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HEALTH & CONSUMER DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO)/2007-7995 – final report

GENERAL AUDIT

AUSTRIA - 2007

FINAL REPORT

Please note that factual errors in the draft report have been corrected. Clarifications provided by the Austrian Authorities are included as footnotes, in bold, italic, type, to the relevant parts of the report.

EXECUTIVE SUMMARY

This report describes the outcome of a general audit carried out by the Food and Veterinary Office in Austria in 2007. It was conducted as a pilot exercise to test and develop a harmonised approach and methodology for general audits.

The overall objective was to verify that official controls were carried out in compliance with Community law and in accordance with the Austrian multi-annual national control plan (MANCP) drawn up in accordance with Art. 41 of Regulation (EC) No 882/2004. The general audit comprised seven specific audits carried out between January and November 2007.

In terms of scope, it focused on the measures taken to ensure compliance with the requirements of Regulation (EC) No 882/2004 concerning official controls, designation of competent authorities and operational criteria, delegation of tasks, staff performing controls, transparency and confidentiality, controls procedures, enforcement measures and MANCP.

On the basis of the results of the specific audits and with all the necessary reservations derived from the pilot nature of this general audit, it can be concluded that, overall, official controls were carried out largely in compliance with Community law, although some weaknesses and areas for improvement were identified, in particular as regards staff resources and verification of the effectiveness of official controls. As to whether or not official controls were carried out in accordance with the MANCP, the general audit did not allow a definite conclusion to be reached given that the plan did not contain sufficient information for all the concerned areas; nevertheless, the plan provided a coherent and integrated framework of the control systems in place which was very useful for the organisation and completion of this general audit.

The report contains a number of recommendations addressed to the Austrian authorities, aimed at further enhancing the control systems in place.

ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

ABP	Animal by-products
AGES	Austrian Agency for Health and Food (*Österreichische Agentur für Gesundheit und Ernährungssicherheit*)
AMA	Agra Markt Austria Marketing GmbH
APF	Action plan on feedingstuffs (*Aktionsplan Futtermittel*)
BAES	Federal Office for Food Safety (*Bundesamt für Ernährungssicherheit*)
BFW	Federal Forestry Office
BIP	Border inspection post
BMGFJ	Federal Ministry for Health, Family and Youth (*Bundesministerium für Gesundheit, Familie und Jugend*)
BMLFUW	Federal Ministry of Agriculture, Foresty, Environment and Water Management (*Bundesministerium für Land und Forstwirtschaft, Umwelt und Wasserwirtschaft*)
BVD/MD	Bovine Viral Diarrhoea / Mucosal Disease
CA	Competent authority
CCA	Central competent authority
FI	Food Inspectorate
FVO	Food and Veterinary Office
GMO	Genetically modified organism
HACCP	Hazard analysis and critical controls points
IBR/IPV	Infectious Bovine Rhinotracheitis / Infectious Pustular Vulvovaginitis
ICT	Intra-Community trade
LMSVG	Food Safety and Consumer Protection Act
MANCP	Multi-annual national control plan
MS	Member States
NRL	National reference laboratory
OV	Official veterinarian
PPPS	Provincial plant protection services
RASFF	Rapid alert system for food and feed
SOP	Standard operating procedure
TRACES	Trade controls and expert system

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1. INTRODUCTION

Art. 45 of Regulation (EC) No 882/2004 [1,2] requires that Commission experts shall carry out general and specific audits in Member States (MS); the main purpose of the audits, which are to be carried out on a regular basis, is to verify that, overall, official controls take place in MS in accordance with the multi-annual national control plans (MANCPs) and in compliance with Community law. The general audit represents the comprehensive process of evaluating the performance of the competent authorities (CAs) of a MS as regards both the implementation of the MANCP and the EU feed and food legislation. It consists of a number of specific audits which provide objective evidence concerning the effectiveness of the control systems in place.

This report presents the outcome of a pilot general audit carried out in Austria during 2007. It was designed to assist in the development of a *modus operandi* for this new type of comprehensive audit, and it was carried out in close cooperation with the Austrian CAs who volunteered to participate in this exercise [3]. The reports of the specific audits are divided in two parts: Part A, which addressed the horizontal aspects related to the implementation of Regulation (EC) No 882/2004, and Part B, which addressed the implementation of sector specific Community rules in the areas subject to evaluation. The horizontal information gathered during the course of the specific audits is presented under section 5 of this report, while sector specific issues for each of the areas concerned is included in the Annex to this report.

2. OBJECTIVES AND SCOPE

The objective of the general audit was to verify that official controls were carried out in compliance with Community law and in accordance with the Austrian MANCP drawn up in accordance with Art. 41 of Regulation (EC) No 882/2004.

In terms of scope, the general audit covered the following horizontal issues:

- Organisation and implementation of official controls;
- Designation of CAs and operational criteria;
- Delegation of specific tasks related to official controls;
- Staff performing controls;
- Transparency and confidentiality;
- Control and verification procedures, and reports;
- Enforcement measures;
- MANCP implementation.

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1 Legal acts quoted refer, where applicable, to the last amended version.

2 Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules; OJ L 165, 30.04.2004, p.1; corrected and republished in OJ L 191, 28.05.2004, p. 1.

3 A pilot general audit has also been carried out in the Netherlands.

3. AUDIT PROCESS

The general audit commenced with an opening meeting held on 29 January 2007 between the audit team and the Austrian authorities. During this meeting the objectives and scope of the evaluation, the reporting procedures for the general audit and the programme of specific audits were discussed and agreed. The preliminary review of the Food and Veterinary Office (FVO) concerning the MANCP was also presented. The table below sets out the list of specific audits.

DG(SANCO) references	Specific audits	Dates
2007-7177	Food, feed and seed consisting of or produced from genetically modified organisms	29 Jan. – 02 Feb.
2007-7224	Import controls on food and feed of non-animal origin	05 – 09 Nov.
2007-7350	Intra-Community trade in live animals	25 Jun. – 06 Jul
2007-7370	Intra-Community trade in semen and embryos of domestic animals of the bovine species	04 – 11 Jun.
2007-7500	Official controls on feed and compliance with requirements for feed hygiene	04 – 12 Sep.
2007-7518	Health rules on animal by-products	22 – 30 May
2007-7602	Plant passport system, the current situation of *Erwinia amylovora* (Burr) and the system of import controls for plant health	04 – 12 Sep.

In the framework of the general audit, prior to its start, the Austrian CAs were asked to submit the MANCP to the FVO; at that stage, the general audit team carried out an evaluation concerning the plan as regards its completeness and appropriateness (the results of the assessment are presented in section 4). Under normal circumstances, this analysis of the MANCP would have informed the selection of specific audits; however, given the pilot nature of this general audit, the choice of specific audits had been made prior to the analysis of the MANCP and in the framework of the mission programme prioritization process within the Health and Consumer Directorate General. For this reason, the conclusions of the present pilot general audit have to be considered under the clear understanding that the sectors audited may not provide a fully representative picture of the overall control systems in place in Austria.

It should also be noted that only Art. 41 to 46 of Regulation (EC) No 882/2004 are applicable to plant health. However, Directive 2000/29/EC [4] provides for requirements that are broadly equivalent to those established by the said Regulation; for this reason, and because plant health is an integral part of the MANCP, it was considered that a specific audit on plant health would contribute to the objectives of this general audit.

The general audit ended with a closing meeting held on 11 January 2008, during which the main preliminary conclusions were presented to the Austrian authorities by the FVO audit team.

4 Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plants products and against their spread within the Community; OJ L 169, 10.07.2000, p. 1.

4. MULTI-ANNUAL NATIONAL CONTROL PLAN

Legal basis

Art. 41 of Regulation (EC) No 882/2004 requires each MS to prepare a single integrated MANCP. The plan should contain general information on the structure and organisation of the systems of food, feed, animal health, animal welfare and plant health control in the MS concerned. This should include information on the aspects set out in Art. 42 (a-k). The plan should take account of Decision 2007/363/EC [(5)] on guidelines to assist MS in preparing the single integrated MANCP.

Desk analysis

A first draft of the MANCP was received on 26 October 2006 and a revised version on 2 August 2007. These were subject to an assessment concerning their completeness and appropriateness.

The main elements of the plan that meet the requirements of Regulation (EC) No 882/2004 include:

- The period of validity of plan is four years (2007-2010).
- Under Art. 30 of the Austrian Food Safety and Consumer Protection Act (LMSVG), the Federal Ministry for Health, Family and Youth (*Bundesministerium für Gesundheit, Familie und Jugend* – BMGFJ) is the CA for coordination the development and implementation of the plan.
- The plan contains the basic information required on the structure and organisation of official controls covering all sectors and all stages of the food and feed production chain, animal health, animal welfare and plant health.
- Strategic objectives are indicated in very general terms for all control sectors.
- Objectives, tasks and resources are indicated for CAs at central, provincial and local level. A breakdown of human resources is provided in relation to specific control sectors and commodities.
- The control systems applied in the different sectors and system of coordination between them are described.
- Risk categorisation is sufficiently described for the food, feed and ABP sectors.
- The plan includes a very general description of delegated control bodies.
- Documented procedures are described for food, feed, animal health, animal welfare and plant health sectors.
- The plan sets out the operational criteria to be applied to ensure that official controls are performed in accordance with Art. 4 (2) of Regulation (EC) No 882/2004.
- It specifies that staff that carry out official controls have to be free from any conflict of interest and that they have the appropriate legal powers to carry out these controls and to take appropriate measures.

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5 Commission Decision 2007/363/EC on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council; OJ L 138, 30.05.2007, p. 24.

- A description of laboratory capacity is provided and an assurance given that staff resources are adequate to perform official controls effectively.
- Contingency plans for animal or food-borne disease emergencies, feed and food contamination incidents and other human health risks are included in the plan. For each contingency plan, the bodies responsible for their implementation are described.
- Provisions on cooperation and mutual assistance according to Art. 42 (2) (k) of Regulation (EC) No 882/2004 are described.

However, there are gaps in a number of areas in the plan, as follows:

- The strategic objectives of the plan are not linked to the allocation of resources so the prioritisation of control activities according to strategic objectives is not clear.
- Arrangements for assessing progress in the implementation of the plan are not clearly described.
- Audit arrangements are described for food safety aspects only. The feed, animal health and animal welfare sectors are not covered.
- Arrangements for follow-up, independent scrutiny and transparency of audits are not described [6].
- The arrangements to verify the effectiveness of official controls that CAs carry out are not described in the plan.
- A risk categorisation project for the food and feed sectors was completed in 2006 and forms the basis for risk categorisation in the plan but this applies to these sectors only. The animal health, animal welfare and plant health sectors are not covered.
- The scope of the plan covers all relevant commodities at all production stages, but specific information on the frequency of control activities and the control methods is quite limited in certain areas, including: import controls, identification and registration of live animals, intra-Community trade (ICT) in live animals, food contact materials, pesticides and plant protection products, veterinary medicine products, Transmissible Spongiform Encephalopathies, genetically modified organisms (GMOs), irradiation, quality and compositional requirements of feed and food, labelling, nutritional aspects, organic farming, traditional specialities, and geographical indications of origin.
- Apart from organic farming control bodies, a list of all other delegated control bodies is not provided in the plan. There is no description of the arrangements to ensure that these delegated control bodies meet the requirements of Art. 5 of Regulation (EC) No 882/2004 with regard to approval, supervision, coordination and communication [7].
- Guidelines for controls on animal by-products (ABP) and meat are being developed but no indication is given as to when these will be completed.

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6 ***In their response to the draft report the Austrian Authorities indicate the existing arrangements for the drafting of internal audit reports and their follow-up, as well as how independent scrutiny is ensured; this information will be included in the next version of the MANCP.***

7 ***In their response to the draft report the Austrian Authorities note that delegated control bodies have to be accredited by the competent federal ministries, which regularly inspect them in accordance with accreditation rules; moreover, the control bodies have to submit annual reports of their activities to the concerned ministries and provincial authorities.***

– How the training needs are identified and all the areas covered that are referred to in Chapter I of Annex II to Regulation (EC) No 882/2004 is not clear. Training in feed sector is not described in the plan.

The Austrian CAs have indicated that the MANCP is an evolving document which is being adapted regularly; at the closing meeting of the general audit they announced that a revised version would be available early in 2008.

Conclusion

The desk study carried out on the MANCP showed that it is a comprehensive document that served as starting point for the organisation of audits by the FVO. The progress made in the development of the MANCP has also been noticeable when comparisons were made with earlier versions of the plan. However, there were some areas where further development of the MANCP was still needed, namely the degree of information available in several horizontal and vertical areas, the correlation between strategic objectives and resources, and the development of a comprehensive audit system.

5. FINDINGS AND CONCLUSIONS

5.1. ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS

Legal basis

Art. 3 of Regulation (EC) No 882/2004 requires MS to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency. In doing so they must take account of identified risks that may influence feed and food safety, animal health or animal welfare, past records of operators, the reliability of operators own checks, and any information of non-compliance. They shall be carried out at any of the stages of the production and processing chain. In general, such controls are to be carried out without prior warning, except where prior notification of the business operator is necessary.

Audit findings

Official controls in the areas covered under the general audit are generally organised on the basis of annual inspection plans which, as needed, establish the allocation of official controls at different stages of the production chain, and also distribute the number of samples and analyses. Overall, these annual inspection plans are produced on the basis of legal obligations and risk analysis. The principle established by section 35 (3) of the LMSVG that official inspections are to be generally carried out without prior warning is abided by.

Regarding GMOs, annual inspection and sampling plans for food are issued by the BMGFJ on the basis of a proposal from the federal provinces and after consulting the Austrian Agency for Health and Food (*Österreichische Agentur für Gesundheit und Ernährungssicherheit* – AGES); the plans set out the number of inspections and samples from soya and maize products in the provinces' Food Inspectorates (FIs), which decide on operators and products to be sampled. The official control programme for GMO feed is issued by the Federal Ministry of Agriculture, Forestry, Environment and Water (*Bundesministerium für Land und Forstwirtschaft, Umwelt und Wasserwirtschaft* – BMLFUW) on the basis of a proposal from the Institute of

Feedingstuffs and the Federal Office for Food Safety (*Bundesamt für Ernährungssicherheit* – BAES); within the framework of the control plan, inspectors decide on the operators to be visited, taking into account the size of the establishment, previous inspections, products manufactured and messages of the rapid alert system for food and feed (RASFF). However, plans for official controls at farms were still in preparation.

Concerning import controls of products of non-animal origin, Customs notifies all imported consignments included in their working guideline on food to the provincial authorities, which implement official controls on the basis of the relevant Commission Decisions [8,9]. The frequency of official controls was respected, except for consignments of hazelnuts and products derived from figs, hazelnuts and pistachios from Turkey. Moreover, imported foodstuffs of non-animal origin not subject to special conditions, but of known or potential risk, were not submitted to any control as their arrival is not notified to the FIs by Customs (these products are not included in the working guideline). Establishments importing food are categorised according to risk which determines the frequency of inspections; a database is in place for this purpose (it includes information concerning size, production systems, origin of raw materials, in-house controls and results of inspections).

The nature and frequency of official controls for ICT in live animals is established in Federal decrees, which are modelled closely on Community requirements and provide for the frequency of controls to be modified on the basis of risk. Official controls and enforcement actions are carried out by the provincial government (*Landeshauptmann*) and the authorities subordinated to them, with the provincial government being bound by orders from the competent federal minister. In one case, a ministerial order has been misinterpreted by the provincial CAs: the order is intended to ensure that breeding cattle in the 10% of consignments selected for physical checks are tested for Infectious Bovine Rhinotracheitis / Infectious Pustular Vulvovaginitis (IBR/IPV), but the provincial authorities understood this order in the sense that breeding cattle in all consignments had to be tested. In general, official veterinarians (OVs) in the districts comply with the provisions issued by the provincial government; however, in one case an OV decided not to comply with the minimum frequency of inspections to assembly centres set out by a Federal decree (one a year).

In the area of ICT in bovine genetic material, centres for collection and storage of semen and embryo collection teams are inspected according to the requirements set out by Community and national legislation. The inspections of centres and teams are carried out at appropriate frequencies, in line with the relevant Directives [10,11]; however, one semen collection centre and one embryo collection team was not inspected according to schedule.

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8 Commission Decision 2005/402/EC of 23 May 2005 on emergency measures regarding chilli, chilli products, curcuma and palm oil; OJ L 135, 28.05.2005, p. 34.

9 Commission Decision 2006/504/EC of 12 July 2006 on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins; OJ L 199, 21.07.2006, p. 21.

10 Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species; OJ L 194, 22.07.1988, p. 10.

11 Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species; OJ L 302, 19.10.1989, p. 1.

Regarding feed safety, the general organisation of controls, responsibilities, procedures and reporting systems are defined in the action plan on feedingstuffs (*Aktionsplan Futtermittel* – APF) prepared by BMLFUW. Within the framework of the APF, BAES prepares each year a control plan for feedingstuffs in conjunction with the AGES Biostatistics Institute. The control plan establishes the overall number of samples and analyses and the distribution of controls and sampling at the different stages of the feed chain; the sampling plan takes account of the risk principles outlined in relevant Commission Recommendations [12,13]. However, the APF does not determine the inspection frequency for feed operators based on risk criteria, although this is intended in the future: an inspection frequency of once a year has been set for feedmills irrespective of any other consideration, and no inspection frequency has been set for the remaining operators [14] (apart from those at farm level, of which 2% should be visited each year); moreover, in one province a feedmill with one of the highest outputs in Austria had been inspected once in 2003 but not again until 2007 and, in another province, one feedmill with a relatively high output and producing feed containing coccidiostats was not inspected until seven months after reconstruction work which affected more than 50% of its equipment.

From January 2007 official controls on ABP are organised in accordance with the MANCP, where priorities have been determined on the basis of risk assessments carried out by AGES. However, at this early stage of implementation of the MANCP all establishments of the same type have been allocated the same frequency of controls. In the ABP area, a specific risk assessment has been carried out which lays down the minimum frequency of control visits that should be carried out during a year in each type of ABP plants and premises, e.g. Category 1 processing plants should be visited twice per year while incineration and co-incineration plants should be visited once every two years. It is intended that establishments where problems are identified will be subject to an increased level of controls.

In the area of plant health, an annual control plan has been prepared by the Federal Forestry Office (BFW) and AGES based on risk assessments and the capacities of the laboratory of AGES and the provincial plant protection services (PPPS); the plan includes targets for checks for plant passports, sampling and other surveys required with a certain frequency by the relevant Commission Decisions. Import controls are carried out as needed and each consignment declared to contain plants or plant products is inspected, the intensity of checks being based on risk (number of interceptions on the same commodity/origin and climate at the MS of destination). Following a risk assessment, orchid cut flowers imported in their personal baggage by passengers arriving from Thailand, Malaysia and Singapore must be accompanied by a phytosanitary certificate, and Customs officers have intercepted a considerable number of prohibited orchid cut flowers and other prohibited items. However, the personnel carrying out health checks on commercial shipments of plant products did not perform a risk assessment, as they do not have access to the necessary information (an up-to-date list of interceptions) to do so.

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12 Commission Recommendation 2005/925/EC of 14 December 2005 on the coordinated inspection programme in the field of animal nutrition for the year 2006 in accordance with Council Directive 95/53/EC; OJ L 337, 22.12.2005, p. 51.

13 Commission Recommendation 2006/88/EC of 6 February 2006 on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs; OJ L 42, 14.02.2006, p. 26.

14 ***In their response to the draft report the Austrian Authorities note that the control programme is being revised and, as of 2008, the number of inspections is established.***

Conclusion

Overall, the requirements laid down in Art. 3 of Regulation (EC) No 882/2004 were largely complied with, since official controls were organised regularly, on a risk basis and with appropriate frequencies, and they were carried out without prior warning. However, the said picture was affected by the inspections plans being at an early stage in the areas of feed safety and ABP, the absence of consideration given to certain risks concerning imported food of non-animal origin, plants and plant products, as well as individual deficiencies in controls for ICT in live animals and bovine genetic material.

5.2. DESIGNATION OF COMPETENT AUTHORITIES AND OPERATIONAL CRITERIA

Legal basis

Art. 4 of Regulation (EC) No 882/2004 requires MS to designate the CAs responsible for official controls, and sets out the minimum operational criteria that each CA must meet. There must be efficient and effective co-ordination and co-operation between the various organisations involved at all levels. CAs are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Audit findings

Austria is a Federal Republic comprising nine provinces and 99 districts. At federal level the government consists of the Federal Chancellor and Federal Ministers. In each province there is an executive composed of a Provincial Governor and Councillors. Districts are headed by a District Commissioner who is appointed by the Provincial Governor.

Within the Austrian federal political system, the Federal Government is responsible for most legislation on food and feed safety, animal health, animal welfare and plant health. The competences for implementing the legislation are attributed either to the Federal Government (federal administration) or the provinces (provincial administration).

Where the Federal Government holds the competence, it implements the legislation by use of the Provincial Governors and the provincial authorities; the system is known as indirect federal administration. Under this system, the tasks of the CCAs as regards the implementation of controls are limited to planning and coordination and the issuing of instructions, whereas Provincial Governors and the provincial authorities function as federal authorities; Provincial Governors are bound by instruction from the Federal Government but they are directly responsible for organising controls and ensuring that resources as used as needed.

The only sectors where the Federal Government acts directly (direct federal administration) are import controls on animals and food of animal origin, phytosanitary import controls, controls on the marketing of plant protection products and veterinary medicines. In these cases, the federal administration has both the power to issue implementing legislation and to carry out official controls.

Under the system of provincial administration, the provinces have the sole competence for implementing the legislation. This applies to controls on the use of pesticides and feedingstuffs, animal welfare and monitoring and control measures for plant diseases;

in these cases, the Provincial Government holds the highest authority while the subordinated District authorities acts in first instance.

Concerning GMOs in food, BMGFJ is the designated CA responsible for policy making and legislation and is also in charge of issuing the annual official control programme for inspection and sampling. The FIs of the nine federal provinces are responsible for the inspection and sampling of foodstuffs at production, distribution, storage and retailing; in some cases food inspectors work for local authorities. AGES is responsible for scientific risk assessment, laboratory services and consumer information; its scope covers the whole food chain, from soil, seed, plant health, feed and food control to animal health and prevention and containment of infectious diseases in humans. AGES includes several institutes and competence centres, of which the Institute for Food Control in Vienna carries out activities regarding GMO food.

In the area of import controls of products of non-animal origin, CAs are designated as follows: a) BMFGFJ is the CCA with responsibility for import controls of foodstuffs of non-animal origin; it is responsible for legislation, policy development, communication of guidelines and instructions to the provincial authorities. b) The provincial authorities are responsible for implementing the controls and instructions issued by BMGFJ; they carry out inspection and sampling of imported consignments where appropriate, and are also responsible for controls on food importers. c) AGES is responsible for co-ordinating risk assessment, analysing import samples and issuing expert opinions, and it is also the RASFF national contact point; four of the five laboratories that are relevant in this area belong to AGES. d) Customs, under the Federal Ministry of Finance, are the competent body for the clearance of imported consignments, which are managed by a comprehensive database system based on CN codes which identifies consignments that need to be submitted to food inspection authorities before they are released into the market.

The Consumer Health Department of BMGFJ is the main authority responsible for official controls on ICT in live animals. They are also the senior authority for controls on the identification and registration of animals, apart from cattle; Agra Markt Austria Marketing GmbH (AMA) is responsible for related controls performed on the identification and registration of cattle, where the senior authority is BMLFUW. However, none of the different ministries involved in breeding, keeping or trading of horses has been given responsibility as the CA for the identification and registration of equidae.

In the area of ICT in bovine genetic material, there is a clear division of roles and responsibilities within the scope of the relevant Directives between the federal, provincial and district authorities. National legislation currently assigns the highest level of responsibility for the implementation of the relevant provisions to the provincial CAs. Some provincial CAs have appointed veterinarians to act as trade controls and expert system (TRACES) officers; they are responsible for providing technical support to OVs, who use the system for monitoring notifications to and from units within their province.

