authorities

1. To review the supervision within the different levels of the federal controls in order to be able to demonstrate the correct and complete application of the controls.

With regard to the official inspections in the field of animal nutrition

2. To further develop the control programme taking into account all risks as set up in Article 4 of Council Directive 95/53/EC, in particular as regards the possible risks at operators level such as carry-over and cross-contamination between batches.
3. To ensure that auditable evidences on the implementation of the official control programme is provided for, including mobile mixers.
4. To ensure that random physical checks are performed on imported feed material before they are marketed as set out in Article 7 of Council Directive 95/53/EC, regardless of their destination within the Community.
5. To ensure the application of the procedure provided for in Article 21 of Council Directive 70/524/EEC with regard to tolerances allowed in the content of additives.

With regard to the approval and registration of establishments and intermediaries operating in the animal feed sector

6. To bring national legislation in line with Articles 3 and 8 of Council Directive 95/69/EC as regards approval or registration of intermediaries putting certain additives and premixtures into circulation, regardless whether they operate in national or international trade.
7. To review the practice to authorise approved establishments to add certain additives directly into CFS without having proof that these additives have been authorised for direct mixing into CFS in accordance with Article 13 of Council Directive 70/524/EEC.
8. To ensure that all approved establishments fulfil all the necessary requirements as laid down in Chapter I of the Annex to Council Directive 95/69/EC, in particular as regards a written own control plan.
9. To consider issuing for the federal control staff detailed guidelines or instructions regarding all requirements for approval and registration referred to in the Annex of Council Directive 95/69/EC and on the documentation of their checks carried out in accordance with Article 13 of above Directive in order to ensure a uniform approach.
10. To publish the list of approved E/I and its regular up-dates as referred to in Article 6 of Council Directive 95/69/EC.

ADDENDUM TO THE MISSION REPORT DG(SANCO)/9164/2003

Within the given time, no reaction was received from the competent authorities of Austria in response to the draft report or to the recommendations made in the draft report.