As regards feed safety, including GMO feed, the roles and responsibilities of the CAs involved in official controls are outlined in the APF (which includes a contingency plan for feed), and they were well understood at CCA and province level: a) BMLFUW is the CCA responsible for issuing general instructions and policy making; within BMLFUW, Department I/2 is responsible for feedingstuffs. b) BAES is the

CCA responsible for the implementation of official controls in accordance with Regulation (EC) No 882/2004, while it also the responsible authority as mentioned under Art. 17(2) of Regulation 1829/2003 [15]; it has delegated the physical implementation of controls (inspections and sampling) in the feed sector to the Institute for Feedingstuffs of AGES, with the exception of controls on the use and production of feed at farm level which falls under the responsibility of the veterinary administrations of the provinces and districts. c) AGES provides scientific and technical support in this field: it coordinates all technical measures, carries out risk assessments, organises training courses, and analyses samples taken by the CAs in its Institutes for Feedingstuffs. d) Border inspection posts are responsible for import controls of feedingstuffs of animal origin while Customs are responsible for controls on imports of feedingstuffs of non-animal origin in cooperation with BAES.

The CCA for ABP is BMGFJ. The responsibility for coordination of food controls and hygiene, other than in connection with primary production, rests with Section IV (Consumer Health) of Department IV/B/7 of BMGFJ; controls of slaughterhouses, meat processing plants and ABP plants fall under the remit of Department IV/B/4. BMFLUW and AGES are responsible for ABP used as organic fertilisers and soil improvers, and the waste department of BMFLUW is responsible for waste related aspects of biogas and composting plants; the waste departments of the provinces are responsible for the authorisation and monitoring of incineration plants.

BMLFUW is the Single Authority for plant health. BAES, BFW and the nine PPPS are responsible official bodies for plant health in the context of Art. 2(1)(g) of Directive 2000/29/EC. The nine PPPS consist of four provincial administrative authorities and five Chambers of Agriculture in the provinces. Contingency planning for the management of outbreaks is the responsibility of individual PPPS; AGES provides technical advice to the PPPS for this purpose. Customs are responsible for performing checks of arriving passengers and commercial shipments. The division of tasks has been determined by the Plant Protection Act 1995 and the Plant Protection Framework Law: a) import checks are a direct federal authority task, i.e. they are funded and implemented by BAES and BFW; and b) plant passport controls are an indirect federal administration task, i.e. they are funded and implemented by the PPPS through the Governor of each province; monitoring activities, surveys and the management of outbreaks of harmful organisms are also direct provincial administration tasks.

Regarding the mechanisms to ensure that staff are free from any conflict of interest, most official controls are carried out by full-time civil servants, who are bound by civil service rules to act in the public interest (in the area of plant health, the Chambers operate under a legal basis which imposes to their staff the same rules and obligations applicable to public servants). In this sense, the Federal Civil Service Act and Provincial Civil Service Laws prohibit public servants from undertaking political or personal activities that may result in a conflict of interest with their duties; all potential conflicts must be declared.

Official controls for ICT in live animals are predominantly carried out by full-time OVs, who need an official authorisation before undertaking any private practice. Although private veterinary practitioners may be authorised to carry out official duties,

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15 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed*;* OJ L 268, 18.10.2003, p. 1.

the role of these authorised veterinarians is limited to performing identity checks, *ante* and *post mortem* inspections in slaughterhouses as well as collecting diagnostic samples on farm holdings; they are allowed to perform inspections in their clients' animals but, in order to avoid potential conflict of interest, they are not authorised to carry out the final health inspection or issue health certificates for ICT.

In the area of ICT in bovine genetic material, veterinary officers may obtain a separate income from private veterinary practice, provided that they have received an authorisation from the provincial authorities, although in one province the CAs no longer grant this authorisation to newly recruited officers. In one province an OV had also operated in the capacity of centre veterinarian for a semen collection centre; given that the provincial CAs acknowledged that there was a potential conflict of interest, the situation was dealt with by their participation in the inspections of the centre. The issue was regularised in 2004 with the appointment of a full time centre veterinarian.

Concerning human resources, these are sufficient to perform the planned checks in the area of import controls of products of non-animal origin. However, OVs in several districts were unable to complete some of their official duties on ICT in live animals and bovine genetic material due to lack of staff resources; in one case this problem had been partially addressed by the appointment of an additional part time veterinarian. Moreover, officials in the provinces were unsure of whether sufficient staff would be available to carry out the number of controls for ABP required by the MANCP. In the area of feed safety, while the CAs in three provinces had enough resources to complete their current tasks satisfactorily, they were aware that the existing staffing level would not be sufficient to execute their tasks appropriately once official controls of primary producers in order to check compliance with the requirements of Regulation (EC) No 183/2005 [16] commenced, partly due to the commitments relating to cross-compliance checks; the said CAs had notified their hierarchy in writing about the staff shortage, but they have not yet received an answer. Finally, the CAs in the area of plant health noted that there had been reductions in staff resources; as a consequence, there was only adequate staff to perform high priority checks and not all the planned tasks could be completed.

As regards facilities and equipment, overall, these were sufficient. However, the CAs responsible of feed safety in one province did not have sufficient equipment to achieve their sampling targets. Moreover, in the area of plant health, the CAs noted that there has been a reduction in financial resources and, in particular, the BFW acknowledged that because of the insufficient allocation of resources by the concerned province, the measures taken in response to an outbreak of *Anoplophora glabripennis* near Braunau in Upper Austria were inadequate. Control of outbreaks is a provincial task, thus there is no federal budget to fund them; in the opinion of the federal CAs, the only option would be to approach the EU for financial assistance, given that the Austrian Constitution prevents one province from providing funding to another one.

In general, the CAs have the legal powers to carry out official controls, however, this was not always the case for ICT in live animals. This is because the provisions of Directive 2003/85/EC [17] have not been fully transposed into Austrian law, and Art. 10

16 Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene; OJ L 35, 8.02.2005, p. 35.

17 Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC; OJ L 306, 22.11.2003, p. 1.

of Regulation (EC) No 1/2005 [18] concerning requirements for transporters' authorisation was not yet implemented into Austria (although the Federal Ministry for Traffic, Innovation and Technology informed the provincial CAs in December 2006 that the said Regulation would apply directly from August 2007).

Coordination between all the CAs involved in official controls is usually achieved through various reporting obligations. In the area of GMO food, the LMSVG requires the federal provinces to report to BMGFJ infringements involving several provinces, the results of specific campaigns and cases where there is a health hazard (the municipal authorities should report to the provincial authorities); the provincial governors must submit to BMGFJ an annual report on the implementation of control and sampling plans by 31 March of the following year. The provincial activities report regularly to the CCA on activities performed on import controls of products of non-animal origin. In the area of feed safety, including GMO feed, the federal provinces and BAES submit to BMLFUW an annual report on the controls carried out by 1 March every year; the official control programme contains an obligation for the federal provinces to inform BAES in cases of non-compliance; a designated person in each province has to be informed about non-compliances found, and coordinates measures to be taken, if necessary. The PPPS submit annual reports to BMLFUW of their activities concerning plant health; each PPPS has designated one person who is responsible for coordinating with the other services, and with the EU Standing Committee on Plant Health

In the area of ICT in live animals and bovine genetic material, information on movement restrictions applied to animals and holdings for animal health or animal identification reasons is available on the AMA and Veterinary Information System databases, to which all OVs have access; up-to-date data on the animal health status of other MS are published on the Veterinary Service's intranet. However, while information concerning the granting and withdrawal of approval of holdings is exchanged between the CAs using the monthly official veterinary journal (*Amtliche Veterinärnachrichten*), the withdrawal of the approval of assembly centres and dealers' premises do not result in movement restrictions of the concerned holdings being reflected on the AMA database, and there is no system to inform OVs or centre veterinarians in other provinces about the suspension of the approval of a semen collection or storage centre, or embryo collection team.

Meetings are other coordination mechanisms frequently used. For GMO food these are meetings of the Food Control Coordination group, which includes BMGFJ, the federal provinces, AGES and the provincial food institutes; these are held twice a year to adopt the control and sampling plans for GMO food, discuss the results and establish targets and strategies. Meetings between the heads of the FIs and BMGFJ are also held twice a year to coordinate ongoing activities, exchange views and discuss food safety and legal questions; in addition, *ad hoc* meetings are convened and working parties are set up when required. In the area of feed safety, including GMO feed, communication between the relevant ministries takes place when the need arise and it has recently been developed through the preparation of the MANCP. Joint meetings between the CAs involved in official controls organised by BMLFUW at least twice a year. Regular meetings are held between BMGFJ and the other authorities involved in the ABP

18 Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97; OJ L 3, 5.01.2005, p. 1.

sector at central level. Meetings between the BMGFJ and the provincial officials responsible for ABP are held at least three times per year, and Joint conferences between Food inspection officials of the provinces and BMGFJ are held twice per year; the issues discussed in these forums are the MANCP and its implementation, new legislation and the current status of controls, as well as quality management matters. In the area of plant health, bi-annual meetings are held between BMLFUW and the responsible official bodies, in addition to regular contact between these services, including regular telephone contact between AGES and the PPPS.

Regular meetings with the directors of the veterinary services of the provinces (*Länderveterinärdirektoren*) are used to coordinate activities on ICT in live animals. These are supplemented by meetings held at both provincial and district level, during which information is passed on to OVs and authorised veterinarians. The CAs consider that these meetings are essential for maintaining staff competence and all OVs should attend; indeed authorised veterinarians must participate in these meetings in order to be offered official employment. E-mails are used to distribute relevant information on an *ad hoc* basis within and between the provincial CAs. However, the approach taken to implementing national and Community requirements differs between the provinces; for example, while in some provinces premises could only be approved as either an assembly centre or as dealer's premises, others considered, contrary to EU requirements, that a single facility could be approved simultaneously as both types; the Federal CAs were not aware of this situation.

Similarly, regular meetings are also used to coordinate the controls carried out by different CAs dealing with ICT in bovine genetic material. For example, the head of the federal veterinary administration organises meetings with leading veterinary officials of the *Bundesländer* (veterinary directors of the provinces) at least three times a year to discuss the implementation of all veterinary activities, including controls in this area; representatives from the national laboratory service (*Unternehmensbereich Veterinärmedizin*) and the veterinary faculty in the University of Vienna are also involved in these meetings. Moreover, the federal CA is planning to organise meetings of a working group of veterinary experts of the provinces who are involved in collecting bovine semen and embryos with the intention of harmonising the implementation of official controls on ICT; a small working party, which includes veterinarians from each level, has already been established and has convened three times. However, in spite of the above communication mechanisms, OVs are largely autonomous and are expected to be able to cope with most situations alone; for instance, the OV responsible for controlling a Campylobacter outbreak in one semen collection centre received little direct support from the federal or provincial CAs.

In the areas covered under the general audit, the audits requested by Art. 4(6) of Regulation (EC) No 882/2004 have only been organised in the plant health sector, where one inspector was trained for this purpose and audits on the quality of the checks have been carried out since July 2006. Nevertheless, according to the CCAs, internal audits are already operating in the area of food safety, organised in accordance with the principles set out in the MANCP: two trained auditors from two different provinces audit a third province accompanied by an observer from the CCA. There are plans for the organisation of the said audits in line with the MANCP in the areas of feed safety, ABP and ICT in live animals and bovine genetic material, although there is no timeline for their implementation (the CA responsible for ICT in live animals in one province is planning to employ an inspector to audit veterinary control activities within the districts). There are no plans in the near future for organising such audits as regards import controls of products of non-animal origin.

Conclusion

The requirements laid down by Art. 4 of Regulation (EC) No 882/2004 for the designation of CAs and for staff being free from any conflict of interest were satisfactorily complied with, although no authorities have been identified for the registration and identification of equidae, which is required for ICT in live animals. Staff were adequate for carrying out import controls of products of non-animal origin, but they were insufficient to deal with official tasks in all the other areas, in particular for controls on ABP and feed safety requirements (notably in view of the additional obligations introduced, respectively, by the MANCP and current legal requirements) and in plant health. Overall, facilities and equipment were also adequate, but they had been affected by the existing arrangements for allocating financial resources in the area of plant health. The CAs had the legal powers to carry out their duties, except in specific cases of delays in the transposition or implementation of EU legislation in the area of ICT in live animals. There was efficient and effective coordination between the CAs, although some minor deficiencies were noted. Finally, the audits required by point 6 of the said article were not organised in most cases; nevertheless, it is acknowledged that they are being carried out in other areas that were not covered by the specific audits.

5.3. DELEGATION OF SPECIFIC TASKS RELATED TO OFFICIAL CONTROLS

Legal basis

Art. 5 sets out the scope of possible delegation to control bodies, the criteria for delegation, and the minimum criteria which must be met by control bodies. Where such delegation takes place, the delegating CA must organise audits or inspections of the control bodies as necessary. The Commission must be notified about any intended delegation.

Audit findings

There is no delegation to control bodies as defined in Art. 5 of Regulation (EC) No 882/2004 of specific tasks concerning GMOs, import controls of products of non-animal origin, ABP and plant health. The only official tasks within the scope of ICT in live animals that have been delegated to control bodies are post-slaughter checks on the identification of animals carried out by the meat classification service (*Service Stelle für Tierproduktion*), which is an independent agency audited by AMA.

Regarding ICT in bovine genetic material, most official tests carried out on bulls in semen collection centres are performed in laboratories of AGES, but tests for Bovine Viral Diarrhoea / Mucosal Disease (BVD/MD) are also carried out by approved private laboratories, some of which are not yet accredited but are allowed to perform the tests on a transitional basis and subject to an official appointment. These laboratories participate in proficiency tests organised by the national reference laboratory (NRL), but they are not subject to audits or inspections by the CAs.

In the area of feed safety, only official controls at farm level have been delegated. For instance, in one province the delegation concerned cross-compliance checks, which also include the verification of whether establishments fulfil the requirements of Regulation (EC) No 183/2005. While only verbal arrangements have been made with

the concerned control body, the CA confirmed that the requirements of Art. 5 of Regulation (EC) No 882/2004 are being met [19].

Conclusion

There was almost no delegation of official tasks to controls bodies and, where it existed, its significance was marginal. In the latter cases the requirements laid down by Art. 5 of Regulation (EC) No 882/2004 were generally complied with, although there were minor deficiencies.

5.4. STAFF PERFORMING CONTROLS

Legal basis

Art. 6 requires CAs to ensure that staff receive appropriate training and are kept up-to-date in their competencies.

Audit findings [20]

Formal training for food inspectors responsible for GMO labelling was organised in 2004 and 2005. Regarding feed, inspectors have not received formal training on GMOs; nevertheless, they have access to written information material on GMOs and if necessary they could contact the Institute of Feedingstuffs.

As regards import controls of products of non-animal origin, specific training sessions on the quality management system for official controls have been held for all provincial staff involved. Training on specific SOPs for import controls takes place according to a cascade system, and regular updates are organised as the legislation in this area changes. Training has been also organised in the provincial offices and at the laboratory.

In the area of ICT in live animals, OVs are required to pass a state examination in addition to their professional qualifications before they are engaged but once they are appointed and without training they carry out a range of official duties, including issuing health certificates for live animals; applicants for a recently advertised OV post in one district were required to have had experience working in veterinary practice in order to be considered eligible; in this case, the OV responsible for the district had intended to provide one-to-one training for the two newly recruited OVs before they undertook official duties (although this was only possible in one case). Several training courses for OVs have been organised at federal level. For example, training sessions covering the correct use of TRACES and certification principles for ICT in cattle, pigs, sheep and goats have been held and each course was attended by approximately 80 OVs; in addition, on-line training material on veterinary checks at the point of destination is available to OVs on the Veterinary Service's intranet. However, auxiliaries employed in approved slaughterhouses are not required to have

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19 ***In their response to the draft report the Austrian Authorities note that the concerned control body had been given only specific technical details, since it had already carried out cross-compliance checks delegated by another authority. In the future, all the requirements under Regulation (EC) No 882/2004 will be set out in writing.***

20 ***In their response to the draft report the Austrian Authorities note the legal basis to address training needs, according to which BMGFJ set up a committee to develop this issue. Further details are provided concerning the content of the training programme developed within this framework, as well as the number of officials who have completed it since 2007.***

undergone training, and there are no official training courses for OVs or other staff responsible for marking the description of horses on identity documents.

OVs dealing with ICT in bovine genetic material are highly motivated, technically proficient and, with the exception of one veterinarian responsible for an embryo collection team, they all understand their official responsibilities. However, OVs are appointed after they pass a state examination which does not require them to have a detailed knowledge of the implementation of legislation concerning ICT in bovine genetic semen and embryos; therefore, they have to developed their expertise following their appointment. Centre veterinarians and team veterinarians are not required to undergo any specialised training before commencing their duties; one centre veterinarian took the initiative of organising visits to other approved centres following her appointment in order to understand her duties. Official, centre and team veterinarians are invited to periodical information meetings organised by the federal CA to have an update about their official duties. Many centre veterinarians also attend technical meetings at EU level and are expected, in order to maintain proficiency, to study their subject area independently, but their participation in training events is not compulsory.

In the area of feed safety, staff are trained to conduct official controls following the requirements of Directive 95/69/EC [21] and Directive 95/53/EC [22]. Training with regard to new requirements of Regulation (EC) No 183/2005 and Regulation (EC) No 882/2004 has been given to new officials between 2005 and 2007 but, in general, not to staff conducting official controls which were already employed [23]. Indeed, AGES inspection staff and inspectors from two provinces declared that they had not yet received training in order to allow them to execute all their tasks competently concerning new requirements of Regulation (EC) No 183/2005 and Regulation (EC) No 882/2004, and import and export requirements for feedingstuffs; by contrast, Customs and border inspection posts staff stated that they had sufficient training to execute their tasks competently. The CAs are currently developing a new training plan which will focus on the new feed hygiene and official control requirements, and on requirements for imports and exports of feedingstuffs of animal and non-animal origin.

Staff responsible for the implementation of official controls in the food and ABP sectors have to hold a professional veterinary qualification or other relevant degree and they need to undergo training and successfully complete an examination in food hygiene in accordance with an ordinance on training inspectors (Federal Law Gazette No. 397/1983). In two provinces, regular training of staff is organised and, in particular, training sessions were held in January 2007 to explain the implications of the MANCP in the implementation of controls.

In the area of plant health, minimum educational requirements have been established for staff performing official controls, including Customs officials performing plant

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21 Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and amending Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC; OJ L 332, 30.12.1995, p. 15.

22 Council Directive 95/53/EC of 25 October 1995 fixing the principles governing the organization of official inspections in the field of animal nutrition; OJ L 265, 8.11.1995, p. 17.

23 ***In their response to the draft report the Austrian Authorities note that a new scheme for training staff conducting official controls has been developed, and it targets all staff. The training programme, which started in March 2008, covers in detail the new provisions of Regulation (EC) No 183/2005 and Regulation (EC) No 882/2004.***

health checks. Training courses are planned annually by AGES for all officials, and these could include an annual refresher course for staff of the PPPS; however, none of the PPPS staff met had attended the refresher course. Customs officers have attended a two-day induction course on the inspection of plants and plant products, but the course placed the emphasis on administrative issues. While information and training have been provided to officers performing checks of arriving passengers and their personal baggage, the staff met did not appear to be aware of the risk assessments or familiar enough with inspection techniques for commercial shipments of plant products [24].

Conclusion

Overall, staff performing official controls received, for their area of competence, appropriate training for undertaking their duties competently, as required by Art. 6 of Regulation (EC) No 882/2004. However, this training has not been updated to cater for the more recent rules on feed safety, and not all the training needs were satisfactorily addressed for Customs officers responsible for inspecting commercial shipments of plant products neither for staff working in some specific areas of ICT in live animals or bovine genetic material.

5.5. TRANSPARENCY AND CONFIDENTIALITY

Legal basis

Art. 7 requires CAs to carry out their activities with a high degree of transparency, in particular by giving relevant information to the public as soon as possible. The public is to have access to information on the control activities of the CAs and their effectiveness, and to information on food or feed risks when they arise, and to the measures which are to be taken to prevent, reduce or eliminate such risks. However, information covered by professional secrecy and personal data protection is not to be disclosed.

Audit findings

In the area of feed safety, the annual control programme and its results are available on the website of AGES (http://www.ages.at); the same applies to GMOs where, for food, this information is also available on the website of BMGFJ (http://www.bmgfj.gv.at). In both cases, data are published in an aggregate and anonymous form. In addition, BMGFJ has published a leaflet for the general public on labelling of GMO food, and stakeholders are consulted on a regular basis and for the development of new legislation

Information concerning inspections on imports of products of non-animal origin is available in the home page of the provincial authorities and in the above mentioned home page of BMGFJ. Moreover, pursuant to section 43 of the LMSVG, where it is suspected that food may present a risk, or the obligations of food business operators

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24 ***In their response to the draft report the Austrian Authorities note that BAES, as authority responsible for phytosanitary import controls, has already developed strategies to improve certain areas. This includes the accreditation of procedures under ISO 17020, and the development of training in accordance with this standard, as well as the inclusion of a supervisor to assist staff carrying out on-the-spot checks and to liaise with other national authorities.***

(under Art. 19 of Regulation (EC) No 178/2002 [25]) are not being met, the BMGFJ must inform the public. Relevant information is also transmitted to the general public when the nature, seriousness and extent of that risk are significant; the requirements for confidentiality are observed.

BMFGJ informs the public about its activities in the area of ABP by issuing an annual report and through the above-mentioned website. On this site, published in an aggregate and anonymous form, information is available on food and animal health controls and the risk analysis which forms the basis for the MANCP; at present the results of controls carried out under the MANCP are not published on the website although it would be possible to quickly publish information related to specific food scares if necessary. In the provinces, annual reports are published giving details of the control activities undertaken by their veterinary services; statistics about the flow of ABP are included in the reports but information on the results of official controls is not included.

Overall, there is no policy in place for the public to have access to information on the control activities of the CAs on ICT in live animals and bovine genetic material. The CAs do not publicise the details of premises (collection centres, farms, assembly centres and dealers' premises) from which approvals have been suspended, due to confidentiality reasons as this information is considered commercially sensitive; for instance, the official veterinary journal (*Amtlicher Tierseuchenbericht*) contains regular reports on animal disease outbreaks in semen collection centres, but the details of each case are limited and the identity of affected centres is not provided.

As regards plant health, the concerned federal authorities, as well as the PPPS, have established websites to inform the public; BAES and Customs have developed publicity material for passengers regarding the concession and prohibited items. The Civil Service Law and provincial Acts contain provisions relating to confidentiality and protection of official information, and there are similar requirements for Customs.

Conclusion

The requirements laid down by Art. 7 of Regulation (EC) No 882/2004 for transparency and confidentiality were complied with, except in relation to ICT in live animals and bovine genetic material, where no information about official controls was made available to the public.

5.6. CONTROL AND VERIFICATION PROCEDURES, AND REPORTS

Legal basis

Art. 8 requires that CAs carry out their official controls in accordance with documented procedures, containing information and instructions for staff, and must keep those procedures up to date. CAs must have procedures in place to verify effectiveness of official controls and to ensure effectiveness of corrective action.

Art. 9 requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained

25 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; OJ L 31, 1.02.2002, p. 1.

and any action taken by the business operator concerned. At least in the case of non-compliance, a copy must be given to the business operator.

Audit findings

Concerning documented procedures, official controls for GMOs are carried out in accordance with standard operating procedures (SOPs) which cover, among others, sampling of food and feedingstuffs, as well as food and feed inspections. For plant health, AGES has issued written guidelines for performing official checks; these include instructions for Customs officers on performing documentary checks, including checks of additional declarations included on phytosanitary certificates.

The Food Control Authorities have developed and implemented a standard quality management system for official controls since February 2006. The system is followed in all provinces for imports controls of products of non-animal origin, where updated official instructions are sent to the relevant bodies (food inspection authorities of the provinces, Customs, laboratories and food organisations); SOPs and checklists to support inspection activities are available in provinces, the laboratory and Customs offices. The same quality system is used for ABP inspection in food establishments, where the relevant checklists make reference to ABP requirements where appropriate. However, there were no guidelines for the controls to be carried out in ABP plants and premises, apart from some checklists for controls in biogas and composting plants; nevertheless, in the provinces there were some guidelines specific to the ABP plants and premises located therein.

In the area of ICT in live animals and bovine genetic material, in the past there were few documented procedures for official controls. For ICT in bovine genetic material, a recent decree has established official checklists to be used during the regular inspections of centres and teams; in this sense, a working party in charge of harmonising the implementation of official controls of bovine semen and embryo collection has developed new inspection checklists, which are now used throughout the country. For ICT in live animals, checklists for the inspection of assembly centres and dealer's premises have been recently updated, enabling OVs to evaluate the premises in a more methodical way. While in one province there were some initiatives to carry out inspections in a more uniform way through SOPs, OVs in other provinces had to decide how to implement provincial decrees on their own.

Official controls on feedingstuffs in business operators are carried out on the basis of guidelines, checklists, report templates and sampling instructions included in the APF; in particular, the APF contains guidelines on how to take samples on the basis of Directive 76/371/EEC [26] and includes guidelines and checklists on how to conduct official controls at farm level. However, APF guidelines, checklists and report templates do not yet reflect the new requirements of Regulations (EC) No 183/2005 and No 882/2004 [27] and no guidance regarding official controls on imported or exported feedingstuffs is included; representatives from the CCA and AGES noted that they intend to update the APF accordingly and one province has modified these

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26 Commission Directive 76/371/EEC of 1 March 1976 establishing Community methods of sampling for the official control of feedingstuffs; OJ L102, 15.04.1976, p. 1.

27 ***In their response to the draft report the Austrian Authorities note that the checklists for inspecting establishments have already been revised to take account of Regulation (EC) No 183/2005 and Regulation (EC) No 882/2004, and are being used since 2008.***

checklists to include controls for some of the new requirements of Regulation (EC) No 183/2005.

Concerning the verification of the effectiveness of official controls, there were no procedures to this end for import controls of products of non-animal origin. In the area of ABP, the supervision system had not detected that the deficiencies identified by previous inspections in some slaughterhouses had not always been corrected. Moreover, sampling plans regarding plant health were not always followed, given that its implementation is a direct provincial administration task and, as such, it is at the discretion of individual PPPS; nevertheless, surveys on this aspect are planned.

In the context of ICT of live animals, the Federal Ministry laid down, in July 2002, a procedure for random checks at destination, and set out a table to be used for recording them as well as the shortcomings ascertained; OVs have to present bi-annual reports to the provincial authorities, which in turn have to submit reports to the Federal Ministry. Furthermore, OVs are now required to enter the results of these checks on TRACES and, in one province the CAs monitor these reports. However, on a more general note, neither the federal nor the provincial CAs had an overview of whether the district OVs or authorised veterinarians completed the official controls as planned, as they do not supervise the undertaking of these controls and, instead, they rely on the reports of these controls submitted by officials at the lower levels. For example: while district OVs are obliged to inspect all assembly centres and dealer's premises annually and must submit copies of these reports to the provincial CA, this was not done in many cases and the provincial CAs, unaware of this situation, have not taken actions to correct it; similarly, the provincial CAs received summary reports on the progress of bovine brucellosis and leucosis monitoring programmes, but they could not verify whether the herds in each district are being tested every five years, as required by the national plan. The CAs plan to use a database to record these activities in the future, which will provide a tool for monitoring control.

In the area of ICT in bovine genetic material, the federal CAs do not supervise official controls carried out by OVs, and not all provincial CAs adopt a consistent approach on this issue; for example, the CAs in one province participate in the biannual inspections of semen collection centres, which were carried out solely by OVs in other provinces. Overall, OVs provide little feedback on the quality or effectiveness of the official controls they carry out. In some centres and teams where official inspections had been performed, they had not been able to detect certain deficiencies in the operation of quarantine facilities and the maintenance of records. Similarly, the provincial CAs had not detected that the OV responsible for one semen collection centre had not sent copies of official inspection reports.

With regard to procedures for verifying the effectiveness of official controls for feed safety, including compliance with sampling and inspections targets, the following was observed. The AGES sampling target for feed business operators other than on-farm mixers was not met in 2006: for example the targets for analyses were missed for PCB (by 32%) and for pesticides (by 27%), while the targets were exceeded for dioxin and dioxin-like PCB, and also for trace elements (in the latter case, by 270%); AGES plans to monitor these data in the future more closely to meet set targets. In one province the sampling and inspections targets for farms were met, however, in another province sampling targets were missed by 50% partly due to shortage of sampling equipment. The inspection frequency of once per year for feedmills has not been always been met,

and of AGES do not supervise whether the set inspection targets are me; nevertheless, they plan to do so in the future [28].

Concerning reports of official controls, in the area of GMO these include the inspections' minutes, the analyses carried out and the notification to the operator of their results, and the follow-up. Reports of control visits, which concerned partly ABP, were available in slaughterhouses; in ABP plants, reports (including deadlines for the correction of any deficiencies noted) were also produced and a copy was left to the business operators.

As regards ICT in live animals and bovine genetic material, in the past the contents of inspection reports were incomplete (sometimes not all requirements of the relevant Directives were covered) and not consistent and, in most cases reports were only produced if shortcomings were detected. For example, in one slaughterhouse the *post mortem* records only included cases where abnormalities were detected and did not show the total number of animals inspected, and *ante mortem* records did not indicate that several animals had been selected by the OV for separate slaughter (including a lame animal and dirty cattle). Moreover, until recently, operators did not receive copies of inspection reports and were only informed orally about non-compliances.

In feed business operators, reports of official controls conducted therein did often not contain information on whether the operators complied with legal requirements or not. In cases where non-compliances had been noted, sometimes no deadlines to remedy those were set and the follow-up inspection reports also lacked information concerning whether the previous non-compliance has been addressed [29]. As official controls with regards to new requirements of Regulation (EC) No 183/2005 and Regulation (EC) No 882/2004 have almost not started, those were also not captured in reports drawn up during inspections.

Conclusion

Official controls were largely carried out in accordance with the documented procedures laid down by Art. 8 of Regulation (EC) No 882/2004, albeit this has been done only recently in some areas; but documentation was not developed enough to cater for requirements concerning feed safety and ABP plants. Procedures to verify the effectives of official controls were either not in place or not able to ensure that they were rectified where needed; nevertheless, in some areas there were ongoing plans to address this issue. Finally, as regards reports of official controls, overall they were being drawn up, as requested by Art. 9 of Regulation (EC) No 882/2004, and a copy was provided to operators where necessary, albeit this has been done only recently in some areas. However, these reports did not always take account of all the necessary information.

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28 ***In their response to the draft report the Austrian Authorities note that the provincial authorities will be kept informed about the sampling situation, so that they can comply with the objectives set out in the inspection plan.***

29 ***In their response to the draft report the Austrian Authorities note that, as of 2008, a report is drawn up for every inspection and handed over to the operator; the report contains details of any irregularity detected.***

5.7. ENFORCEMENT MEASURES

Legal basis

Art. 54 requires a CA which identifies non-compliance to take appropriate action to ensure that the operator remedies the situation. In deciding on the action, it must take account of the nature of the non-compliance and the past record of the operator involved. The article prescribes the nature of the measures which such action should include, where appropriate. The operator concerned, or a representative, must be given written notification of the decision for action, the reasons involved, and the rights of and procedures for appealing that decision. The expense for the action is to be borne by the operator. In certain circumstances, the CA of the MS of dispatch is also to be informed the decision.

Art. 55 requires MS to have rules on sanctions applicable to infringements of feed and food, animal health and welfare law, and to ensure that they are implemented. The sanctions must be effective, proportionate and dissuasive.

Audit findings

As regards action in case of non-compliance, where unauthorized GMOs are detected, the concerned products are either recalled from the market by the operator or seized by the CAs. If the GMOs are authorized but not labelled, operators are notified and are liable to pay the costs of the sampling and analysis, and administrative procedures are launched. If the product is a feedstuff containing banned genetically modified maize over the threshold limit of 1%, the operator receives a notification and an administrative procedure is launched.

In the area of import controls on products of non-animal origin, the food inspection authorities have the right and the duty, according to Section 39 of the LMSVG, to impose appropriate measures in case of infringements; in particular, specific provisions with regard to import controls are detailed in Section 48 of the LMSVG. These measures include, among others, a ban on importing a product, seizure, an obligation to recall the product or the imposition of corrective measures on the establishment; food inspection authorities can also forward evidence of infringements to the competent judicial authorities. There has been no need to use the afore-mentioned enforcement measures, since the shortcomings have been always remedied. For example, where official controls of imported products detected the absence of the analytical reports concerning Sudan dyes requested by EU legislation, consignments have been detained and reports requested; moreover, in one province, there were notifications sent to importers requesting the rectification of shortcomings found during previous inspections, and follow-up visits to confirm that this rectification has been done.

Concerning ICT in live animals, district OVs are directly empowered to issue warnings and take other administrative actions (e.g. movement restrictions and the suspension or withdrawal of approvals) if animal keepers or business operators fail to comply with Community or national requirements; if keepers or operators object to these actions, they can appeal to the authorities at *Bundesland* level, in which case, the provincial CAs are called to provide an expert opinions. Although there were cases in which OVs were aware that keepers or operators had not met legal requirements, there was little evidence that the above described sanctions have been applied. For example, in one province several assembly centres and dealers' premises remained on the approved list although they had not been inspected for many years, contrary to the requirements of

the Austrian legislation (Art. 64(1) of the *Einfuhr und Binnenmarktverordnung* – 2001); the provincial CAs explained that these premises were not actively involved in ICT at present, but they did not want to withdraw the approval as the operators may wish to resume activities in the future and, in the meantime, they could not ask operators to pay for inspections of inactive premises.

In the area of ICT in bovine genetic material, official inspections had detected deficiencies in the implementation of the requirements and corrective actions and deadlines were specified. For example, a routine inspection of an embryo collection team in one province detected that the team had not been active for an extended period and no longer had the minimum necessary equipment; its approval was formally withdrawn. In other cases, however, although OVs had detected or been made aware of non-compliance with the requirements of Directives 88/407/EEC and 89/556/EEC, no corrective actions were taken: for example, the veterinarian of one semen collection centre permitted semen to be collected from bulls during quarantine, and this practice continued over several months, during which time the OV made numerous visits, until the centre veterinarian changed the quarantine policy; in another province, the veterinarian responsible for one embryo collection team informed the provincial CA when its mobile laboratory was decommissioned, but the OV did not review the approval and permitted the embryo collection team to continue in operation with inadequate facilities.

The CA can take different actions depending on the gravity of non-compliances with feed safety requirements. In case of minor deficiencies they can file a written objection or charge for the cost of sampling and analysis, and in more serious cases they can seize non-compliant products and order their destruction or even submit a complaint to the penal authorities; there were examples where the non-compliant feed business operators had to carry the cost of the sampling and analyses, and others where non-compliances have been simply remedied. However, in one primary producer recycling cereal products from bakeries and retailers into raw material for feed, cereal products containing meat were going into end products used for feed. The same problem had been detected by the CAs during a previous inspection, where a sample was taken and tested positive for products of animal origin, but, given that it took four weeks to get this result [30], when the CA returned to the producer all the material had left the premises and been probably consumed (a second sample taken from a different batch tested negative for products of animal origin [31]). The CA had not initiated an upward tracing to determine the source of the cereal products containing meat to avoid their delivery as raw material for feed; nevertheless, they committed to launch these actions [32]. Moreover, in one province, samples were sometimes taken without noting the batch number of the feed on the sampling protocol, which would make it difficult for the CA to initiate a recall, withdrawal or the destruction of non-compliant feed in

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30 ***In their response to the draft report the Austrian Authorities note that this turnaround time should be considered within the average; while efforts are made to reduce this time, the constraints related to quality procedures are to be considered. Moreover, a large number of samples or staff shortages could also cause delays.***

31 ***In their response to the draft report the Austrian Authorities note that this negative result was expected, in view of the dilution effect that occurred in the compound feed in question.***

32 ***In their response to the draft report the Austrian Authorities note that the identification of the source of contamination was not possible given that no samples from the individual bakeries or containers were retained. The suppliers have received written instructions from the feed manufacturer in order to avoid placing products containing meat in the collection containers. Finally, BAES intends to increase the number of checks on the processing of returned goods in the food industry and in the suppliers of these raw materials.***

case of a positive test result; nevertheless, officials from AGES noted that they will change the sampling protocol in order to always have the batch number noted.

Actions to be taken in case of non-compliance with requirements for ABP in the context of food legislation are laid down in the LMSVG. In addition, measures to be taken in plants failing to comply with the requirements laid down in Chapters III and IV of Regulation (EC) 1774/2002 are included in the Austrian Animal Materials Act (BGBl. I No 141/2003). If deficiencies are detected, on-the-spot inspectors may request in writing that the firm takes the necessary action to rectify the situation. If the firm does not respond to this, the matter can pass to the Provincial Governor who can order measures to correct any breaches of food legislation within specified deadlines. In one of the provinces an ABP technical plant failing to meet operational requirements had its approval withdrawn.

In the area of plant health, the PPPS are responsible for determining what measures should be taken in case of non-compliance; in this sense, AGES has issued guidance and recommended measures for a number of harmful organisms. After an inspection at farm level, a written record should be issued, which is to be communicated to the farm's representative together with the official orders given by the inspector; if the farmer does not comply with the said orders, an official letter is produced by the CAs and a complaint is issued. In the event of an offence, the PPPS report it to the competent district authority, so that administrative penalty proceedings can be undertaken. The PPPS and federal authorities for plant health had taken appropriate measures in case of interceptions or non-compliances; however, despite the afore-mentioned obligation, the official decision was normally communicated orally by the PPPS inspector and a written decision was only issued if the establishment did not comply with the oral decision.

Concerning sanctions applicable to infringements, sections 35 (7) of the LMSVG contain provisions for these, which, in principle, are effective and proportionate. Evidence was gathered by the audit team in some areas. For example, if animal keepers or business operators fail to comply with Community or national requirements for ICT in live animals, district OVs may also apply to the district (municipal) authorities to impose financial penalties, which are set out in national legislation. In the area of feed safety, the maximum fine which can be imposed is €7,200, which, in the view of the CCA and the AGES, is effective and dissuasive. Sanctions applicable to infringements of requirements for ABP are also laid down in the Austrian Animal Materials Act. For serious non-compliance with food legislation, criminal proceedings may be taken with fines of up to €40,000 being applicable; there where no cases of criminal proceedings for deficiencies in meeting requirements for ABP.

Conclusions

Overall, the requirements laid down by Art. 54 of Regulation (EC) No 882/2004 for action in case of non-compliance were largely met, albeit there were some minor deficiencies, notably the absence of written notifications to operators in the area of plant health. However, there were no actions to consistently ensure that feed operators remedied non-compliance.

Provisions were in place to ensure that the requirements laid down by Art. 55 of Regulation (EC) No 882/2004 for sanctions are complied with.

5.8. MULTI-ANNUAL NATIONAL CONTROL PLAN

Legal basis

Art. 45 (1) of Regulation (EC) No 882/2004 sets out that one of the main purposes of general and specific audits shall be to verify that, overall, official controls take place in accordance with the MACP referred to in Art. 41 of the said Regulation. Art. 45 (2a) further states that specific audits shall serve to verify the implementation of the MANCP.

Audit findings

The MANCP available at the time of the specific audits did not cover official controls in the areas of GMOs, and ICT in live animals and embryos, while it did not take account of official controls to ensure compliance with feed hygiene requirements laid down in Regulation (EC) No 183/2005. Moreover, the MANCP contained little information as regards import controls of products of non-animal origin: the import procedure was not sufficiently described; the basis for the organisation of import controls in the light of potential risks was not included; no risk-based priorities were established in respect of those foodstuffs not covered by the relevant Commission Decisions; and the responsibility for establishing risk-based priorities and for communicating these priorities to the relevant CAs was not established [33].

In the area of ABP, while the animal heath section of the MANCP deals with compliance with ABP requirements in ABP plants and premises, official controls therein were not yet carried out in line with the requirements of the MANCP. Moreover, there is very limited information regarding ABP controls under the MANCP section on controls on food, utility articles and cosmetics.

Concerning plant health, the MANCP did not include Pepino mosaic virus, which was explained by representatives from BMLFUW due to the difficulties in persuading the provinces to carry out sampling in the absence of specific legislation on this. On the other hand, the MANCP includes the need to conduct monitoring inspections for *Diabrotica virgifera*, *Phytophthora ramorum*, *Dryocosmus kuriphilus* and *Bursaphelenchus xylophilus*, but the number of samples to be taken has not been determined, which, according to representatives from BMLFUW, is because the actual number of samples will depend on the outcome of the forthcoming review of the relevant Commission Decisions. Finally, official controls were generally carried out in accordance with the MANCP; however, the PPPS did not fully comply with the sampling plans developed by AGES and the implementation of the guidelines and instructions for official controls, as well as compliance with the plan in general, is largely at the discretion of each PPPS.

Conclusions

On the basis of the information collected during the specific audits it was not possible to reach a definite conclusion as to whether all official controls were carried out in

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33 ***In their response to the draft report the Austrian Authorities note that the section on import controls for food of non-animal origin has been revised in the current version of the MANCP, where the procedures are described in more detail; in the future, priorities in this area (other than those covered by Commission Decisions) will be established on the basis of RASFFS reports, which will be reflected in the inspection and sampling plan.***

accordance with the MANCP, since it did not always include sufficient information regarding the official controls concerned.

6. OVERALL CONCLUSION

On the basis of the results of the specific audits and with all the necessary reservations derived from the pilot nature of this general audit, it can be concluded that, overall, official controls were carried out largely in compliance with Community law, although some weaknesses and areas for improvement were identified, in particular as regards staff resources and verification of the effectiveness of official controls. As to whether or not official controls were carried out in accordance with the MANCP, the general audit did not allow a definite conclusion to be reached given that the plan did not contain sufficient information for all the concerned areas; nevertheless, the plan provided a coherent and integrated framework of the control systems in place which was very useful for the organisation and completion of this general audit.

7. RECOMMENDATIONS

The authorities of Austria are invited to provide, within 25 working days following the receipt of the report, details of the actions taken and planned to address the following recommendations:

1. To ensure, in the areas where this is not the case, that official controls are organised and carried out on a risk basis and with appropriate frequency, as laid down in Art. 3(1) of Regulation (EC) No 882/2004.

2. To designate, in the areas where this is not the case, the CAs responsible for official controls, as required by Art. 4(1) of Regulation (EC) No 882/2004.

3. To allocate sufficient number of staff for the undertaking of official controls, as laid down by Art. 4(2c) of Regulation (EC) No 882/2004.

4. To allocate appropriate facilities and equipments to ensure that staff can perform official controls, as laid down by Art. 4(2d) of Regulation (EC) No 882/2004.

5. To ensure, in the areas where this is not the case, that the CAs have the legal powers to carry out official controls, as set out by Art. 4(2e) of Regulation (EC) No 882/2004.

6. To extend the undertaking of the audits required by Art. 4(6) of Regulation (EC) No 882/2004 to all areas where official controls are organised.

7. To ensure, in the areas where this is not the case, that staff performing official controls receive appropriate training for their area of competence, as laid down in Art. 6 of Regulation (EC) No 882/2004.

8. To make available to the public relevant information concerning control activities in all areas, as required by Art. 7 of Regulation (EC) No 882/2004.

9. To ensure that all official controls are carried out in accordance with the requirements for documented procedures set out by Art. 8(1) of Regulation (EC) No 882/2004.

10. To put in place procedures to verify the effectiveness of official controls, as requested by Art. 8(3) of Regulation (EC) No 882/2004.

11. To ensure that reports of official controls include all the information set out in Art. 9(2) of Regulation (EC) No 882/2004.

12. To take action to ensure, in the areas where this is not the case, that operators remedy identified non-compliance, as requested by Art. 54(1) of Regulation (EC) No 882/2004.

13. To continue the development of the MANCP to take account of the requirements for its contents laid down by Art. 42(2) of Regulation (EC) No 882/2004, in order to allow verification that official controls take place in accordance with the plan, as requested in Art. 45(1) of the said Regulation.

COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS

The CAs' response to the above recommendations can be found at:

http://ec.europa.eu/food/fvo/ap/apA_austria_7995_2007.pdf

The CAs' response to the recommendations contained in the sector specific reports included in the Annex can be found at:

http://ec.europa.eu/food/fvo/ap/apB_austria_7995_2007.pdf

ANNEX: SECTOR SPECIFIC REPORTS

EUROPEAN COMMISSION
HEALTH & CONSUMER DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO)/2007-7177 – MR final

PILOT GENERAL AUDIT AUSTRIA – 2007

FINAL REPORT OF

A SPECIFIC AUDIT

CARRIED OUT FROM 29 JANUARY TO 2 FEBRUARY 2007

IN ORDER TO EVALUATE OFFICIAL CONTROL SYSTEMS FOR

FOOD AND FEED CONSISTING OF OR PRODUCED FROM

GENETICALLY MODIFIED ORGANISMS (GMOs)

PART B – SECTOR SPECIFIC ISSUES

1. INTRODUCTION

The audit took place in Austria from 28 January to 2 February 2007. The audit team comprised two inspectors from the FVO, one expert from the Swedish National Food Administration and one trainee from the FVO.

The audit was undertaken as part of a Pilot General Audit carried out in accordance with Art. 45(1) and (2) of Regulation (EC) No 882/2004. It is also part of the FVO's planned mission programme.

The audit team was accompanied during the whole mission by representatives from the CCA.

An opening meeting was held on 29 January 2007, with representatives from BMGFJ, BMLFUW**,** the Federal Ministry of Finances, AGES and the Vienna FI. At this meeting, the inspection team confirmed the objectives and the itinerary of the mission. Moreover, additional information required for the satisfactory completion of the mission was requested.

2. SCOPE AND OBJECTIVES OF THE AUDIT

The overall objective of the audit was to evaluate the official control systems for food and feed containing, consisting of or produced from GMOs. Within this context the audit team evaluated the following:

- the supervision performed by the CA to ensure compliance with Regulation (EC) No 1829/2003, with the exception of the authorisation procedure;
- the application of Regulation (EC) No 1830/2003 [34];
- the implementation of Directive 2002/53/EC [35] in so far as it relates to the placing on the market of varieties of genetically modified agricultural plant species contained in the common catalogue, and Decision 2004/842/EC [36] in so far as it relates to national authorisations for placing on the market of genetically modified varieties not yet entered in this common catalogue;
- any action taken by the CAs in order to comply with the requirements of Decisions 2006/578/EC [37], 2006/601/EC [38] and 2006/754/EC [39].

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34 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC; OJ No L 268, 18.10.2003, p. 24.

35 Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species; OJ No L 193, 20.07.2002, p. 1.

36 Commission Decision 2004/842/EC of 01 December 2004 concerning implementing rules whereby Member States may authorise the placing on the market of seed belonging to varieties for which an application for entry in the national catalogue of varieties of agricultural plant species or vegetable species has been submitted; OJ No L 362, 9.12.2004, p. 21.

37 Commission Decision 2006/578/EC of 23 August 2006 on emergency measures regarding the non-authorised genetically modified organism LL RICE 601 in rice products; OJ L 230, 24.08.2006, p. 8.

In addition, and in the context of the pilot general audit, the audit team assessed general operational criteria of the system of official controls in accordance with Titles II and VII of Regulation (EC) No 882/2004.

In pursuit of these objectives, the sites visited and meetings held are outlined in the following table:

Table 1: Audit visits and meetings

Visits/meetings		Comments
COMPETENT AUTHORITIES		
Central	6	BMGFJ, BMLFUW, CAs for Environmental protection and controls, Federal Ministry of Finances, AGES, BAES.
Provincial	1	FI of the city of Vienna
Import point (BIP)	1	BIP for feed in Krems
LABORATORIES		
Public	1	AGES Competence Centre Biochemistry in Vienna
FOOD AND FEED ESTABLISHMENTS		
Feed mill company	1	Producing 400,000 tonnes compound feed/annum
Food processor plant	1	Producing 12,000 tonnes maize and potato's products

3. LEGAL BASIS FOR THE AUDIT

The audit was carried out under the general provisions of Community legislation, in particular, Art. 45 of Regulation (EC) No 882/2004.

4. BACKGROUND

4.1 Summary of previous mission series results

Prior to this mission series, the FVO carried out a number of missions to MS in order to evaluate the implementation of previous EU legislation on GMO products. The final reports of these missions can be found on the Health and Consumer Directorate General Internet site at: http://europa.eu.int/comm/food/fvo/index_en.htm

Overall, it was found that the level and scope of enforcement in MS varied and analytical activities, if carried out, were impeded by the lack of quantitative GMO detection methods and the lack of certified reference materials. Prior to the entry into force of current EU Regulations, imported GMO raw materials, such as grains and

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38 Commission Decision 2006/601/EC of 5 September 2006 on emergency measures regarding the non-authorised genetically modified organism LL RICE 601 in rice products; OJ L 244, 7.09.2006, p. 27.

39 Commission Decision 2006/754/EC of 6 November 2006 amending Decision 2006/601/EC on emergency measures regarding the non-authorised genetically modified organism LL RICE 601 in rice products; OJ L 306, 7.11.2006, p. 17.

milling products, were not covered by EU legislation and the findings of the mission series indicated that these commodities were infrequently inspected and/or sampled.

The previous mission with the same objectives to Austria was undertaken from 23 June to 26 June 2003. The report of this mission is available under reference number DG SANCO/9141/2003 – MR – final at the above Internet site.

4.2 Background to present mission series

This report is part of a pilot general audit to Austria. It is also part of a series of missions to MS with similar objectives concerning the evaluation of the implementation of the new EU Regulations on official controls in the area of GMOs in food, feed and seed. The final reports of these missions are also available on the Health and Consumer Directorate General Internet site.

According to the report "Global Status of Commercialized Biotech/GM crops 2005" [40] the cultivation area of biotech crops increased from 1.7 million hectares in 1996 to 90 million hectares in 2005. The main producers of biotech crops are outside Europe, led by the USA and followed by Argentina, Canada, Brazil and China. The most important crops are soy beans, maize, cotton and rapeseed. It is estimated that genetically modified crops cover almost 4% of total global arable land [41].

Several authorisations for placing on the market and for deliberate release into environment of genetically modified plants have been granted under previous and current legislation. The current situation is shown on the following website:

http://europa.eu.int/comm/food/food/biotechnology/authorisation/index_en.htm

5. MAIN FINDINGS

5.1 Economic statistics

In their response to the pre-mission questionnaire, the CA estimated that 3,300,000 tonnes of genetically modified compound feed were produced in Austria yearly. Regarding flour and soya bean meal entering Austria as feedstuffs, the CA considered that 95% of it contains genetically modified material.

Extracted soy oilcake is the only raw material of relevance to the mission which is traded in substantial amounts, at present. Statistics on trade between Austria and other MS and third countries in certain commodities of plant origin, including soya beans, rapeseed and maize and products thereof are summarized in Table 2.

No GMO varieties, listed in the common catalogue, are grown for commercial cultivation, feed or food, or seed production in Austria.

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40 James, C. 2005. Preview: Global Status of Commercialized Biotech/GM Crops: 2005. ISAAA Briefs No. 34. ISAAA; Ithaca, NY.

41 WHO biotechnology report 2005 - http://www.who.int/foodsafety/publications/biotech/biotech_en.pdf.

Table 2: Relevant trade statistics into Austria in tonnes (source: Pre-mission questionnaire)

Quantities imported products	2004	2005
Soya beans (excl. for sowing)	74.5	410.5
Soya beans for sowing	23,096.7	32,037.8
Soya bean flour and meal	2,649.9	1,989.8
Oilcake/pellets from extraction of soy-bean oil	490,183.7	499,954.4
Rape seeds	34,171.8	6,077.5
Oilcake/pellets from extraction of rape seed oil	7,486.5	11,269.0
Cotton seeds	3.0	7.8
Oilcake/pellets from extraction of cotton seeds	1,684.8	2,104.1
Maize (excl. seed)	228,280.3	176,041.8
Maize seeds	23,934.2	13,348.0
Corn gluten feed	8,398.3	6,850.2
Brewers grain	3,261.3	3,157.8

5.2 Legislation

Austria has national legislation on food produced from GMOs in addition to the directly applicable EU Regulations (EC) No 1829/2003 and (EC) No 1830/2003. This includes specific provisions to restrict GMO content in organic food to less than 0.1% and guidelines for using "GMO free" claims; the latter is given in the Austrian Codex Alimentarius.

Moreover, four national ordinances ban the import of genetically modified maize MON810, T25 and BT176 and rapeseed GT73 for use as food, feed and seed. In addition, the Feed – GMO Threshold Value Ordinance (BGBl. I Nr. 394/2001) sets a threshold of 1% in respect of these GMO maize and rapeseed prohibited in Austria.

Regarding GMO food, the Food Safety and Consumer Protection Law (BGB1. I Nr. 13/2006) defines the CAs and the penalties for implementation of Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003. The audit team was informed by the Austrian CA that the labelling of foodstuffs, as set down in Directive 2000/13/EC [42], has been transposed by the Food Labelling Ordinance (BGBl. Nr. 72/1993).

Regarding GMO feed, the Feed Law (BGB1. I Nr. 139) establishes the CAs and the penalties for implementation of EU Regulations. In addition, the Feed Ordinance (BGBl. II Nr. 24/2006) implements Regulation (EC) No 1829/2003 regarding labelling of feedstuffs. Moreover, the BMLFUW has produced guidelines for the identification of GMO in feedstuffs.

Regarding genetically modified seed, the Ordinance on genetically modified seed (BGBl. II 478/2001) prescribes mandatory labelling for all genetically modified seed varieties covered by Directive 2001/18/EC [43]. Furthermore, the latter Ordinance sets

42 Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs; OJ No L 109, 6.05.2000, p. 29.

43 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC; OJ No L 106, 17.04.2001, p. 1.

thresholds for accidental contamination of conventional seed with genetically modified seed (see section 6.6).

5.3 Competent authorities

The competencies of those organisations with responsibility for the official control within the scope of this mission are summarised in the following table:

Table 3: Structure and responsibilities of CAs

Ministry	Levels	Organisation	Competencies
Food			
BMGFJ	Central	Section Departments IV/ 7, IV/ 8 and IV/ 9	Legislation and policy, planning of official controls
		AGES	Risk assessment, scientific advice, planning of official controls
Government federal provinces	Federal provinces	FIs	Planning and implementation official controls.
Feed			
BMLFUW	Central	Department I/2	Legislation and policy
		Institute of Feedingstuffs of AGES	Planning of official controls
		Inspection Service of BAES (BAES-ZK)	Implementation and coordination of official controls in production and marketing
Government federal provinces	Federal provinces	Veterinary Services	Implementation of official controls in farms
		Veterinarians of the District Administrative Authorities	Organisation of official controls in farms
Seeds			
BMLFUW	Central	Department I/2	Legislation and policy
		Institute for Seeds of AGES	Planning of official controls
		BAES-ZK	Implementation of official controls
Customs			
Federal Ministry of Finance	Central	Departments IV/6 and IV/8	Legislation and policy
	Economic provinces	Customs offices	Control of food, feed and seed at point of import

5.4 Controls on GMOs in food

5.4.1 Structure and organisation of responsible authorities

BMGFJ is responsible for policy making and legislation for GMOs in food and is also in charge of issuing the annual official control programme for inspection and sampling, which includes GMO food.

The nine FI of the federal provinces are responsible for inspection and sampling of foodstuffs at production, distribution, storage and retailing. The FIs act as federal authorities when implementing the federal legislation, in the so called indirect federal

administration system. In some cases food inspectors are employed by the municipal administration. A total of 204 full-time-equivalents work as food inspectors.

AGES, a private agency with limited liability owned by the State, is responsible for scientific risk assessment, laboratory services and consumer information. Its scope covers the whole food chain, from soil, seed, plant health, feed and food control to animal health and prevention and containment of infectious diseases in human. AGES includes several institutes and competence centres, of which the Institute for Food Control Vienna is under the scope of this mission regarding GMO food.

5.4.2 Communication among the central, provincial and local authorities and with other relevant ministries

The LMSVG requires the federal provinces to report to BMGFJ infringements involving several provinces, results of specific campaigns and when there is a health hazard. The municipal authorities should report to the provincial authorities. Moreover, the Provincial Governors must submit to BMGFJ an annual report on implementation of the control and sampling plans by 31 March of the following year.

Meetings of the Food Control Coordination group, which includes BMGFJ, the federal provinces, AGES and the provincial food institutes, are held twice a year to adopt the control and sampling plans, discuss the results and establish targets and strategies. Meetings between the heads of the FIs and BMGFJ are also held twice a year to coordinate ongoing activities, exchange views and discuss food safety and legal questions. In addition, ad hoc meetings are convened and working parties are set up when required.

Communication between relevant ministries takes place when the need arise and it has recently been developed through the preparation of the MANCP (Artt. 41, 42 and 43 of Regulation (EC) No 882/2004).

5.4.3 Planning of controls on GMOs (inspection and sampling)

Annual inspection plans are issued by BMGFJ on the basis of a proposal from the federal provinces and after consulting AGES. Annual sampling plans are issued by BMGFJ on the basis of a proposal produced by AGES and after consulting the federal provinces.

The annual control and sampling plans include the total number of GMO inspections and samples of soya and maize products to be implemented by each FI. The FI decide on the operator and the product to be sampled.

Sampling takes place in the course of some inspections for traceability and labelling. In 2004, the plan for GMO control involved 345 inspections and the taking of 255 samples at producer and retail level. The plans for GMO control for 2005 and 2006 included 400 inspections and the taking of 300 samples from soy and maize products at producer and retail level, for each year.

In 2006, as part of the emergency measures regarding LL601 rice and in order to comply with the requirements of Decisions 2006/578/EC, 2006/601/EC and 2006/754/EC, the FI were requested to collect 100 samples. Regarding the Bt63 rice, the BMGFJ asked the Vienna FI to take 50 samples.

5.4.4 Performance of inspection and sampling

The audit team observed the inspection for traceability and sampling at a food processor. The food processor had been inspected for hygiene and GMO traceability in July 2006. The inspection was confined to those areas relevant to the scope of this mission and was carried out by an inspector from FI of Vienna. The inspection began with the selection of an end product containing maize that was traced to its batch of maize grit. The company produced a supplier certificate stating that the maize grit was produced from non-genetically modified maize.

The sampling procedure observed was a demonstration, under national sampling standard operating procedures, which followed the provisions of Recommendation 2004/787/EC [44], including incremental samples.

The inspector explained that one sample is kept by the company, a second one is transported to the AGES Competence Centre Biochemistry in Vienna and a third one is sent to the manufacturer.

BMGFJ informed the audit team that formal training for inspectors on GMO labelling was organised in 2004 and 2005.

5.4.5 Results of controls on GMOs (inspection and sampling)

In 2004, 241 samples were analysed for presence of GMOs. The results showed that eight samples were positive but only two were considered non compliant due to incorrect labelling. Extraction of DNA was possible in all samples.

In 2005, 242 food samples were taken and all of them were assessed as complying with the legislation. Extraction of DNA was possible in all samples.

Table 4: Number of food samples analysed and results

	2004	**2005**
No. of samples	241	242
No. of samples where extraction of DNA is not possible	0	0
No. of positive and type of GMO	8 RR soya	5 RR soya
No. non compliant	2	0

In 2006, 220 samples were analysed for LL601 rice and 50 were positive. Regarding Bt63 rice, 58 samples were tested and 1 was positive.

44 Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003; OJ No L 348, 24.11.2004, p. 18.

5.4.6 Follow-up of infringements

All non-compliances detected to date involved either the failure to label food, shown on analysis to contain genetically modified material, as containing GMOs or the detection of unauthorized GMOs. The results of non-compliant samples are communicated to the FIs by the AGES Institute for Food Control Vienna for follow-up. At present, BMGFJ does not receive regular information on the follow-up taken by the federal provinces in case of infringements.

The FIs inform the operator in writing in case of infringement and request that corrective measures are taken. If the operator does not implement the corrective measures, the commodity is provisionally confiscated and either an administrative or judicial procedure is launched. The operator may also be fined, in case of infringement.

The Vienna FI showed the audit team evidence of follow-up of a sample of rice noodles positive for Bt63. The retailer received written notification of the results of the laboratory analysis and of the product being unsuitable for human consumption under the Food Safety and Consumer Protection Law (BGB1. I Nr. 13/2006). Moreover, the retailer was warned that this was a serious infringement and was requested to provide information on the follow-up taken.

The audit team was informed by BMGFJ that the products that tested positive for LL601 had been withdrawn from the market.

5.5 Controls on GMOs in feed

5.5.1 Structure and organisation of responsible authorities

BMLFUW, specifically the Department I/2, is responsible for policy making and legislation for GMO feed.

BAES is the central CA for implementing official controls in feedstuffs under Regulation (EC) No 882/2004. BAES is also the responsible authority as mentioned under Art. 17.2 of Regulation (EC) No 1829/2003.

At central level, the Institute of Feedingstuffs of AGES/BAES is responsible for drafting inspection and sampling plans, reporting, inspection manuals and for organisation of training in relation to official feed control.

The inspection and sampling plans are carried out by the 10 BAES-ZK inspectors based in Linz and Vienna, who are responsible for execution of controls for GMOs in feedstuffs at production and marketing. Official controls in farms are organised by the Veterinary Services of the federal provinces and implemented by the veterinarians of the District Administrative Authorities.

5.5.2 Communication among the central, provincial and local authorities and with other relevant ministries

Coordination meetings with all the bodies with responsibilities on feedingstuffs are organised by BMLFUW twice a year.

The federal provinces and BAES submit to BMLFUW an annual report on the controls carried out by 1 March every year. The official control programme contains an obligation for the federal provinces to inform BAES in cases of non compliances.

5.5.3 Planning of controls on GMOs (inspection and sampling)

Priorities for the official control programme, which also includes GMO feed controls, are based on a number of factors, such as risk assessment and legal obligations. The official control programme covers only production and marketing of feedstuffs and a future programme on controls in the farms is in preparation.

The official control programme details inspection and sampling plans and is issued by BMLFUW on the basis of a proposal from the Institute of Feedingstuffs and BAES-ZK.

In 2007, the plan for GMO control requires the taking of 270 samples from specified commodities. Priority is given to compound feed, 192 samples, containing maize, rape or soya. In addition, 78 samples should be taken from these raw materials. The plan targets unauthorized GMOs, either in the EU or in Austria, and the amount of authorized ones when a threshold applies. Regarding inspections for GMO traceability and labelling, it is foreseen to include them in half of the official controls of feedstuff manufacturers. These are controlled between one and four times a year, depending on their size.

The inspector, within the framework of the control plan, decides on the operator to be inspected taking into account the size of the establishment, previous inspections, products manufactured and RASFF.

Table 5: Number of samples on GMO feed planned for 2004-2007

No. of samples	2004	2005	2006	2007
Compound feed	270	270	240	192
Raw materials	78	78	78	78
Total	348	348	318	270

5.5.4 Performance of inspection and sampling

An inspection for traceability and sampling at a feed processing company was demonstrated to the audit team. The feed processor had been inspected in September 2006, but not for GMO labelling or traceability. The inspection was conducted by one inspector from the BAES-ZK, and was confined to those areas relevant to the scope of this mission.

The inspection began with an evaluation of the company's internal control system for deliveries. The inspector requested delivery and receipt notes of all consignment received on the day and selected a consignment of rapeseed oilcakes for sampling. The inspector stated that the sampling will be in line with Directive 76/371/EEC. The number of incremental samples would depend on the volume of the consignment being sampled. The final sample would be divided in three sub samples: the enforcement one to be sent to the AGES laboratory, the defence one to stay with the company and the counter sample would be kept by AGES. The CA stated that Recommendation 2004/787/EC on sampling is taken into account insofar further samples are collected from the consignment in case of doubt or non compliance.

The inspector informed the audit team that the AGES laboratory decides on the analysis to be performed for each sample on a random basis, except when the inspector informs the laboratory of a suspicion. The inspector receives the results only for non-compliances.

The inspector had access to written information material on GMOs and if necessary he could contact the Institute of Feedingstuffs but he had not received any formal training on GMOs.

5.5.5 Results of controls on GMOs (inspection and sampling)

In 2004, 196 samples of feedstuffs were analysed for content of GMOs. Only 15 of them were considered as not complying with the legislation. Extraction of DNA was possible in the case of all samples.

In 2005, 164 feed samples were taken and only 10 were assessed as not complying with the legislation. Extraction of DNA was possible in the case of all samples.

Table 6: Number of feed samples analysed and results

	2004	2005
No. of samples	196	164
No. of samples where extraction of DNA is not possible	0	0
No. of positive and type of GMO	15 RR Soya	10 RR Soya
No. non compliant	15	10

The mission team was informed that feedstuffs based on non labelled raw materials sharing the same production line with GMO ones are generally labelled as containing GMOs, although its presence has not been confirmed by analytical testing. The CA stated that the results of research demonstrated that cross-contamination among productions lines occurs in almost all cases.

5.5.6 Follow-up of infringements

All non-compliances detected to-date involved the failure to label feed, shown on analysis to contain genetically modified material, as containing GMOs. The results of non-compliant samples are communicated to the BAES-ZK by the AGES Institute for Feedingstuffs for follow-up.

The mission team was informed that in case of unauthorized GMOs, the product is either seized or recalled from the market and the operator receives an official notification. If the GMO is authorized but not labelled, the operator is notified and is liable to pay the costs of the sampling and analysis, and an administrative procedure is launched. If the product contains banned genetically modified maize over the threshold limit of 1%, the operator receives a notification and an administrative procedure is launched.

5.6 Controls on GMOs in propagating materials

The Institute for Seed of AGES is responsible for planning annual controls on seeds, including genetically modified seeds. BAES-ZK implements the labelling checks and sampling of genetically modified seed and non-genetically modified seed. In case of non compliance, BAES informs the operator and may confiscate the consignment, ban its distribution or withdraw it from the market.

In 2006, samples for GMO analysis were taken from 82 seed lots certified in Austria, 51 seed lots produced and certified in other MS or third countries, 26 varieties that had applied for registration, 21 seed lots and 368 leaves from lots used in seed production, and 46 leaves from control plots. Only one of the results was not compliant and the lot was confiscated. No infringements were detected in 2004 and 2005.

There is a zero tolerance policy in place for seed undergoing the certification procedure. For seed being marketed, a threshold of 0.1% for authorized events is applied. At present, there are no GMO varieties, as listed in the common catalogue, grown for seed cultivation in Austria.

5.7 General import control procedures

Consignments of food and feed of plant origin and seed can be imported from third countries through approved points of entry or, in case of consignments crossing other MS, through designated interior Custom points. Customs Services are organised in nine economic provinces and avail of an electronic Customs clearance, E-zoll, since last year. E-zoll includes an automatic electronic notification to BMGFJ and BMLFUW on relevant consignments received by Customs. E-zoll includes also instructions for Customs officials on import controls of food, feed, and specific commodities under safeguard clauses such as LL REIS 601 and Bt10.

Customs Services are responsible for the release of consignments of food and feed products of plant origin and seed imported from third countries. Inspections at border inspection posts (BIPs) are performed by the Customs officials, which in case of infringement or suspicion of infringement, involving foodstuffs or feedstuffs, should inform and may request assistance from either the FIs or BAES. Moreover, BAES has provided training to Customs officials on legislation and sampling of feedstuffs at import. The audit team was informed that the importer has to declare to Customs if the consignment consists or contains GMOs under national legislation.

The audit team visited the BIP for feedstuffs at the Port of Krems. Customs officials of this BIP have received training from BAES on inspection and sampling of feedstuffs. The Customs officials stated that the last feed consignment for import at this BIP was received in 2004. The audit team was informed that imports have dramatically decreased since the accession to the EU of all neighbouring countries.

5.8 Laboratories

In Austria analysis of samples taken within the framework of official controls of genetically modified food, feed and seed are performed by the Analytical Competence Centre Biochemistry of AGES in Vienna. This laboratory and the Federal Environmental Agency have been appointed as NRLs for GMOs in Austria.

The audit team was informed that the Carinthian Institute for Food Analysis and Quality Control (LUA Kaernten) analysed 15 samples for GMOs in 2006, and none in

2005 and 2004. This laboratory is accredited according to ISO/IEC 17025 by the Austrian Ministry of Economic Affairs. The accreditation covers qualitative PCR based methods for screening and for detection of four genetically modified events (Roundup Ready soya and the maize events Bt176, Bt11 and MON810). According to the information provided, the laboratory has not participated in proficiency testing within the GMO area for the last five years.

Laboratory of the Analytical Competence Centre Biochemistry of AGES

The audit team visited the Analytical Competence Centre Biochemistry of AGES, which is accredited under ISO/IEC 17025 by the Austrian Ministry of Economic Affairs. The scope of the accreditation is open (group of tests) for biochemical analysis, including GMO analyses. The Competence Centre Biochemistry is a member of the European Network of GMO Laboratories, organised by the Joint Research Centre in Ispra, Italy.

In total 10 people are working in the Competence Centre Biochemistry laboratory, of which more than half is directly involved in the GMO work. The laboratory has the managerial and technical personnel and resources needed to carry out their duties. The staff is well trained and has the proper competence and knowledge in the specific area of GMO detection.

The laboratory analyses mainly samples from official controls and to a smaller extent also private samples. About 1,000 samples of food, feed and seed are analysed for GMOs annually, which ensures that the competence of the personnel is maintained.

The Competence Centre Biochemistry has excellent facilities and the general layout of the rooms is appropriate. The laboratory has implemented the general laboratory and procedural requirements laid down in ISO 24276 on general requirements for nucleic acid based methods of analysis for the detection of GMOs and derived products. The organisation of the work area in the laboratory is based on a “forward flow” principle of sample handling with separate work areas for the different methodological steps in the analytical procedure. Physical separation of areas with incompatible activities, together with the use of adequate PCR controls ensure that the laboratory can avoid or reveal possible cross-contamination. The laboratory has all the equipment required for the correct performance of the tests and the equipment is properly maintained.

The Competence Centre Biochemistry uses mainly real time PCR based methods for screening, identification and quantification of GMOs. Only a few methods are based on traditional end-point PCR. Analytical methods for screening and identification of 14 genetically modified events of different species (soya bean, maize, rapeseed, tomato, potato and rice) are in place and four more are in preparation. The laboratory has implemented quantitative methods for eight genetically modified events. The choice of methods is appropriate and most of the methods used have undergone collaborative trials. SOPs are well written, controlled and authorised editions of documents are available at essential locations. Procedures to implement new methods are in place.

Methods are applied on all kinds of matrices from seeds and raw materials to final processed food products. However, PCR controls to expose reduced amplification efficiency in quantitative analyses of unknown samples are not used.

The laboratory participates, within the European Network of GMO Laboratories, on a regular basis in validation studies of detection methods for GMO food and feed. Passable internal procedures to ensure traceability are present for samples from

reception until release of results. Test reports were found to be in line with Chapter V of Recommendation 2004/787/EC.

To monitor the validity of tests performed, the laboratory uses, when available, certified reference materials either from the Institute for Reference Materials and Measurements (IRMM) or from the American Oil Chemists' Society (AOCS). Procedures for internal quality control in quantitative analyses (e.g. control charts) to uncover bias and trends are not in place.

The Competence Centre Biochemistry participates regularly in proficiency tests on genetically modified seeds organised by the International Seed Testing Association (ISTA). The laboratory has not yet participated in proficiency testing on complex matrices, food and feed, but is planning to do so this year.

6. CONCLUSIONS

6.1 Legislation

(1) National provisions provide for an adequate basis for the implementation of EC legislation. National legislation, regarding food and feed, setting down the penalties in case of infringement of Regulation (EC) No 1830/2003 fulfils the requirements of Art. 11 of the said Regulation.

6.2 Competent authorities

(2) Competencies for policy making, legislation, planning and execution of controls for GMOs in food, feed and seeds at import and market level are clearly defined.

(3) Vertical communication within each of the CAs with responsibilities within the scope of the mission is satisfactory.

6.3 Controls on GMO in Foods

(4) Specific training for food inspectors regarding GMO controls has taken place.

(5) Annual inspection and sampling plans satisfactorily address the requirements of Art. 9 of Regulation (EC) No 1830/2003 and Regulation (EC) No 1829/2003.

(6) The traceability and labelling requirements of Regulation (EC) No 1830/2003 were satisfactorily addressed at a demonstration of a routine inspection of the premises visited during the mission.

(7) The standard operating procedure for sampling of foodstuffs is applied across all federal provinces and addresses the main requirements of Recommendation 2004/787/EC.

(8) The CA has fulfilled the requirements of Decisions 2006/578/EC, 2006/601/EC and 2006/754/EC.

6.4 Controls on GMO in Feed

(9) The annual official control plan satisfactorily addresses the requirements of Art. 9 of Regulation (EC) No 1830/2003 and Regulation (EC) No 1829/2003.

(10) The traceability and labelling requirements of Regulation (EC) No 1830/2003 were satisfactorily addressed at a demonstration of a routine inspection of the premises visited during the mission.

(11) The standard operating procedure for sampling of feedstuffs is based on Directive 76/371/EEC and takes partially into account Recommendation 2004/787/EC.

6.5 Controls on GMO in propagating materials

(12) The annual control plans for sampling and inspection of seeds produced and certified in Austria, other MS and third countries satisfactorily address the requirements of Art. 9 of Regulation (EC) No 1830/2003.

6.6 Laboratories

(13) The Competence Centre Biochemistry of AGES in Vienna is accredited under ISO 17025 for biochemical analysis in an open scope. It is very well structured, staffed and equipped to carry out its official control responsibilities.

(14) Analytical methods for 14 genetically modified events are in place and four more are in preparation. Participation in proficiency tests is foreseen for food and feed for this year.

(15) The laboratory of the province of Carinthia analysed 15 samples for GMOs last year. The laboratory has not participated in proficiency testing within the GMO area for the last five years.

(16) The NRLs for GMOs are the Competence Centre Biochemistry of AGES and the Federal Environmental Agency.

6.7 Overall conclusion

Overall, there is a satisfactory system in place for the implementation of Regulation (EC) No 1829/2003 and (EC) No 1830/2003. A shortcoming was noted regarding participation of laboratories in proficiency testing.

7. CLOSING MEETING

A closing meeting was held on 2 February 2007 with the CCAs, BMGFJ, BMLFUW**,** Federal Ministry of Finances, AGES and the Vienna FI. At this meeting, the initial findings and conclusions of the mission were presented by the FVO inspection team. The representatives of the CAs provisionally accepted these findings and offered some clarifications and comments.

8. RECOMMENDATIONS

1. The CA should consider extending the participation of laboratories, in charge of official controls for GMOs, in proficiency testing schemes, in accordance with Art. 33.2(c) of Regulation (EC) No 882/2004.

EUROPEAN COMMISSION
HEALTH & CONSUMER DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO)/2007-7224 – MR final

PILOT GENERAL AUDIT AUSTRIA – 2007

FINAL REPORT OF

A SPECIFIC AUDIT

CARRIED OUT FROM 5 TO 9 NOVEMBER 2007

CONCERNING

IMPORT CONTROLS ON FEED AND FOOD OF NON-ANIMAL ORIGIN

PART B – SECTOR-SPECIFIC ISSUES

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

1. INTRODUCTION

The previous mission concerning import controls on food of non-animal origin in Austria was carried out from 20 to 24 October 2003. The results of that mission are described in report DG (SANCO)/9251/2003 – MR Final. The relevant report can be accessed at:

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

2. FINDINGS AND CONCLUSIONS

2.1 Organisation of import controls

Legal Basis

Art. 15 of Regulation (EC) No 882/2004 establishes that CA shall carry out regular official controls on food and feed of non-animal origin imported into the EU.

Art. 24 of Regulation (EC) No 882/2004 requires that, for the organisation of the official controls, the CAs and the Customs services shall cooperate closely.

Art. 11 of Regulation (EC) No 178/2002 requires that food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law.

Findings

The import procedure starts when operators notify the consignment to be imported to Customs (via a Customs database based on CN codes). When an entry declaration is lodged, the Customs database (eZoll) automatically identifies the commodities listed in Customs working instruction VB-0200. This working instruction contains all foodstuffs covered by the relevant Commission Decisions.

A message indicates to Customs that all documents relating to the consignment must be sent to the relevant provincial FI, and the consignment cannot be released until the provincial inspectorate notifies whether or not it intends to carry out an identity check and/or physical check of the consignment. In situations where a physical check is appropriate, the sampling and analysis is carried out and the food inspection authority informs the Customs authority, by means of an official accompanying document, whether the product complies with Regulation (EC) No 1881/2006 [45] and therefore can be released onto the market. If the consignment is not in compliance, this is notified to Customs and the accompanying documents are stamped as follows: "Dangerous product, release for free circulation not authorized, Regulation EEC 339/93 [46]".

The mission team was informed that feed and premixtures which contain plant components, and also additives, are controlled in accordance with feedstuffs legislation. The official control is carried out pursuant to section 11 (3) of the Feedstuffs Act 1999 by specially trained Customs bodies at certain Customs entry points.

At present, all notified feedstuffs imports are controlled. Consignments of imported feed that have been cleared into the market are traced to the first establishment of destination in every single case.

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45 Commission Regulation (EC) No 1881/2006 of 19 December setting maximum levels for certain contaminants in foodstuffs; OJ L 364, 20.12.2006, p. 5.

46 Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries; OJ L 40, 17.2.1993, p. 1.

Where the intended use of the consignment at import is not clear and the consignment is not declared as feed, it is considered as food and the import controls on food apply.

The mission team examined several files and noted that documentation relating to consignments included in specific Commission Decisions was duly sent by Customs to the relevant provincial FIs.

The mission team saw evidence of documentation of non-compliant consignments that had been properly stamped, both in the files of the provincial food authority in Upper Austria and in the Suben Customs office.

Conclusions

The import procedure is adequately implemented and is very well defined allowing for the application of regular official controls on food of non-animal origin imported into the EU in line with Art. 15 of Regulation (EC) No 882/2004.

Co-ordination and co-operation between Customs and food provincial authorities is very good and in line with Art. 24 of Regulation (EC) No 882/2004.

2.2 Frequency of controls

The list of commodities included in working guideline VB-0200 is drawn up by Customs in consultation with AGES and BMGFJ.

2.2.1 Foodstuffs imported from certain third countries submitted to special conditions

Legal basis

Art. 5 of Decision 2006/504/EC establishes that in each MS a sample for analysis of aflatoxins should be taken from consignments of foodstuffs with a specific origin and frequency described in this article.

Decision 2005/402/EC requires that CAs in MS check that each consignment of chilli, chilli products, curcuma, and palm oil presented for importation is accompanied by an analytical report demonstrating that the product does not contain Sudan I, II, III, IV.

Audit findings

All commodities included in current Commissions Decisions are listed in Customs working instruction VB-0200 and notified to the provincial FI on arrival.

The number of samples taken and analyzed for this group of foodstuffs is shown in Table 1. The frequency of sampling for hazelnuts from Turkey (CN 0802 21 00, 0802 22 00) in 2006 was 2.7% instead of the 5% established in Decision 2006/504/EC. The frequency of sampling for derived products from figs, hazelnuts and pistachios (0813 50, 2007 99 98, 2008 19, 1106 30 90) from Turkey was 7.2 % instead of the established 10%.

For 2007 (up to October) the sampling frequencies for derived products from figs, hazelnuts and pistachios (CN 0813 50, 2007 99 98, 2008 19, 1106 30 90) from Turkey is 6.5%.

In Upper Austria, 324 consignments of Hazelnuts from Turkey have been imported in 2007 and 18 samples were taken and analysed (five consignments were not in compliance).

In Vienna, 226 consignments of Hazelnuts from Turkey have been imported in 2007 and 25 samples were taken and analysed (five consignments were not in compliance).

In several files verified by the mission team concerning Sudan dyes, it was confirmed that official controls included the check of analytical reports, as requested by EU legislation, and that in the absence of such reports, consignments were detained and reports requested.

Conclusions

At national level, the frequency of sampling for import controls on aflatoxins in foodstuffs under the terms of Decision 2006/504/EC for 2006 is appropriate, except for consignments of hazelnuts (CN 0802 21 00, 0802 22 00) and derived products from figs, hazelnuts and pistachios (CN 0813 50, 2007 99 98, 2008 19, 1106 30 90) from Turkey. For 2007 (up to October) the frequencies are respected, except for consignments of derived products from figs, hazelnuts and pistachios (CN 0813 50, 2007 99 98, 2008 19, 1106 30 90) from Turkey.

In 2007 (up to November), and in both provinces visited (Upper Austria and Vienna), the frequency of sampling required by Commission Decision 2006/504/EC is achieved.

Import controls as regards consignments of chilli, chilli products, curcuma, and palm oil presented for importation are carried out according Decision 2005/402/EC.

2.2.2 Foodstuffs imported from certain third countries not subject to special conditions

Legal Basis

Art. 3(1) of Regulation (EC) No 882/2004 requires the CA to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency.

Art. 15(1) of Regulation (EC) No 882/2004 provides that the CA shall organize import controls on the basis of the MANCP and in the light of potential risks.

Audit findings

Foodstuffs imported from certain third countries not subject to special conditions, but of known or potential risk, are not included in the working guideline on food VB-0200, and, consequently, they are not notified to the FIs by Customs on arrival.

In 2006, 15 samples of rice for the analysis of OTA from several third countries were analyzed and, in 2007, two samples of dates were analyzed for aflatoxins (see table 2 of section 4).

The mission team requested import data for specific commodities and origins with a known or emerging risk (including groundnuts and derived products from Argentina, Brazil, Ghana and India; hazelnuts from Azerbaijan; and almonds from USA). However, the CAs were unable to provide this information by the time this report was finalized [47].

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47 ***In their response to the draft report the Austrian Authorities provided updated information on volumes of imports. Table 2 of section 4 has been updated accordingly***.

Conclusions

No risk assessment is carried out for foodstuffs imported from certain third countries not subject to special conditions which is not in line with Artt. 3(1) and 15(1) of Regulation (EC) No 882/2004.

2.3 Types of checks on food of non-animal origin

Legal basis

Art. 16(1) and (2) of Regulation (EC) No 882/2004 requires that import controls shall include at least a systematic documentary check, a random identity check and, as appropriate, a physical check.

Art. 3(3) of Decision 2006/504/EC requires that the CAs in the MS of introduction shall ensure that imported consignments of foodstuffs are subject to documentary checks to ensure that the results of sampling and analysis and the required health certificate comply with Artt. 3(1) and (5).

Art. 16(3) of Regulation (EC) No 882/2004 establishes that physical checks shall be carried out under appropriate conditions and at a place with access to appropriate control facilities.

Art. 4(2)(c) of Decision 2006/504/EC requires that the unloading and the sampling be performed in a sheltered place at the designated point of import.

Art. 1 of Regulation (EC) No 401/2006 [48] establishes that sampling for the official control of the levels of mycotoxins in foodstuffs shall be carried out in accordance with the methods set out in Annex I to the said Regulation.

Audit findings

All Customs offices in Austria are included in the list of designated points of import through which foodstuffs covered by Decision 2006/504/EC may be imported into the Community. The mission team was informed that foodstuffs covered by the said Decision may be imported via any Customs office, as long as they comply with the necessary requirements.

The mission team observed a sampling procedure carried out by an inspector of the Vienna food control authority at the Wien Inzerdorf Customs office. From a consignment of 20.4 tonnes, inspectors took 100 incremental samples of retail packages of 250 g from a random distribution of sampling points.

The retail packages were mixed and the aggregate sample weighing 25 kg was divided into three sub samples, sealed and sent to the laboratory for analysis. The mission team noted that the consignment was not unloaded before sampling, and that the sampling was not performed in a covered area.

The mission team visited another Customs office in Upper Austria, but the sampling could not be carried out during the mission because there were no consignments available. However, the mission team was able to check the sampling equipment that was available to the inspectors.

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48 Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs; OJ L 70, 9.03.2006, p. 12.

Standard operating procedures covered sampling procedures in line with Community legislation and were being followed by the staff.

The mission team also checked files of imported consignments from Turkey and examined several health certificates and accompanying analytical reports. It was noted that, in some analytical reports, the number of laboratory samples indicated and analysed by the Turkish CAs was not representative and not in compliance with Decision 2006/504/EC.

Conclusions

No covered area was available for unloading and sampling of consignments, which is not in line with Art. 4(2)(c) of Decision 2006/504/EC.

The sampling equipment available for the inspectors is adequate.

The sampling procedure observed was carried out in accordance with Regulation (EC) No 401/2006.

Documentary checks were not carried out in accordance with Art. 3(3) of Decision 2006/504/EC

2.4 Import of foodstuffs for further sorting

Legal basis

Art. 4 of Regulation (EC) No 1881/2006 establishes that groundnuts, nuts, dried fruit and maize not complying with the appropriate maximum levels of aflatoxins can be placed on the market under certain conditions.

Audit findings and conclusions

The mission team was informed that no consignments for further sorting are imported into Austria.

2.5 Procedures for non-compliant lots

Legal basis

Art. 19 of Regulation No 882/2004 establishes that CAs shall place under official detention consignments that do not comply with the food or feed law, and that a number of measures shall be taken in respect of such feed or food. These measures include destruction, special treatment, re-dispatch or use for other purposes. The measures are described in Artt. 20 and 21 of the said Regulation.

Audit findings

The mission team was informed that, for the most part, non-compliant consignments have been re-dispatched to the country of origin (only in one case the consignment was destroyed). The food business operator is responsible for providing the CA of the third country of destination with details of the consignment being re-dispatched.

The mission team was shown evidence of notifications from the operators to the country of origin of the consignment.

As regards other possibilities, such as special treatment, and processing to bring the food into line with the requirements of Community law or with the requirements of a third country of re-dispatch, the mission team was informed that these options are available to the importers but had never yet been requested.

There are no facilities in Austria for the treatment of non-compliant consignments.

Conclusion

Procedures for non-compliant lots are in-line with Art. 19 of Regulation No 882/2004.

2.6 Right of appeal against decisions on consignments

Legal basis

Art. 11(5) and (6) of Regulation (EC) No 882/2004 requires CAs to have adequate procedures in place in order to guarantee the right of operators to apply for a supplementary expert opinion.

Art. 14(6) of Regulation (EC) No 178/2002 lays down that, where any food which is unsafe is part of a consignment of food of the same description, it shall be presumed that all the food in that consignment is also unsafe, unless - following a detailed assessment - there is no evidence that the rest of the consignment is unsafe.

Audit findings

The mission team was informed that in the case of non-compliant consignment, the operators have the option of requesting for the analysis of the defence [49] samples. In such a case, the samples have to be analyzed in an accredited laboratory chosen by the importer and the expert performing the analysis has to be officially authorized and included in a specific list that is available on the web page of BMGFJ.

When the results of the defence and the enforcement sample are different, the analysis of the reference sample would take place but this situation had never yet occurred.

If the results of the defence samples confirm the result of the enforcement samples, the operator still has the option to demonstrate that the rest of the consignment is suitable for consumption. In such a case, he has the option of organizing an additional sampling and analysis of the samples in an accredited laboratory.

The expert performing the analysis has to be officially authorized as mentioned previously. If the result is compliant, the rest of the consignment could be released.

Conclusions

Food operators have a guaranteed right of appeal against rejections in line with Artt. 11(5) and (6) of Regulation (EC) No 882/2004 and Art. 14(6) of Regulation (EC) No 178/2002.

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49 ***In their response to the draft report the Austrian Authorities informed that they would use the term "official counter sample" instead of "defence sample" and "official sample" instead of "enforcement sample"***.

2.7 Controls at visited premises

Legal basis

Art. 10 of Regulation (EC) No 882/2004 lays down that official controls shall, in general, be carried out using appropriate control methods and techniques.

Art. 11 of Regulation (EC) No 178/2002 requires that food and feed imported to the Community shall comply with the relevant requirements of food law.

Art. 10 of Regulation (EC) No 852/2004 [50] establishes that, as regards the hygiene of imported foodstuffs, the relevant requirements of food law referred to in Art. 11 of Regulation (EC) No 178/2002 shall include the requirements laid down in Artt. 3 to 6 of Regulation (EC) No 852/2004.

Art. 18 of Regulation (EC) No 178/2002 establishes traceability requirements.

Audit findings

The mission team observed an inspection of the premises of a company that imports hazelnut products from Turkey. The establishment visited had been implementing hazard analysis and critical control points (HACCP) principles since 2004 and mycotoxin contamination was identified as a hazard. The company had a system for approval of suppliers, and each supplier is visited annually. Facilities are inspected and products tested to check that specifications are met. A sampling plan based on risk analysis for mycotoxins on incoming consignments is in place.

The inspectors visited the company in April 2007 to carry out a complete hygiene inspection, and a follow-up visit took place in October. Inspectors used checklists to support inspection activities. The inspectors also visit the company for other purposes (among others to check the traceability system and sampling).

The company is categorised according to risk and has an allocated frequency of a full inspection twice a year. Visits are unannounced and last an average of 1-2 days.

Conclusions

Inspectors had adequate equipment to perform inspections and checklists were used. There was evidence that shortcomings were being identified by inspectors and that previous inspections were being adequately followed up.

2.8 Rapid alert system for food and feed

Legal basis

Art. 50 of Regulation (EC) No 178/2002 establishes the RASFF system and requires that where a member of the network has any information relating to the existence of a serious risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the RASFF.

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50 Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs; OJ L 139, 30.04.2004. Corrected and re-published in OJ L 226, 25.06.2004 p. 3.

Art. 19(3) of Regulation (EC) No 882/2004 requires CAs, when they do not permit the introduction of feed or food, to notify the Commission and other MS of their findings and of the identification of the product concerned.

Audit findings

In the event of a consignment that is not in compliance, the competent provincial food authority supplies all the information needed for the RASFF notification, such as accompanying documents, results of analyses, and the official document with the decision of the competent food inspection authority on the unsuitability of the consignment, to the Austrian RASFF contact point (the ILMU Salzburg of AGES) and to BMGFJ.

The RASFF contact office produces the RASFF report and sends it to the European Commission. Simultaneously, the same information is passed on to BMGFJ.

If the Austrian RASFF contact point receives information about the rejection of imports by other MS, it sends this information to the provincial offices and also the central Customs authority in the Federal Ministry of Finances. The information is passed on from there, via the Customs internal electronic information system, to the local offices.

The mission team examined several files and noted that non-compliant consignments were notified to the Commission.

Conclusions

An adequate communication network for the transfer of information to and from the RASFF contact point in AGES is in place according to Art. 50 of Regulation (EC) No 178/2002

2.9 Laboratory services

Legal basis

Art. 4(2)(c) of Regulation (EC) No 882/2004 lays down that CAs shall ensure that staff carrying out official controls have access to an adequate laboratory capacity.

Art. 11 of Regulation (EC) No 882/2004 states that sampling and analysis methods used in the context of official controls shall comply with relevant Community rules.

The laboratories designated by the CA for official control shall operate, be assessed and be accredited in accordance with the European standards listed in Art. 12(2) of Regulation (EC) No 882/2004.

Art. 33 of Regulation (EC) No 882/2004 requires MS to designate NRLs. The NRLs will collaborate with the Community Reference Laboratory, coordinate activities, organise comparative tests, ensure the dissemination of information, and provide scientific and technical assistance.

Audit findings

Five laboratories are involved on the official controls of imported foodstuffs of non-animal origin that are relevant to this mission. Four of these are involved in the analysis of mycotoxins and one in the analysis of Sudan dyes. All are accredited to ISO 17025.

The mission team visited the AGES competence centre cluster for chemistry in Linz which is the NRL in Austria for the analysis of mycotoxins and polycyclic aromatic hydrocarbons.

Workshops on mycotoxins, exchange of information with other laboratories and co-operation with the Community Reference Laboratory are some of the activities developed since the laboratory was appointed NRL earlier this year.

The laboratory was re-accredited in 2006 for the analysis of a range of mycotoxins including aflatoxins in food and feed and unprocessed cereals.

All laboratory samples arrive in opaque bags and are then ground using a slurry method. Three sub-samples are then prepared from each of these, one is kept as a reference sample, one for defence upon request, and one for enforcement.

Immunoaffinity columns are used for clean-up and quantification takes place using HPLC with post column derivatisation (PBPB). The method and sample preparation are set out in a written SOP.

In 2006, a total of 296 official samples (62 food and 234 feed) were analysed for the analysis of mycotoxins. In 2007 (up to mid-November), 580 samples (304 food and 276 feed) have been analysed with the same objective.

The mission team examined staff training records, internal and external audit reports, relevant SOPs and calibration records among others. Participation in several FAPAS proficiency tests in 2006 and 2007 was demonstrated with good results (for example, aflatoxins in pistachios, aflatoxins in paprika, OTA in cereals and DON in several matrixes).

The analytical results are not corrected for recovery but the level of recovery is reported. Analytical uncertainty is included in laboratory reports.

Conclusions

Five laboratories, all accredited to ISO 17025, are involved in the analysis of samples relevant to import controls. The laboratory that was visited is well equipped and performs well in proficiency tests.

Recoveries and measurement uncertainties are adequately included in the analytical reports as required by Regulation (EC) No 401/2006.

3. RECOMMENDATIONS

1. To ensure that CAs carry out official controls on a risk basis on all kind of commodities, as required by Artt. 3(1) and 15(1) of Regulation (EC) No 882/2004.

2. To ensure that unloading and sampling of consignments is carried out in accordance with Art. 16(3) of Regulation (EC) No 882/2004 and Art. 4(2)(c) of Decision 2006/504/EC.

3. To ensure that official controls referred to in Art. 15(1) include a systematic documentary check in accordance with Art. 16(1) of Regulation (EC) No 882/2004 and Art. 3.3 of Decision 2006/504/EC.

4. TRADE INFORMATION AND LEVELS OF ANALYSIS

Table 1: Import and sampling data for 2006 and 2007 (January to October) - Food products under Commission Decisions

Product	CN - code	Country of origin	Number of consignments imported		Volume imported in tonnes		Official samples analysed for aflatoxins		Cases of non-compliance (percentage)	
			2006	2007	2006	2007	2006	2007	2006	2007
Peanuts and peanut products	1202 10 90, 1202 20 00, 2008 11 92, 2008 11 96	EGYPT	-	-	-	-	-	-	-	-
Peanuts and peanut products	1202 10 90, 1202 20 00, 2008 11 92, 2008 11 96, 2008 11 94, 2008 11 98	CHINA	5	25	278	671	1	2	0	0
Pistachios	0802 50 00, 2008 19 13, 2008 19 93	IRAN	-	-	-	-	-	-	-	-
Dried figs	0804 20 90	TURKEY	38	20	505,3	209	5	2	1	1
Hazelnuts	0802 21 00, 0802 22 00	TURKEY	72	77	1210	1155	2	11	0	3
Pistachios	0802 50 00	TURKEY	1	-	6	-	0	-	-	-
Figs, hazelnuts, and pistachios and derived products	0813 50, 2007 99 98, 2008 19, 1106 30 90	TURKEY	471	609	4462	8800	34	40	5	8
Brazil nuts	0801 21 00	BRAZIL	-	-	-	-	-	-	-	-

Sudan dyes:

Product	CN - code	Country of origin	Number of consignments imported		Volume imported in tonnes		Official Samples analysed		Cases of non-compliance (percentage)	
			2006	2007	2006	2007	2006	2007	2006	2007
Chilli and chilli products, curcuma	0904 20 90, 0910 50, 0910 30	Third countries	22	14	37,6	18,8	5	7	-	-
Palm oil	1511 10 90	Third countries	-	-	-	-	-	-	-	-

Table 2: Import and sampling data for 2006 and 2007 (January to October) - Other food products

Product	Hazard	Country of origin/ contaminant	Number of consignments imported		Volume imported in tonnes		Official samples analysed		Cases of non-compliance (percentage)	
			2006	2007	2006	2007	2006	2007	2006	2007
Rice	OTA	India	-	-	-	-	5	-	0	-
		USA	-	-	-	-	2	-	0	-
		Thailand	-	-	-	-	6	-	0	-
		China	-	-	-	-	2	-	0	-
Dates	Aflatoxin		-	-	-	-	-	2	-	-
Spices and melon seeds	Aflatoxin	Ghana	-	2	-	0.03	0	0	0	0
Spices	Aflatoxin	India	23	23	13.5	28.4	0	0	0	0
Concentrat. coffee	Mycotoxins	Brasil	7	0	105	0	0	0	0	0
Roasted coffee	Mycotoxins	Several	455	538	4641	1302	0	0	0	0
Almonds	Mycotoxins	USA	6	0	118.9	0	0	0	0	0

(source: BMGFJ and BMF)

EUROPEAN COMMISSION
HEALTH & CONSUMER DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO)/2007-7350 – MR final

PILOT GENERAL AUDIT AUSTRIA – 2007

FINAL REPORT OF

A SPECIFIC AUDIT

CARRIED OUT FROM 25 JUNE TO 6 JULY 2007

IN ORDER TO EVALUATE

THE IMPLEMENTATION OF

EU ANIMAL HEALTH REQUIREMENTS FOR

INTRA-COMMUNITY TRADE IN LIVE ANIMALS

PART B – SECTOR-SPECIFIC ISSUES

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

1. LEGISLATION RELEVANT TO INTRA-COMMUNITY TRADE IN LIVE ANIMALS

The specific audit covered the main elements of the control system ICT in live animals:

- Official supervision and veterinary certification;
- Veterinary checks during trade;
- Notifications made to the TRACES database.

Official supervision and veterinary certification

The main legal requirements concerning the despatch of live animals into ICT are set out in the following trade directives: Directive 64/432/EEC [51], Directive 90/426/EEC [52] and Directive 91/68/EEC [53].

These directives oblige MS to ensure that animals entering ICT are:

- identified in accordance with Community provisions;
- free from clinical signs of disease at a veterinary inspection carried out prior to their departure;
- not subject to restriction under a contagious or infectious disease eradication programme;
- accompanied during transportation to destination by the relevant veterinary health certificate.

The following legal instruments set out the main Community requirements for the identification of animals and movement control: Directive 92/102/EEC [54], Decision 93/623/EEC [55], Decision 2000/68/EC [56], Regulation (EC) No 1760/2000 [57] and Regulation (EC) No 21/2004 [58].

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51 Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine; OJ 121, 29.07.1964, p. 1977.

52 Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of equidae; OJ L 224, 18.08.1990, p. 42.

53 Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals; OJ L 46, 19.02.1991, p. 19.

54 Council Directive 92/102/EEC of 27 November 1992 on the identification and registration of animals; OJ L 355, 5.12.1992, p. 32.

55 Commission Decision 93/623/EEC of 20 October 1993 establishing the identification document (passport) accompanying registered equidae; OJ L 298, 3.12.1993, p. 45.

56 Commission Decision 2000/68/EC of 22 December 1999 amending Commission Decision 93/623/EEC and establishing the identification of equidae for breeding and production; OJ L 23, 28.01.2000, p. 72.

57 Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97; OJ L 204, 11.08.2000, p. 1.

58 Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC; OJ L 5, 9.01.2004, p. 8.

Additional animal health requirements relevant to the audit carried out in Austria include: Directive 2003/85/EC, Decision 93/52/EEC [59], Decision 2003/467/EC [60], Decision 2004/558/EC [61] and Decision 2001/618/EC [62].

Decision 1999/571/EC [63] lays down additional requirements for movement control of animals relevant to the audit carried out in Austria include:

Regulation (EC) No 854/2004 [64] requiring post mortem examination of slaughtered bovine animals is relevant to the audit concerning tuberculosis surveillance, as the CA may dispense with tuberculin testing of the herds when all bovine animals slaughtered are examined for lesions of tuberculosis.

Veterinary checks during trade

The following Directive obliges MS despatching live animals into ICT carry out checks to ensure that they comply with Community requirements. It also places a duty on MS of destination to establish by means of non-discriminatory veterinary spot checks that these requirements have been met. Cases of non-compliance must be notified to the MS of origin, which is obliged to take appropriate measures in accordance with Directive 90/425/EEC [65].

Regulation (EC) No 1/2005 lays down the provisions for the protection of animals during transport:

Directive 96/23/EC [66] obliges MS to ensure that records of medical treatment are kept on farms:

Directive 96/93/EC [67] lays down provisions for certification of animals and animal products:

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59 Commission Decision 93/52/EEC of 21 December 1992 recording the compliance by certain Member States or regions with the requirements relating to brucellosis (*Brucella melitensis*) and according them the status of a Member state or region officially free of the disease; OJ L 13, 21.01.1993, p. 14.

60 Commission Decision 2003/467/EC of 23 June 2003 establishing the official tuberculosis, brucellosis, and enzootic bovine leucosis free status of certain Member States and region of Member States as regards bovine herds; OJ L 156, 25.06.2003, p. 74.

61 Commission Decision 2004/558/EC of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States; OJ L 249, 23.07.2004, p. 20.

62 Commission Decision 2001/618/EC of 23 July 2001 on additional guarantees in intra-Community trade of pigs relating to Aujeszky's disease, criteria to provide information on this disease and repealing Decisions 93/24/EEC and 93/244/EEC; OJ L 215, 9.08.2001, p. 48.

63 Commission Decision 1999/571/EC of 28 July 1999 recognising the fully operational character of the Austrian data base for bovine animals; OJ L 217, 17.08.1999, p. 62.

64 Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption; OJ L 139, 30.4.2004, corrected and re-published in OJ L 226, 25.06.2004, p. 83.

65 Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zoo-technical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market; OJ L 224, 18.08.1990, p. 29.

66 Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decision 89/187/EEC and 91/664/EEC; OJ L 125, 23.05.1996, p. 10.

Notifications made to the TRACES database

MS are obliged by the following regulation to exchange the information contained in veterinary health certificates accompanying live animals involved in ICT as well as the results of checks performed on consignments of live animals arriving on their territories using the TRACES database, in accordance with Decision 2004/292/EC [68] and Regulation (EC) No 599/2004 [69].

2. ANIMAL IDENTIFICATION, HOLDING REGISTRATION AND MOVEMENT CONTROL

2.1 Registration of holdings

Legal basis

Art. 2 of Regulation (EC) No 1760/2000 defines a holding as any establishment, construction, or, in the case of an open-air farm, any place situated within the territory of the same MS, in which animals covered by this Regulation are held, kept or handled.

Art. 2(2)(a) of Directive 64/432/EEC defines a herd as an animal or group of animals kept on a holding (within the meaning of Art. 2(b) of Directive 92/102/EEC) as an epidemiological unit.

Art. 14(3)(c)(2) of Directive 64/432/EEC requires that the computer database as required by this Directive must contain for each holding an identification number.

Art. 5 of Regulation (EC) No 1760/2000 requires the CA to set up a computer database which shall become fully operational no later than 31 December 1999, after which it shall store all data required pursuant to Directive 64/432/EEC.

Art. 1 of Decision 1999/571/EC recognises the Austrian database for bovine animals as fully operational.

Audit findings

The farm holdings, slaughterhouses, assembly centres and dealer's premises visited were in principle all registered. However, in relation to cattle:

- the CA stated that the different parts of a holding are registered under the same holding registration number even when parts of it are located hundreds of km apart and even in other provinces (*Bundesländer*). The animal keepers are obliged to notify the location of these parts of their holding to the CA to which the CA allocate sub-registration numbers. However, one animal keeper visited alleged that it is within the discretion of the animal keepers to apply for either additional registration numbers (*Hauptbetriebsnummern*) or for sub-registration numbers (*Teilbetriebsnummern*) for these parts of their holdings.

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67 Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products; OJ L 13, 16.01.1997, p. 97.

68 Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the TRACES system and amending Decision 92/486/EEC; OJ L 94, 31.03.2004, p. 63.

69 Commission Regulation (EC) No 599/2004 of 30 March 2004 concerning the adoption of a harmonised model certificate and inspection report linked to intra-Community trade in animals and products of animal origin; OJ L 94, 31.03.2004, p. 44.

- assembly centres which were several km apart shared a single holding number in the AMA cattle database. Similarly, in all cases seen when an assembly centre is also approved as dealer's premises, they shared a single AMA holding number.

Conclusions

Cattle holdings are registered in the central cattle database. However, the CCA considers that separate parcels of land on which different herds ("epidemiological units") are kept may comprise a single holding.

2.2 Holding registers

Legal basis

Art. 7 of Regulation (EC) No 1760/2000 requires each cattle keepers to maintain an up-to-date holding register, which can be kept in computerised form.

Art. 11(2) of Directive 64/432/EEC (for cattle and pigs) require the operator of assembly centres and Art. 13(1)(b) of Directive 64/432/EEC (for cattle and pigs) require dealers to record information about the animals for which they are responsible including the address or holding number of the holding of destination in other MS, the registration number of the transporter and the licence number of the lorry delivering or collecting animals.

Art. 7(1) of Directive 90/426/EEC requires horses to be transported from the holding of origin either directly or via an approved market or marshalling centre as defined by Directive 64/432/EEC to the place of destination.

Art. 5 of Regulation (EC) No 21/2004 requires the keepers of sheep and goats to keep an up-to-date register of animals arriving on the holding, the identification code of the holding from which the animal was transferred and the date of arrival.

Audit findings

Holding registers were available on the holdings visited. Entries of the holding data in the AMA database are used as cattle holding registers by the animal keepers who have access to the Internet (5%). Keepers who have access to the Internet may use the AMA database in place of an on-farm register.

At the bovine assembly centres visited the AMA database is also used as holding register. However,

- jointly registered holdings (see section 2.1) share a common holding register; it is not possible to determine which holding the animals passed through or whether animals have moved between holdings.

- in many bovine assembly centres neither the documents kept on the holding nor the AMA database contained the name and address or holding number of the holding of destination in other MS [70];

- the registration number of the transporter and the licence number of the lorry delivering or collecting animals from the assembly centres are not recorded in the AMA database. At some assembly centres visited the operator retained copies of the delivery notes accompanying arriving animals. However, these were often incomplete, particularly with regard to the details of the transporter and the registration numbers of transport vehicles.

Concerning holding registers on equine assembly centres the mission team noted that:

- the records kept in one assembly centre for horses recorded the name and address of the purchaser rather than the destination for each consignment;

- at another equine assembly centre there was no holding register; instead there were invoices of horses which had arrived in the assembly centre, horse passports only for registered horses staying in the assembly centre at the moment and copies of health certificates for horses which had left the assembly centre. Unregistered horses were brought to the assembly centre without identification documents, which were issued there by the responsible OV.

Concerning holding registers kept at sheep holdings the mission team noted that:

- at the sheep holdings visited the quality of the holdings registers varied remarkably: one consisted of a collection of loose leafed papers, which were not organised in any way. The other was structured and allowed the movement of animals through the holding to be traced;

- the provincial CAs permitted sheep keepers to omit details of animals arriving on their holdings in the register if copies of the movement documents (delivery notes) were retained. This is contrary to the requirements of both Community and national legislation.

Conclusions

The registers kept at cattle holdings were generally considered to be satisfactory. However, as some assembly centres and dealers' premises shared the same register, the requirement for each holding to keep a register was not met. Consequently, it was not possible to distinguish between animal movements through or between the different holdings using the holding register.

Moreover, in the assembly centres visited information recorded in the registers was often incomplete.

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70 ***In their response to the draft report the Austrian Authorities stated that the OVs responsible for inspecting the cattle assembly centres visited were already asked to ensure that the shortcomings observed in relation to record-keeping were immediately corrected.***

2.3 Animal identification

Legal basis

Art. 4(1) of Regulation (EC) No 1760/2000 requires cattle to be identified by an ear tag applied to each ear.

Art. 5 (3) of Directive 92/102/EEC requires pigs to marked with an ear tag or tattoo.

Art. 4 (2) of Regulation (EC) No 21/2004 requires sheep and goats to be identified by two means of identification.

Art. 2 of Decision 93/623/EEC requires identification documents in conformity with the Annex of that Decision to accompany registered horses. Art. 3 of Decision 2000/68/EC requires the identification document accompanying equidae for breeding and production during their movement to contain at least information laid down in sections I, II, III, IV and IX of the Annex to Decision 93/623/EEC. EU legislation does not provide for particular passports for slaughter equidae because equidae for breeding and production as well as registered equidae may become equidae for slaughter for human consumption at a certain stage of their life (Point 5 of the preamble of Decision 2000/68).

Audit findings

The cattle, sheep and pigs examined during the mission were generally identified in accordance with Community requirements. However, at one slaughterhouse visited some cattle identified by means of a single ear tag were accepted and the CA took no further action.

With regard to horses, national rules require all registered and all breeding equidae to be accompanied by an identification document conforming to the model set out in Commission Decision 93/623/EEC.

Production and slaughter equidae must be accompanied with a passport for production and slaughter equidae (*Pass für Nutz- und Schlachtequidae*) issued by an OV.

The mission team noted that:

- the equine identification documents issued by breeding associations generally did not adequately identify the animals and the previous owners; for example at one assembly centre visited, in many identification documents of registered horses, checked by the mission team, the most recent owner was not indicated and the description of the horse was missing.

- the Austrian passport for production and slaughter equidae is a one page document not containing all necessary information as laid down in Decision 2000/68/EC (e.g. concerning the history of the ownership, the place where the equidae was bred, the signature and stamp of the qualified veterinary surgeon who has described the horse, information about identity checks and medical records). The mission team noted that:

    - the description of the horse was often omitted or the animals was poorly described or identified by means of chip marks made in the animal's coat.

- at one horse assembly centre visited, the OV responsible for issuing the passports for production and slaughter horses consistently failed to tick the boxes on the documents to confirm that the horse had not been treated before with substances mentioned in Annex IV to Regulation (EC) No 2377/90, that the withdrawal period of administered medicines was respected and the horse was reared in Austria or, if not in Austria, in a country, whose name should be filled in the document by him. He explained that he would be certifying data of which he has no personal knowledge or which cannot be ascertained by him. He agreed, however, that somebody else could easily tick the boxes on the document which he had signed.

Conclusions

Cattle, pigs and sheep inspected during the mission were satisfactorily identified.

As the identification documents for registered and breeding equidae often do not contain the description of the horse, these horses remain un-identified.

The identification document for production and slaughter equidae does not meet the requirements for passports for breeding and production horses concerning format and content as laid down by Commission Decision 2000/68/EC and its value in respect of consumer protection and traceability is limited.

2.4 Movement documents and controls

Legal basis

Art. 6(3) of Regulation (EC) No 1760/2000 allows MS which have a computerised database which the Commission deems to be fully operational to determine that a passport is to be issued only for cattle intended for ICT. Art. 7(1) of the said Regulation requires all movements of cattle from and to holdings to be reported to the CA.

Point 1 of Part C of the Annex to Regulation (EC) No 21/2004 requires the movement document for sheep to contain data concerning the means of transport, including the transporter´s permit number.

Audit findings

Because the Austrian bovine database is considered to be fully operational, passports are issued only for cattle intended for ICT. The passport may be printed at the request of the keeper or dealer, by the OV issuing the veterinary certificate, directly from the internet. Printing is blocked if the animal or herd are subject to movement restrictions for animal health reasons. Keepers of bovine animals are obliged to notify AMA within seven days when animals arrive on or leave their holdings.

However the mission team noted that:

- when cattle returned to the holding of origin from assembly centres, in one case no notification of the movement of the cattle was sent to the AMA database and in another case the cattle keeper alleged that it was left to his discretion whether to notify that movement;

- movements through dealers' premises were not reported to the AMA database, including movements to the dealers' premises from assembly centres and from dealers' premises to other MS.

Cattle, sheep and pigs must be accompanied by a movement document (delivery note - *Viehverkehrsemen storage centrehein*) during movements. Copies of this document must be retained by the seller, the buyer and, if applicable, by the transporter, by the dealer, the slaughterhouse and the meat classification service.

The mission team noted the following:

- Movement documents were usually available at the holdings visited. They generally contained details of the holdings of origin and destination and the identification of animals moved but, in the case of movement documents for sheep, the data concerning the means of transport, including the transporter´s permit number was frequently omitted.

Information on the registration and health status of pig, sheep and goat holdings is kept on the Veterinary Information System; the information relating to cattle is input into this system daily. Movement notification of sheep and goats will start on 1 January 2008.

Conclusions

The system for movement documents, movement notification and movement control in place is in general considered as satisfactory. However, notification of cattle movements from and to assembly centres and dealers' premises visited were sometimes omitted, slightly diminishing the accuracy of the Austrian movement control system in place.

3. ANIMAL HEALTH REQUIREMENTS

Legal basis

Decision 93/52/EEC recognises the status of Austria as officially brucellosis (*Brucella melitensis*) free, and Decision 2003/467/EC establishes the official tuberculosis, brucellosis, and enzootic bovine leucosis-free status of Austria.

Point I, 2. (c) of Annex A to Directive 64/432/EEC allows MS to dispense with tuberculin testing herds provided that all bovine animals slaughtered are examined for lesions of tuberculosis and any such lesions are submitted to a histopathological and bacteriological examination for evidence of tuberculosis.

Section IV Chapter I (B) of Annex I to Regulation (EC) No 854/2004 lays down the post mortem inspection procedure for carcasses and offal of bovine animals over six weeks old and Section III Chapter IV (B) of Annex I to Regulation (EC) No 854/2004 requires professional qualification of official auxiliaries.

Audit findings

Austria has been free of foot-and-mouth disease since 1981, vesicular stomatitis and swine vesicular disease since 1979, rinderpest since 1881, anthrax since 1988, contagious bovine pleuropneumonia since 1921 and classical swine fever since

2001. Bluetongue, lumpy skin disease, rift valley fever, African horse sickness and African swine fever have never occurred in Austria.

Cattle over 24 months are tested by blood sample for bovine brucellosis and enzootic bovine leucosis. In 2006, 202,316 cattle (out of 1,992,716 cattle) in 17,050 cattle holdings (out of 80,257 holdings) were tested for brucellosis and 201,931 cattle in 16,805 holdings for enzootic bovine leucosis. 1,262 abortions were notified to the CA with negative result for isolation of *B. abortus.* One bovine animal turned out to be serologically positive for enzootic bovine leucosis and one tumour suspected of being due to enzootic bovine leucosis was submitted for histopathological examination (with negative result). Implementation of these programmes is managed at district level.

For bovine tuberculosis monitoring is based on the routine *post mortem* examination of slaughtered cattle. However, the following observations were made:

- Auxiliaries performing post mortem examinations are not obliged to participate in a training programme [71],

- In one slaughterhouse visited no *post mortem* examination for the presence of bovine tuberculosis lesions was performed (i.e. palpation of lungs and gastric and mesenteric lymph notes, incision of lymph glands). Moreover, the slaughter line at that slaughterhouse was constructed in a way making it difficult to palpate the gastric and mesenteric lymph notes.

- During 2006, in Austria tissue samples were collected from six animals suspected of having bovine tuberculosis based on pathological findings. These were analysed for the presence of bovine tuberculosis, all with negative results.

For Aujeszky's disease, 10 % of the sows and 100 % of the boars were tested after slaughter. In 2006, 3,109 pigs from 6,695 holdings (out of 60,283 holdings) were tested for Aujeszky's disease with negative result.

For *B. melitensis,* a monitoring programme is in place to provide assurance at a 95% level of confidence that the incidence of the disease is less than 0.2%. The sampling plan is drawn up by the federal veterinary service. In 2006, 11,372 out of 360,397 sheep in 27,780 flocks were tested for brucellosis. One test was positive, probably due to false positive laboratory testing.

In 2006, 108,038 cattle in 10,414 holdings were tested by blood samples for IBR/IPV with two positive results.

Conclusions

Monitoring programmes for bovine brucellosis and enzootic bovine leucosis exceed Community requirements. However, the bovine tuberculosis monitoring system in place is considered as insufficient because auxiliaries are not trained for *post mortem* examination, basic requirements of the *post mortem* examination seen in one

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71 ***In their response to the draft report the Austrian Authorities stated that as part of a comprehensive retraining programme, all OVs and official auxiliaries will be required to undergo refresher training. In addition, detailed administrative instructions have been issued for inspections of animals for slaughter and meat.***

slaughterhouse were not met and the number of tissue samples sent to laboratories indicates a lack of attention to the need to investigate granulomatous lesions for the presences of bovine tuberculosis.

The monitoring programs for Aujeszky's disease, *B. melitensis* and IBR/IPV are considered as being adequate.

4. CONTROLS ON ASSEMBLY CENTRES, DEALERS' PREMISES AND ANIMAL TRANSPORTERS

4.1 Approval

Legal basis

Art. 11 of Directive 64/432/EEC and Art. 8a of Directive 91/68/EC require assembly centres to be cleaned and disinfected before use, as required by the OV (Point 1 (c)), to have a facility dedicated exclusively for this purpose when used as an assembly centre and to have appropriate isolation facilities (Point 1 (d)).

Audit findings

The assembly centres visited generally met the structural requirements set out in the above Directives. However:

- hygiene requirements were not consistently met at the assembly centres visited, particularly regarding the use of wooden materials and the construction and maintenance of loading areas. Procedures for cleaning and disinfection were not drawn up by the OVs responsible for the centre;

- in two of the assembly centres visited, parts of the premises included unpaved outdoor areas which could not be cleaned and disinfected;

- dedicated isolation facilities were present in one of the assembly centres visited. In all other cases, it was explained that parts of the animal housing could serve that purpose when needed.

The assembly centres visited were placed under official control. However, two assembly centres visited were also approved as dealers' premises and their facilities were also used as dealers' premises without separation of operation in time or space. In Austria, in total 10 out of 27 approved dealers' premises are also approved by the CA as assembly centres. Moreover, the same format of the EU approval number for assembly centres (e.g. AT-K-VS-06) is used for dealers' premises.

Conclusions

The overall structure of assembly centres visited is adequate. However, the hygiene conditions are sometimes inadequate and there are generally no dedicated isolation facilities.

Assembly centres are often used as dealers' premises. As assembly centres and dealers' premises can be approved under the same approval number and they can

share the same holding registration number and holding register in the AMA system, their activities can be mixed up [72].

5. CHECKS ON INTRA-COMMUNITY TRADE IN LIVE ANIMALS

5.1 Checks on animals arriving in Austria

Legal basis

Art. 6 (1) of Directive 90/425/EEC requires that quarantine can only take place when it is required by Community rules or, in areas which have not yet been harmonized, by national provisions.

Art. 5 (1) (a) of Directive 90/425/EEC lays down that the CA may establish by means of non-discriminatory veterinary spot checks at the place of destination that the ICT requirements have been complied with.

Art. 3(1) of Decision 2004/558/EC lays down the additional guarantees which cattle for breeding and production have to meet in order to be dispatched to Austria from MS which are not listed in Annex II to the said Decision.

Art. 2 of Decision 2001/618/EC does not require specific conditions for pigs intended for slaughter when they are dispatched from a MS which is free of Aujeszky's disease and listed in Annex I to the said Decision.

Art. 5(1)(B)(ii) of Directive 90/425/EEC requires the OV responsible for the supervision of the slaughterhouse to ensure, in particular on the basis of the certificate or accompanying document, that only animals that meet the requirements of Art. 3 (1) of the said Directive are slaughtered. Section II Chapter III (1) of Annex I to Regulation (EC) No 854/2004 requires the OV to verify compliance with the food operator's duty to ensure that animals accepted for slaughter for human consumption are properly identified.

Art. 4(1)(b) of Directive 96/93/EC requires the certifying OVs to be fully aware of the significance of the content of each certificate which they sign and Art. 5(1) of the said Directive requires the CA to take any control measures necessary to prevent the issuing of false or misleading certificates.

Audit findings

Checks on arrival of animals in Austria were performed by the OV at the sites visited. The CA stated that all veterinary certificates of the arriving animals were checked and physical checks were performed on at least 5 % of the consignments sent from other MS to Austria. The results of the physical checks have been entered in part III of the veterinary document in TRACES since early this year.

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72 ***In their response to the draft report the Austrian Authorities stated that the OVs responsible for running checks on the cattle AC visited were asked to ensure that the structural defects observed (lack of isolation facilities) and shortcomings in hygiene (disinfection) were immediately corrected or, failing this, that ICT approval was set aside or revoked. Assembly centres and dealers' premises will be separately approved.***

The mission team noted the following:

- Cattle and pigs for breeding and production traded from other MS are only allowed to enter the holding of destination in Austria following action taken by the district administration in order to ensure that the health status of the holding is not jeopardized. (§ 53 (5) of the *Einfuhr- und Binnenmarktverordnung* – EBVO, 2001).

  To implement this requirement 5 % of the arriving consignments have to be checked at random in such way that 10 % of the breeding cattle over six weeks of age have to be tested for bovine tuberculosis, and over 12 months of age for brucellosis and leucosis (also applicable for production and slaughter cattle), that 10 % of the breeding and production pigs have to be tested for Aujeszky's disease and that 10% of the breeding and production sheep and goats for *B. melitensis* (rams for *B. ovis*). However:

  - 100 % of the breeding cattle of each consignment arriving in Austria have to be isolated and to be tested 21 days after arrival for IBR/IPV. When up to 10 cattle for production arrive in Austria all of them have to be tested for IBR/IPV within the first week after arrival. When up to 20 cattle for production arrive only 12 have to be tested – and so on. The mission team visited one isolation facility of a diary holding where all breeding cattle were tested for IBR/IPV 21 days after arriving at the holding from another MS.

  - in one province visited the CA confirmed that 100 % of the breeding pigs arriving from other MS could be tested for Aujeszky's disease. Moreover, at one slaughterhouse visited the responsible OV stated that all pigs arriving from MS which are free of Aujeszky's disease were serologically tested for Aujeszky's disease.

- OVs in the slaughterhouses visited did not verify that the identification numbers of the animals matched their accompanying documents before accepting them for slaughter. Instead, they relied on checks following stunning (cattle) or slaughter (pigs) performed by a private company (meat classification company) [73].

- The OVs took no action in cases where the veterinary certificates accompanying animals arriving from other MS were wrongly filled in or parts of part II were wrongly deleted [74].

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73 ***In their response to the draft report the Austrian Authorities stated that in the past, meat classification veterinarians have been instructed on several occasions to perform an identity check on all animals arriving for slaughter using the delivery notes or TRACES documents. Spot checks were carried out by the OV in each case, which are compared with the classifier data.***

74 ***In their response to the draft report the Austrian Authorities stated that in relation to the health certificates containing insufficient information and the measures taken in this respect, it is asserted that there are many animal health certificates in TRACES that can demonstrate how shortcomings in certificates are dealt with. Shortcomings are entered in part III of the animal health certificates, which is how the OV working for the CA at the place of departure reports the defective animal health certificate via TRACES. In some cases, a temporary slaughter ban is imposed and a corrected certificate requested. Furthermore, letters are drafted to the central veterinary authorities concerned, drawing their attention to the shortcomings.***

Conclusions

There is comprehensive system for checks on animals arriving in Austria in place in order not to jeopardize the health status of the holding of destination.

However, checks for cattle diseases and in one province, checks for Aujeszky's disease on pigs are discriminatory because they go beyond the requirements for these animals traded within Austria.

As identity checks on cattle and pigs at slaughterhouses visited are generally not carried during *ante mortem* inspection, the OVs do not verify that only animals which fulfil the requirements for ICT are slaughtered.

Health certificates accompanying animals arriving in Austria which were insufficiently completed were accepted by the CA without notification of shortcomings of the health certificates to the CA responsible for completing the certificates at the place of dispatch.

5.2 Controls on animals leaving Austria

Legal basis

Art. 5(2)(a) of Directive 64/432/EEC and Art. 9(4) of Directive 91/68/EEC require certification for animals passing through an assembly centre to be on the basis of an official document containing the health information completed by the OV for the holding of origin.

Art. 6(1) of Directive 64/432/EEC requires cattle and pigs for breeding and production to remain in a single holding of origin for a period of 30 days prior to loading and, if an animal from a third country is introduced into a holding, not to be traded for 30 days following introduction unless the imported animal is isolated from all other animals on the holding.

Art. 4a(1) of Directive 91/68/EEC requires sheep and goats intended for ICT to have been continuously resident on the holding of origin for at least 30 days, not to come from a holding into which sheep or goats have been introduced during the 21 days prior to dispatch and not to come from a holding into which bi-ungulate animals imported from third countries have been introduced during the 30 days prior to dispatch.

Art. 5(2) of Directive 64/432/EEC requires the health inspections for the issuing the health certificate (including additional guarantees) for consignment to be carry out in the holding of origin or an assembly centre.

Art. 6(1) of Directive 64/432/EEC requires that animals for breeding and production transiting through an approved assembly centre in the MS of origin are not outside the holding of origin for more than six days. Art. 4b (2) of Directive 91/68/EEC requires sheep and goats not to be outside their holding of origin for more than six days before being last certified for trade to the final destination in another MS. Art. 2 (q) of Directive 64/432/EEC defines a dealer as be a natural or legal person who within a maximum of 30 days of purchasing animals resells them or relocates them from the first premises to other premises not within his ownership.

Art. 3(1) of Directive 64/432/EEC requires each MS to ensure that only animals that fulfil the relevant conditions laid down in that Directive are sent from its territory to that of another MS, and Art. 5(1) of the said Directive requires animals to be accompanied during transport to destination by a health certificate. Art. 2(a) of Decision 2004/292/EC requires MS to ensure that the health certificates relating to trade are entered in TRACES.

Art. 9(2) of Directive 64/432/EEC requires that additional health guarantees for one of the contagious diseases listed in Annex E (II) to the said Directive required for ICT are only to be determined after examination of the control programmes presented by the MS to the Commission and after their approval. BVD/MD is not listed in Annex E (II) to Directive 64/432/EEC

Art. 4 of Directive 90/426/EEC requires horses to be free of clinical sign of disease at inspection (Point 1) and to be identified prior to entering ICT (Point 4).

Art. 10 of Directive 96/23/EC requires the veterinarian to enter in a register kept on farm the date and nature of any treatment prescribed or administered, the identification of the animals treated and the corresponding withdrawal period and the stockfarmer to enter in the register the date and the nature of the treatment administered.

Art. 4(1)(b) of Directive 96/93/EC requires the certifying OVs to be fully aware of the significance of the content of each certificate which they sign and Art. 5(1) of that Directive requires the CA to take any control measures necessary to prevent the issuing of false or misleading certificates.

Audit findings

Animals leaving Austria generally meet EU identification and health requirements.

The mission team noted that:

- at the assembly centres visited, no official document containing the necessary health information and completed by the responsible OV for the holding of origin accompanied arriving cattle [(75)];

- neither the movement documents ("*Viehverkehrsemen storage centrehein*") accompanying animals for breeding or production arriving at the assembly centres nor the in Veterinary Information System database state, in the case of pigs, whether they have been resident on the holding of origin for 30 days; in the case of sheep or goats intended for ICT the movement document provides no information about whether the sheep or goats had resided on the holding of origin for 30 days prior to dispatch, whether other sheep and goats had been introduced into the holding during the 21 days prior to dispatch, and whether bi-ungulate animals imported from a third country have been introduced during the 30 days prior to dispatch;

- cattle for breeding and production have been dispatched to other MS although they had not been resident on the holding of origin for at least 30 days (cattle

75 ***In their response to the draft report the Austrian Authorities stated that in future all (preliminary) certificates for animals intended for ICT will be signed by an OV.***

were moved through another assembly centre a few days prior to arriving at the second assembly centre or returned to their holding of origin and then brought back to the assembly centres) [76];

- health certificates were issued for cattle at dealers' premises and the animals were then dispatched directly to other MS. Moreover, cattle frequently remained on dealers' premises for more than 30 days and in one case up to three months;

- the six day maximum stay in assembly centres was often not respected for cattle (a few days up to months) and sheep were kept at one assembly centres visited for some months [77];

- at an assembly centre visited in one case a horse was dispatched to another MS although no incoming identification document was available. Moreover, at the horse assembly centres visited records of medical treatment were not always available which limits the possibility of the responsible OV to verify the health condition of the animal to be traded;

- there are agreements between Austria and neighbouring regions of MS (Bolzano in Italy and Bayern in Germany) in place in order to facilitate the cross-border movement for animals (cattle, sheep, goats, equidae and pigs) for common grazing during summer in the Alps. The CA stated that a similar agreement with Slovenia is under preparation at present. For this kind of cross-border movement, official documents (*Amtstierärztliches Zeugnis für den Alpenweideverkehr*) are required containing information about the ownership, the number, the identity and the health status of the animals, the holding of origin and the place of destination (Alpe). These documents must be signed by an OV and by the owner of the animals. The mission team noted that,

    - no health certificates for ICT are issued and details of the movements are not entered in TRACES;

    - for cattle, additional health guarantees in respect of BVD/MD are to be met by Austria and neighbouring regions of MS (Bolzano in Italy and Bayern in Germany) in order to participate in the common grazing during summer. However, in these MS the national control programmes for BVD/MD are not approved by the EU.

- concerning health certificates, most of them were filled in correctly. However, some inaccuracies were noted in respect of the completion of parts I and II, for example:

    - certificates for pigs indicated destinations that were different from their actual intended destination;

    - certificates for cattle were issued although all categories (i.e. breeding, production and slaughter) had been crossed out [78].

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76 ***In their response to the draft report the Austrian Authorities stated that the OVs were instructed to observe the timing requirements (30 days on the holding of origin) closely.***

77 ***In their response to the draft report the Austrian Authorities stated that sheep for ICT are now introduced into the assembly centre in such a way that they have no contact with other animals being traded and spend a maximum of six days there.***

The CA stated that in 2007 some provincial CAs appointed veterinarians to act as TRACES officers in order to provide technical support to the OVs issuing health certificates.

Conclusions

The system of controls in place for animals leaving Austria is in some aspects unsatisfactory.

Although animal health certificates are generally issued correctly, the movement documents accompanying animals from the holding of origin to assembly centres were considered as insufficient as they are not official documents as required and do not include all necessary health information. The requirements for residency of breeding and production animals at the holding of origin and the maximum duration of stay of animals at assembly centres were often not met. Health inspections for certification prior to dispatch to another MS were carried out at dealers' premises.

The basic requirement of EU legislation in respect of health certificates to accompany live animals when moved from one MS to another MS was not met when animals were brought up to grazing areas up in the Alps of a neighbouring MS during summer. Moreover, for cattle participating in common grazing during summer additional health guarantees for a contagious disease are required although additional health guarantees for ICT can only be granted to a MS when the national control programmes for this disease are approved by the EU.

6. TRACES

Legal basis

Decision 2004/292/EC and Regulation (EC) No 599/2004.

Audit findings

Generally the health certificates are produced within TRACES and are confirmed and entered into TRACES within 24 hrs after the animals´ departure. In addition, the original certificates accompanying the consignments matched the information entered on TRACES.

In some provinces TRACES officers actively scanned the certificate issued within the province concerned in order to detect inaccuracies or inconsistencies.

Conclusions

The requirements for the use of the TRACES system were in general met.

7. RECOMMENDATIONS

1. To bring the definition of "holding" into line with Art. 2(2)(a) of Directive 64/432/EEC, and to ensure that each holding is registered under one single

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[78] ***In their response to the draft report the Austrian Authorities stated that the OVs had already been informed about to delete these sections of the certificates.***

registration number in the cattle database as required by Art. 14(3)(C)(2) of Directive 64/432/EEC.

2. To ensure that holding registers are kept on each holding and the registers contain all information as required by Art. 7 of Regulation (EC) No 1760/2000, Artt. 11(2) and 13(1)(b) of Directive 64/432/EEC, Art. 5 of Regulation (EC) No 21/2004, and Artt. 8a(2) and 8b of Directive 91/68/EEC.

3. To bring the identification documents for equidae for breeding and production into line with Decision 2000/68/EC and to ensure that the identification documents for equidae are correctly filled in and, in particular, the description of the equidae is carried out by qualified veterinarians as required by Section III of the Annex to Decision 93/623/EC and by Art. 3 of Decision 2000/68/EC.

4. To urgently improve the bovine tuberculosis monitoring programme in particular in respect of :

   - the performance of the *post mortem* examination as laid down by Section IV Chapter I (B) of Annex I to Regulation (EC) No 854/2004;

   - the professional qualification of official auxiliaries as required by Section III Chapter IV(B) of Annex I to Regulation (EC) No 854/2004;

   - the submission rate of lesions to a histopathological and bacteriological examination for evidence of tuberculosis as required by Point I, 2. (c) of Annex A to Directive 64/432/EEC.

5. To review the approval of all approved assembly centres and dealers' premises in respect of their infrastructure conditions and to ensure that the facilities of the assembly centres are dedicated exclusively for that purpose as required by Art. 11(1)(d) of Directive 64/432/EEC and Art. 8a(1)f of Directive 91/68/EC.

6. To urgently cease the discriminatory checks for cattle diseases and for Aujeszky's disease on pigs arriving in Austria as required by Art. 5 (1)(a) of Directive 90/425/EEC.

7. To ensure that at slaughterhouses the responsible OVs ensure that only animals which fulfil the requirements for ICT are slaughtered as required by Art. 5(1)(b)(ii) of Directive 90/425/EEC and that OVs verify compliance with the food operator's duty to ensure that animals accepted for slaughter for human consumption are properly identified as required by Section II Chapter III (1) of Annex I to Regulation (EC) No 854/2004.

8. To bring the control system on animals leaving Austria into line with EU legislation in particular in respect of:

   - the official documents containing the necessary health information completed by the OV for the holding of origin as required by Art. 5(2)(a) of Directive 64/432/EEC and Art. 9(4) of Directive 91/68/EEC;

   - cattle and pigs for breeding and production to remain in a single holding of origin for a period of 30 days prior to loading and, if an animal from a third country is introduced into a holding, not to be traded for 30 days following

introduction unless the imported animal is isolated from all other animals on the holding as required by Art. 6(1) of Directive 64/432/EEC;

- sheep and goats intended for ICT to be continuously resident on the holding of origin for at least 30 days, not to come from a holding into which sheep or goats have been introduced during the 21 days prior to dispatch and not to come from a holding into which bi-ungulates animals imported from third countries have been introduced during the 30 days prior to dispatch as required by Art. 4a(1) of Directive 91/68/EEC;

- the health inspections necessary for issuing health certificates (including additional guarantees) to be carried out in the holding of origin or an assembly centre as required by Art. 5(2) of Directive 64/432/EEC;

- in the case of cattle and pigs for breeding and production transiting through an approved assembly centre in the MS of origin, the period during which the assembly of these animals takes place outside the holding of origin not to exceed six days as required by Art. 6(1) of Directive 64/432/EEC;

- sheep and goats not to be outside their holding of origin for more than six days before being last certified for trade to the final destination in another MS as required by Art. 4b(2) of Directive 91/68/EEC;

- dealers to respect the maximum time limit of 30 days for reselling, or relocating from the first premises to other premises not within his ownership, the purchased animals in line with Art. 2 (q) of Directive 64/432/EEC.

9. To ensure that only animals that fulfil the relevant conditions laid down in Art. 3(1) of Directive 64/432/EEC are sent from its territory to that of another MS, and that these animals are accompanied during transport to destination by a health certificate (Art. 5(1) of Directive 64/432/EEC).

EUROPEAN COMMISSION
HEALTH & CONSUMER DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO)/2007-7370 – Final

PILOT GENERAL AUDIT 2007 – AUSTRIA

REPORT OF

A SPECIFIC AUDIT

CARRIED OUT FROM 4 TO 11 JUNE 2007

IN ORDER TO EVALUATE THE IMPLEMENTATION OF

EU ANIMAL HEALTH REQUIREMENTS FOR

INTRA-COMMUNITY TRADE IN SEMEN AND EMBRYOS OF

DOMESTIC ANIMALS OF THE BOVINE SPECIES

PART B – SECTOR-SPECIFIC ISSUES

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

1. LEGISLATION RELEVANT TO INTRA-COMMUNITY TRADE IN BOVINE SEMEN AND EMBRYOS

The specific audit covered the main elements of the control system in place for ICT in bovine semen and embryos, which is laid down in Directive 88/407/EEC and Directive 89/556/EEC.

Specific conditions for veterinary certification of animals and animal products, including bovine semen and embryos are laid down by Directive 96/93/EC.

2. APPROVAL OF SEMEN COLLECTION CENTRES, SEMEN STORAGE CENTRES AND EMBRYO COLLECTION TEAMS

Legal basis

Point 1 (a) of Chapter I of Annex B to Directive 88/407/EEC requires specific approval of the quarantine accommodation used by semen storage centres.

Point 1 (b) (i) of Chapter I of Annex A to Directive 88/407/EEC requires semen collection centres to have isolation facilities.

Point (d) of Annex A to Directive 89/556/EEC requires embryo collection teams with a permanently sited laboratory to have a room where embryos can be manipulated. This must be adjacent to but physically separated from the area used to handle the donor animals during collection.

Audit findings

The Austrian *Veterinärbehördliche Einfuhr- und Binnenmarktverordnung* (EBVO) states that the conditions for approval and official supervision of semen collection centres, semen storage centres and embryo collection teams are those laid down in Directive 88/407/EEC and Directive 89/556/EEC, in their last amended version. Centres and teams must be inspected before approval is granted. These inspections are generally performed by the District CAs, although in one of the three provinces (*Bundesländer*) visited the inspections were carried out by the provincial CAs. If the conditions are satisfactory, approval is granted by the provincial CA and is valid following publication in the official veterinary journal (*Amtliche Veterinärnachrichten*). The names of the authorised centre veterinarians are also included in this publication. However:

- no specific approval was granted for the quarantine accommodation used by the semen collection centres visited;

- a lay off station (i.e. a holding at which bulls are kept between semen collection periods), which was located in a separate location 80 km away, was considered to be part of one semen collection centre visited but was not mentioned in the approval document and was not subject to official controls;

- one semen collection centre visited had been approved although there was no isolation facility for sick animals;

- one embryo collection team visited continued to be approved although the disposal of its mobile laboratory had been reported during an official inspection. Manipulation of

embryos was carried out in an animal treatment room, without physical separation from other clinical activities. This room was situated a significant distance from the area used to handle the donor animals during collection. During the course of the inspection by the mission team the provincial CA agreed that the facilities no longer met the minimum requirements and withdrew the embryo collection team's approval immediately.

Conclusions

The district administrative authorities do not specifically approve quarantine accommodations used by semen collection centres. Moreover, it was not always clear what facilities were included in the approvals and if all the needed requirements had been considered.

The approval of one embryo collection team was not withdrawn although it no longer met basic conditions in respect of its facilities.

3. PERFORMANCE OF CENTRE VETERINARIANS AND TEAM VETERINARIANS

Legal basis

Point (a) of Chapter I of Annex A to Directive 88/407/EEC requires that the semen collection centres must be placed under the permanent supervision of a centre veterinarian authorised by the CA.

Art. 2 (b) of Directive 89/556/EEC establishes the definition of an embryo collection team as an officially approved group of technicians or structure supervised by a team veterinarian competent to perform the collection, processing and storage of embryos according to the requirements of the said Directive.

Point 1 (d) of Chapter II of Annex A to Directive 88/407/EEC requires semen collection centres to be supervised so that the entry of unauthorised persons is prevented. Furthermore, authorised visitors must be required to comply with the conditions laid down by the centre veterinarian.

Point 3 of Chapter I of Annex B to Directive 88/407/EEC requires that animals are only admitted to semen collection centres with the expressed permission of the centre veterinarians.

Audit findings

The semen collection centres visited during the audit were placed under the permanent supervision of centre veterinarians authorised by the CAs. They were highly motivated. Similarly, the team veterinarians met during the audit were officially approved and generally performed their duties well.

The centre veterinarians in the semen collection centres visited did not authorise access to visitors. However, the conditions with which authorised visitors must comply were outlined in one semen collection centre.

Animals were only admitted to semen collection centres with the permission of the centre veterinarians.

Conclusions

The centre veterinarians and the team veterinarians were authorised, approved by the CA, highly motivated and competent to carry out their job well.

4. INFRASTRUCTURE AND OPERATIONS

Legal basis

Point 1 (a) of Chapter I of Annex B to Directive 88/407/EEC requires that only cloven-hoofed animals having at least the same health status are present in quarantine accommodation approved by the CA.

Point 2 of Annex C to Directive 88/407/EEC lays down special conditions for the addition of certain antibiotics to semen, for the concentration of antibiotics in final diluted semen and for the keeping of the semen afterwards.

Point 1 (i) of Chapter II of Annex A to Directive 89/556/EEC requires the use of trypsin in the washing fluid for embryos. However, pending the adoption of more detailed rules on enzymatic treatment of embryos, MS may establish different rules on the use of trypsin.

Point 1 (f) (iv) of Chapter II of Annex A to Directive 88/407/EEC and Point 1 (e) of Chapter II of Annex A to Directive 89/556/EEC require products of animal origin used in the processing of semen and collection of embryos and in the transport medium used for embryos to be obtained from sources which present no animal health risk or to be so treated prior to use that such risk is prevented.

Point 1 (f) (ii) of Chapter II of Annex A to Directive 88/407/EEC requires that collection, processing and storage of semen takes place only on premises set aside for the purpose and under the strictest hygienic conditions.

Audit findings

The quarantine accommodation of the semen collection centres visited was well-constructed, maintained and sufficiently isolated. The bio-security measures applied were of a general high standard. At two out of three semen collection centres visited an "all-in all-out" policy for the quarantine accommodation was not applied but has been applied to one since 1 March 2007. However, only one of these quarantine accommodation was subdivided and precautions were taken to prevent the transmission of diseases between bulls kept in the different subunits. At the quarantine accommodation of the other semen collection centre the bio-security measures were less restrictive prior to 1 March 2007 and there was no protocol for hygienic operation.

The animal housing and collection areas of the semen collection centres visited were maintained hygienically and to a high standard. The centres were fenced and contact with livestock outside the perimeter was sufficiently prevented.

The semen processing rooms were suitably equipped and maintained hygienically. The technical staff supporting the centre veterinarians learned the disinfection procedures and hygiene techniques under the supervision of the centre veterinarians. Semen and embryos

were generally collected and processed in accordance with Community rules to preserve its health status. However:

- the concentration of antibiotics in the commercial extender added to semen matched the levels established in Community rules. As no additional antibiotics are added to the semen, the final diluted semen does not contain the required final concentration of antibiotics.

- although the final diluted semen was not always kept above 5 ^{o}C, it was always maintained for longer than the minimum required period of 45 minutes. The thermometers used were not calibrated and the temperatures and times were not recorded;

- only one of the three visited embryo collection teams used trypsin during washing;

- sufficient guarantees in writing were not always provided that products of animal origin used in the processing of semen and embryos had been checked in order to exclude possible animal health risks.

The semen storage rooms, in particular those in the semen storage centre, were hygienically maintained, hygienic and contact with outside livestock was prevented. However:

- at one semen collection centre visited semen was stored in an area, which also served as an office as a passage to other parts of the centre and – separated by a counter – as the distribution point for semen collected by veterinarians and artificial inseminators;

- at the semen storage unit of another semen collection centre, the 30-day quarantine containers were kept in a storage room for equipment and office supplies.

Conclusions

In general, the hygienic standard at all semen collection centres, semen storage centres and embryo collection teams visited was very high. However, at the quarantine accommodation of one semen collection centre visited, where an "all-in all-out" policy was not in place, the bio security measures applied were insufficient.

The processing of semen and embryos was in some aspects not in accordance with Community requirements and the storage of semen was not always under the strictest conditions of hygiene.

5. ANIMAL HEALTH TESTING

Legal basis

Point 1 (d) (i) of Chapter I of Annex B to Directive 88/407/EEC requires intradermal tests for bovine tuberculosis to be carried out in accordance with the procedure laid down in Annex B to Directive 64/432/EEC.

Point 2 (e) (i) of Chapter II of Annex A to Directive 88/407/EEC requires that only semen collected at semen collection centres approved in accordance with this Directive is

stored in approved semen storage centres and that it must not come in contact with any other semen.

Art. 3 (b) of Directive 88/407/EEC lays down that only semen collected from domestic animals of the bovine species whose health status complies with Annex B to the said Directive may enter ICT.

Audit findings

Austria is officially free from bovine tuberculosis, brucellosis, enzootic bovine leucosis, IBR/IPV and there is an eradication programme for BVD/MD and a paratuberculosis programme in place. In general, the animal health testing during pre-quarantine and quarantine and for routine testing of bulls residing in the semen collection centres was carried out as required. In addition to these tests, tests are carried out for leptospirosis, paratuberculosis, bluetongue and Q fever. However,

- the bovine tuberculosis tests performed in two semen collection centres visited were not carried out in accordance with Community requirements, in particular with regard to measurement of the initial skin fold thickness;

- at two of the three semen collection centres visited, semen collected from bulls during quarantine was allowed to enter ICT after all the necessary tests had been carried out with negative results and the 30 days storage period had been complied with. This practice stopped in one of the semen collection centres in 2005 and in the other at the end of 2006. At both centres, the semen was stored with EU eligible semen and was identified in the same manner. The CA provided details of the number of straws (i.e. the small plastic tubes holding frozen semen) collected during quarantine in both centres, the number of straws still in storage and the number and destination of the straws that have entered ICT. The CA gave the commitment that this semen will be properly separated and will never enter ICT.

Conclusions

Austria enjoys a high animal health status. The testing of bovine animals during the pre-quarantine and quarantine periods and the routine annual testing of the bovine animals in the semen collection centres visited is satisfactory. However, bovine tuberculosis testing was not always carried out as required by EU legislation.

Basic requirements in respect of semen collection during the quarantine period, labelling of ICT eligible semen and the storage of that semen were not respected [79]. However, the CA ensured that semen collection during the quarantine period stopped, that semen collected during quarantine is separated from semen eligible for ICT and is no longer allowed to enter ICT.

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79 ***In their response to the draft report the Austrian Authorities stated that they took steps immediately in order to meet the requirements of the Directive.***

6. ANIMAL HEALTH FILES

Legal basis

Point 1 (b) and (c) of Chapter I of Annex B to Directive 88/407/EEC requires that the herds of origin of bovine animals entering semen collection centres must meet specific conditions in respect of their health status.

Point 1 (d) of Chapter I of Annex B to Directive 88/407/EEC requires cattle entering semen collection centres to pass specified animal health tests within the 28 days preceding the period of quarantine.

Point 2 (a) of Chapter II of Annex A to Directive 88/407/EEC requires semen storage centres to keep records of all movement of semen (in and out of the centres) and of the status of the donor bulls whose semen is stored there. The same applies for storage units of semen collection centres (point 1 (f) (viii) of Chapter II of Annex A to Directive 88/407/EEC).

Point 2 (iii) of Chapter II of Annex A to Directive 89/556/EEC requires embryo collection teams to keep permanent records of all incoming and outgoing movements of embryos including the final destination of the embryos.

Points 1 and 2 of Annex B to Directive 89/556/EEC lay down certain requirements in respect of the residency and the health status of donor cows and the health status of their herds of origin.

Audit findings

In two of the three semen collection centres visited, the records of the required animal health tests were generally clear and in good order. However:

- the records in all of the semen collection centres did not include information on the animal health status of the holdings of origin;

- in one case a bull was admitted to a semen collection centre without all required test results being available (tests for tuberculosis and brucellosis during the pre-quarantine period);

- at one semen collection centre, the CA decided to approve the semen storage unit as a separate semen storage centre. A single record of the animal health status of the bulls was kept for both centres and the records of semen movements between the centres were incomplete;

- the records of all ingoing and outgoing movements of embryos in one embryo collection team were poorly organised and in some respects incomplete;

- at another embryo collection team, there were no records of embryos traded on the national market and there was no list of incoming and outgoing embryos until recently;

- at both embryo collection teams visited, no animal health data on donor animals and their herds were gathered, documented and filed [80].

Conclusions

Although the animal health files at the semen collection centres and embryo collection teams visited were generally well-kept, information about the health status and the residency of donor animals and the animal health status of the herd of origin of donor animals were insufficiently recorded.

At the embryo collection teams visited, there were insufficient records of the movement of ingoing and outgoing embryos.

7. FOLLOW UP AFTER POSITIVE RESULTS

Legal basis

Point 1(e) of Chapter I of Annex B to Directive 88/407/EEC requires that in the case of positive test results during quarantine, the CA must take all necessary measures to re-establish the eligibility of the remaining animals for entry into the semen collection centre in accordance with the Annex.

Point 2 (a) of Chapter II of Annex A to Directive 88/407/EEC requires that the status of the bulls whose semen is stored at semen storage centres (or semen storage units) must comply with the requirements of the said Directive.

Point 3 of Chapter II of Annex B to Directive 88/407/EEC requires that, in case of a positive test result during routine testing of animals residing in the semen collection centre, the animals must be isolated and any semen collected from them since the last negative test may not enter ICT.

Audit findings

A case of campylobacteriosis occurred during the quarantine period in 2005 at one semen collection centre. Bulls kept together with the infected bull were admitted to the collection centre without being tested three times for Campylobacter following the removal of the infected animal.

At another semen collection centre, a campylobacteriosis outbreak occurred in the main stables in spring 2005. The bulls were treated and tested sufficiently and semen collected from these bulls since the last negative test was seized and not used for ICT. However:

- the semen of the infected bulls collected between the last negative test and the confirmation of the disease was stored in the same storage unit without sufficient separation from EU eligible semen;

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80 ***In their response to the draft report the Austrian Authorities stated that the approval of the first embryo collection team visited was immediately withdrawn after the inspection, and that the second embryo collection team visited has had a software programme since 1 August 2007 (extended SESAM programme) which contains all the required data.***

- the semen of the infected bulls collected following the last negative Campylobacter test was dispatched to another MS in the days prior to the confirmation of the outbreak without being recalled or notification being given to the CA of the MS concerned [81].

Conclusions

In two cases, the follow-up measures taken after receiving positive test results were insufficient in respect of testing of bulls in the quarantine period prior to access into the semen collection centre, the storage of semen of infected bulls within the semen collection centre and the recall of semen from infected bulls collected since the last negative result which had already entered ICT.

8. CERTIFICATION

Legal basis

Art. 6 (1) (b) of Council 88/407/EEC requires that the original veterinary certificates for bovine semen intended for ICT must accompany the consignment to its destination.

Point 2 (a) of Chapter II of Annex A to Directive 88/407/EEC requires that records must be kept of the status of the bulls whose semen is stored at semen collection centres and semen storage centres, and that they must comply with the requirements of the Directive.

Audit findings

Two consignments of bovine semen were sent from one semen collection centre visited to another MS without being accompanied by the original health certificates but by a copy of it.

In general, semen consignments traded between Austrian semen collection centres and semen storage centres are accompanied only by delivery notes.

Conclusions

Bovine semen collected at approved semen collection centres and traded within Austria were not accompanied by supporting documents providing guarantees that the semen was collected, processed and stored in accordance with the requirements of Directive 88/407/EEC.

9. LABORATORY

Legal basis

Point 2 of Chapter I of Annex B to Directive 88/407/EEC requires that all tests on bovine animals during the pre-quarantine and quarantine period and during residence on the semen collection centres must be carried out in a laboratory approved by the MS.

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81 ***In their response to the draft report the Austrian Authorities stated that in the meantime the semen of these infected bulls has been destroyed for commercial reasons.***

Audit findings

Official animal health testing is carried out by four institutes of AGES and by the *Landesanstalt für veterinärmedizinische Untersuchungen*.

The analyses of samples collected from bulls during the pre-quarantine and quarantine period and routinely at semen collection centres were carried out at laboratories approved by the federal CA for this purpose.

The AGES NRLs participate in international proficiency tests and organises similar tests for the other approved national laboratories. However, whilst records of the comparative results of the proficiency tests in which the NRLs participated were available during the audit comments on the results were not available in writing.

In April 2007 AGES implemented a new information and management system. The system enables the laboratory to make the results of tests available to OVs via the internet. However, at the laboratory visited it was not possible to provide the results of official tests carried out on bulls of the semen collection centres visited during the audit.

Conclusions

The performance of the NRLs is generally considered to be satisfactory.

10. RECOMMENDATIONS [82]

1. To review the approvals of all approved semen collection centres (including the quarantine accommodation), semen storage centres and embryo collection teams in order to ensure that they are granted only when all relevant provisions of Directive 88/407/EEC and Directive 89/556/EEC are complied with.

2. To ensure that the other MS and the Commission Services are duly notified of all updates regarding approvals of semen collection and storage centres and embryo collection teams as required by Art. 5 (2) of Directive 88/407/EEC and Art. 5 (2) of Directive 89/556/EEC.

3. To ensure a real and effective supervision of all semen collection centres, semen storage centres and embryo collection teams by centre veterinarians and team veterinarians, particularly regarding operational and hygienic requirements, and the control of the storage of semen as required, respectively, by point 1 (a) of Chapter I of Annex A to Directive 88/407/EEC and by Point (a) of Chapter I of Annex A to Directive 89/556/EEC.

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82 ***In their response to the draft report the Austrian Authorities already stated that the working party which already exists for the subject "Semen, Ova and Embryos" and/or the working party of the provinces will address the recommendations and implement them as financial and human resources permit. The shortcomings which have been ascertained will be discussed and solutions will be devised which should translate into, for example, guidelines. The findings of the FVO inspection will be passed on to all CAs, semen collection centres (veterinarian), semen storage centres (veterinarian), and embryo collection teams (responsible veterinarian) by means of information events.***

4. To ensure that at the semen collection centres, semen storage centres and embryo collection teams the required records are kept concerning the movement of bovine semen and embryos, the animal health status of the donor herd and of the donor animals whose semen or embryos are stored there, as required by point 2 (a) of Chapter II of Annex A to Directive 88/407/EEC, by point 2 (iii) of Chapter II of Annex A and points 1 and 2 of Annex B to Directive 89/556/EEC.

5. To address deficiencies in follow up measures taken following the receipt of positive test results during the quarantine period and during routine testing of bulls in semen collection centres in order to ensure that only bovine semen meeting the requirements of Directive 88/407/EEC may enter ICT.

6. To ensure that certifying officers do not certify data of which they have no personal knowledge or which cannot be ascertained by them as required by Art. 3 (2) of Directive 96/93/EC.

EUROPEAN COMMISSION
HEALTH & CONSUMER DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO)/2007-7500 – MR final

PILOT GENERAL AUDIT AUSTRIA – 2007

FINAL REPORT OF

A SPECIFIC AUDIT

CARRIED OUT FROM 4 TO 12 SEPTEMBER 2007

IN ORDER TO EVALUATE

THE IMPLEMENTATION OF MEASURES CONCERNING

OFFICIAL CONTROLS ON FEED AND COMPLIANCE WITH

REQUIREMENTS FOR FEED HYGIENE

PART B – SECTOR SPECIFIC ISSUES

1. INTRODUCTION

The previous mission concerning feed safety in Austria was carried out from 15 to 19 September 2003, the results of which are described in report DG(SANCO)/9164/2003 – MR Final (hereafter: report 9164/2003). This report is accessible at:

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

2. FINDINGS AND CONCLUSIONS

2.1 COMPLIANCE WITH REQUIREMENTS FOR FEED HYGIENE

2.1.1 Registration and approval of feed business operators

2.1.1.1 Implementation of the requirements

Legal basis

Artt. 9 and 10 of Regulation (EC) No 183/2005 set down requirements for the registration and approval of feed business operators, respectively.

Audit findings

Observations:

- The procedures to be followed and the information to be submitted by feed business operators to be registered or approved according to Regulation (EC) No 183/2005 are set down in national legal provisions. AGES is responsible for approving feed business operators, while the CAs in the provinces are responsible for the registration of feed business operators, using data entered into the farm business information system.
- According to the CCA, food businesses in operation before 1 January 2002 were automatically registered and those supplying feed material are required to register both as a food business according to Regulation (EC) No 852/2004 and also as feed business operators according to Regulation (EC) No 183/2005. It was estimated that 90% of food business operators supplying feed are known and registered.
- According to the CCA, the majority of farms producing feed are known as these were required to be registered according to national legal provisions prior to the entry into force of Regulation (EC) No 183/2005. However, it was noted that it could be problematic to identify which of these should comply with Annex II to Regulation (EC) No 183/2005. According to the CCA, the registration of transporters of feed materials has started but is not yet complete.
- The CCA noted that feed business operators operating prior to the 1 January 2006 will not be required to satisfy the new feed hygiene requirements before the expiry of the transitional arrangements set down in Art. 18 of Regulation (EC) No 183/2005.

Conclusion

Procedures have been put in place which will enable all feed business operators to be approved or registered as required by Regulation (EC) No 183/2005, and the process is largely complete, although there could be difficulties in the identification of on-farm mixers which have to comply with the requirements laid down in Annex II to Regulation (EC) No 183/2005.

2.1.1.2 Transitional measures

Legal basis

Art. 18 of Regulation (EC) No 183/2005 sets down transitional arrangements for feed business operators already operating prior to the 1 January 2006.

Audit findings

Observations:

- All feed business operators visited which were either registered or approved according to Directive 95/69/EC had notified their intention to continue operating, as required by Art. 18 (1) of Regulation (EC) No 183/2005.
- According to the CCA, those feed business operators which were operating prior to 1 January 2006 but did not need to be approved or registered according to Directive 95/69/EC were being registered following the procedures set down in national legal provisions.
- According to the CCA, feed business operators are required to declare conformity with Regulation (EC) No 183/2005, as provided for in Art. 18(3), when submitting a notification to continue activities or an application for registration.

Conclusion

The transitional arrangements have been largely applied as required by Art. 18 of Regulation (EC) No 183/2005.

2.1.1.3 List of establishments

Legal basis

Art. 19 of Regulation (EC) No 183/2005 requires the CA to maintain up to date lists of feed business operators approved or registered according to the said Regulation and to make these available to the public.

Audit findings

Observations:

- According to the CCA, the list of approved feed business operators has been published on the website where it is available to the public.
- The CCA has assigned a single approval number to feed business operators with more than one site, or to cover all feed business operators involved in a co-operative. In one example, 35 feed business operators have the same approval number. The CCA stated that it would still be possible to suspend or revoke the approval of one of the establishments without affecting the others.
- One large approved feed business operator visited which was previously approved according to Directive 95/69/EC was not included on the published list of approved feed business operators.
- The CCA stated that the list of food business operators supplying feed materials is not yet available.

Conclusion

Arrangements are in place to list publicly those feed business operators approved or registered according to Regulation (EC) No 183/2005, but the lists are not yet complete and are not always up to date.

2.1.1.4 Amendment to status, including its suspension or revocation

Legal basis

Artt. 14, 15 and 16 of Regulation (EC) No 183/2005 require the CCA to amend the approval or registration status of feed business operators, including their suspension or revocation, to reflect changes in activities or where the feed business operator concerned does not fulfil the relevant feed hygiene requirements.

Audit findings

Observations:

- According to the CCA, it has the ability to amend the status of registrations or approvals of feed business operators including their suspension or revocation where it is considered necessary.
- The CCA stated that feed business operators which cease operation do not always inform the relevant CA which leads to delays in amending the approval or registration.

Conclusion

The CCA has procedures in place which enable the approval or registration status of feed business operators to be amended, suspended or revoked as required by Artt. 14, 15 and 16 of Regulation (EC) No 183/2005.

2.1.2 Specific obligations of primary producers

Legal basis

Part A of Annex I to Regulation (EC) No 183/2005 lays down requirements for feed business operators at the level of primary production referred to in Art. 5(1).

Audit findings

Observations:

- Hygiene provisions at the primary producers visited were largely satisfactory.
- Record keeping provisions at the primary producers visited were largely satisfactory.
- Official controls to verify compliance with hygiene requirements at the level of primary production have mostly not yet started. The CA of the provinces in charge of those controls informed the mission team that they intend to start those controls soon.

Conclusion

Official controls to verify compliance with hygiene provisions laid down in Part A of Annex I to Regulation (EC) No 183/2005 at the level of primary production have not been carried out yet, although in the premises visited, these requirements were being complied with.

2.1.3 Specific obligations of feed operators other than primary producers

Legal basis

Annex II to Regulation (EC) No 183/2005 lays down requirements for facilities and equipment for feed business operators other than primary producers referred to in Art. 5(1). Artt. 6 and 7 of Regulation (EC) No 183/2005 lay down requirements on HACCP procedures in the afore-mentioned feed business operators.

Audit findings:

Observations:

- Quality control plans based on HACCP principles were in place in the feed business operators visited as required. However, verification procedures with regard to critical points (i.e. cross-contamination and homogeneity) were often not in place.
- In one feed business operator visited, which had one production line and produced compound feedingstuffs with and without coccidiostats, no cross-contamination tests were carried out to verify that the layout of and the procedures (e.g. flushing) in the production facilities minimised the risk of cross-contamination. In another feed business operator visited, scales and metering devices had not been tested for accuracy regularly and no homogeneity tests had been conducted to verify that the mixers were capable of manufacturing suitable homogeneous mixtures. None of these deficiencies had been noted in official inspection reports of previous inspections.
- Staff responsible for quality control had been designated in two feedmills visited and access to a laboratory with adequate staff and equipment was available. Documentation relating to incoming and outgoing feedingstuffs was in place and samples drawn as required by Annex II to Regulation (EC) No 183/2005.
- Feed business operators visited had record keeping and product recall instructions in place in line with the requirements of Annex II to Regulation (EC) No 183/2005 and executed them mostly in line with those instructions.

Conclusion

Feed business operators (other than at the level of primary producers) often do not yet comply with the hygiene requirements set out Annex II to Regulation (EC) No 183/2005, notably regarding facilities and equipment, and measures to avoid cross-contamination.

2.2 IMPORTS AND EXPORTS

Legal basis

Art. 24 of Regulation (EC) No 183/2005 provides that, as an interim measure, imports of feed shall continue to be authorised under the conditions laid down in Art. 6 of Directive 98/51/EC [83].

83 Commission Directive 95/51/EC of 9 July 1998 laying down certain measures for implementing Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector; OJ L 208, 24.7.1998, p. 43.

Audit findings

Observations:

- According to the CCA, relatively little feed material is imported directly into Austria as the majority enters the EU via other MS. In addition, the CCA stated that feed is rarely exported directly.
- According to representatives of the Customs service met, a procedure is in place to ensure that the import of consignments of feed materials of non-animal origin are notified to the BAES which can decide the nature of any controls to be performed.
- The CCA provided an up-to-date list of representatives in the EU of establishments located in third countries from which imports of feed materials are authorised.
- In the traders visited which were importing consignments of feed materials, it was possible to see that the procedures followed were in accordance with those set down in Directive 98/51/EC.

Conclusion

The procedures in place concerning the imports of feed materials generally fulfil the relevant requirements set down in EU legislation.

2.3 OTHER REQUIREMENTS ALONG THE FEED CHAIN

2.3.1 Phasing out of antibiotics

Legal basis

Art. 11 of Regulation (EC) No 1831/2003 [84] phased out the use of antibiotics [85] as feed additives.

Audit findings

Observations:

- The CA stated that all feed business operators concerned had been informed about the phasing out or antibiotics as feed additives. The mission team found that all feed business operators met during the mission were fully aware about this ban.
- The Austrian annual sampling plan for feedingstuffs follows Recommendation 2005/925/EC on the coordinated inspection programme in the field of animal nutrition, also with regards to the analysis of medicinal substances. In 2006, 741 samples collected from compound feed, additives and pre-mixtures of additives were analysed to check for the presence of prohibited antibiotics. According to the AGES none tested positive.
- In one feedmill visited, which had used certain medicinal substances as feed additives until their use was no longer authorised, the CA took samples to verify that no contamination with these medicinal substances occurred after the date of entry of the ban. The sample results were negative.

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84 Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition; OJ L 268, 18.10.2003.

85 Other than coccidiostats and histomonats.

Conclusion

Official controls to ensure compliance with the phasing out of antibiotics as feed additives, as laid down in Art. 11 of Regulation (EC) No 1831/2003 were largely satisfactory.

2.3.2 Rules on undesirable substances

Legal basis

Directive 2002/32/EC [86] lays down the rules on undesirable substances in animal feed.

Audit findings

Observations:

- The Austrian sampling plan for feed takes into account the principles outlined in Commission Recommendations on the coordinated inspection programme in the field of animal nutrition for 2006, and on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs. AGES stated that the analytical capabilities to verify compliance with the requirements of Directive 2002/32/EC are in place.
- The sampling plan analysed samples from various types of feedingstuffs for a broad range of undesirable substances in line with above mentioned Recommendations.
- Sampling targets for undesirable substances like dioxins and PCBs were in 2006 missed by 50%.

Conclusion

Official controls to ensure that the maximum content of undesirable substances is not exceeded in feed, as laid down in Directive 2002/32/EEC were largely satisfactory, with the exception of official controls regarding dioxins and PCB, where sampling targets were not always met.

2.3.3 Rules on prohibited materials

Legal basis

Commission Decision 2004/217/EC [87] adopts a list of prohibited materials in feed.

Audit findings

Observations:

- All feedmills had measures in place to prevent the circulation of prohibited substances such as packaging or parts of packaging or solid urban waste.

Conclusion

Rules on prohibited substances as laid down in Commission Decision 2004/217/EC are mostly followed.

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86 Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed; OJ L 140, 30.05.2002, p 10.

87 Commission Decision 2004/217/EC of 1 March 2004 adopting a list of materials whose circulation or use for animal nutrition purposes is prohibited; OJ L 67, 5.03.2004, p. 31.

2.4 LABORATORIES CARRYING OUT OFFICIAL ANALYSES

Legal basis

Artt. 12 and 33 of Regulation (EC) No 882/2004 lay down requirements with regards to laboratories carrying out official analysis.

Audit findings

Observations:

- A NRL for additives has been nominated and a representative of this laboratory informed the mission team that all laboratories conducting official controls on feedingstuffs are accredited and take regularly part in comparative tests. He further stated that current laboratory and staffing resources are sufficient to execute their tasks satisfactorily.
- Laboratories failing a comparative test for a certain substance could continue to officially analyze for this substance. According to a representative of the NRL, a laboratory failing to a comparative test continues to carry out official analyses, since it exclusion would jeopardize the reaching of analysis targets, as resources would be then too tight.

Conclusion

The CA has designated accredited laboratories to carry out the analysis of samples taken during official controls in line with Art. 12 of Regulation (EC) No 882/2004. The laboratory network is capable of exercising its responsibilities in relation to feed safety. A NRL for additives for use in animal nutrition has been nominated and it organizes comparative tests between the official national laboratories; however, comparative tests, in accordance with Art. 33 (2) of Regulation (EC) No 882/2004, were not always organised satisfactorily by the NRL, since laboratories failing to pass them continues to carry out official analyses.

3. RECOMMENDATIONS

1. To continue efforts to register all feed business operators, as required by Art. 9 of Regulation (EC) No 183/2005.
2. To update the lists of registered feed business operators as required by Art. 19 of Regulation (EC) No 183/2005.
3. To take steps to verify that feed business operators at the level of primary production comply with the feed hygiene requirements laid down in Annex I to Regulation (EC) No 183/2005.
4. To ensure that feed business operators (other than at the level of primary production) comply with the feed hygiene requirements laid down in Annex II to Regulation (EC) No 183/2005.
5. To ensure that the sampling targets to ensure compliance with the rules on dioxins as undesirable substances laid down in Directive 2002/32/EEC are met.
6. To ensure that laboratories carrying out official analyses for feed subject to comparative tests in line with Art. 33(2) of Regulation (EC) No 882/2004 are able to undertake their duties satisfactorily.

EUROPEAN COMMISSION
HEALTH & CONSUMER DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO)/2007-7518 – MR final

PILOT GENERAL AUDIT AUSTRIA – 2007

REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN AUSTRIA

FROM 22 TO 30 MAY 2007

IN ORDER TO EVALUATE THE IMPLEMENTATION OF

HEALTH RULES ON ANIMAL BY-PRODUCTS

PART B – SECTOR-SPECIFIC ISSUES

Please note clarifications provided by the Austrian competent authority are given as footnotes, in bold, italic type, to the relevant part of the report

1. INTRODUCTION

The previous mission concerning ABP in Austria was carried out from 6 to 17 September 2004, the results of which are described in report DG(SANCO)/7275/2004 – MR Final (hereafter: report 7275/2004). This report is accessible at:

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

2. FINDINGS AND CONCLUSIONS

2.1 STRUCTURE IN PLACE

Legal basis

Art. 3 of Regulation (EC) No 1774/2002 [88] requires that MS shall, either individually or cooperatively, ensure that adequate arrangements are in place, and that a sufficient infrastructure exists, to ensure compliance with the requirement for handling ABP laid down therein.

Audit findings

A detailed description of the structure in place for handling of the different Categories of ABP in the different production chains can be found in report 7275/2004, and it is mostly applicable to the situation encountered by the mission team during this specific audit. A significant change is that the feeding of catering waste to pigs has been banned since 30 October 2006 as the derogation that permitted this practice (Decision 2003/238/EC [89] expired on that date. A number of recommendations in report 7275/2004 related to controls on swill feeding. These have been superseded as swill feeding is now banned.

Observations:

- The BMGF issued a decree to provinces on 8 November 2006 requesting control visits to verify that feeding of catering waste to pigs had ceased. The mission team saw reports confirming that control visits had been carried out and samples of feed had been taken from farms to verify that catering waste was no longer being fed.

Conclusion

A sufficient infrastructure exists to allow compliance with EU requirements for ABP.

2.2 APPROVAL OF ABP PLANTS AND PREMISES

2.2.1 Approval procedure

Legal basis

Chapters III and IV of Regulation (EC) No 1774/2002 require that all types of ABP plants shall be subject to approval by the CAs and Art. 23 requires authorisation and

88 Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption; OJ L 273, 10.10.2002, p. 1.

89 Commission Decision 2003/238/EC of 12 May 2003 on transitional measures under Regulation (EC) No 1774/2002 of the European Parliament and the Council as regards the use of Category 3 catering waste in feed for pigs and the intra-species recycling ban on the feeding of swill to pigs; OJ L 117, 13.05.2003, p. 46.

registration of users and collection centres availing of derogations contained therein regarding uses of ABP for specific purposes.

Audit findings

The relevant recommendations of report 7275/2004 concerned taking appropriate actions to complete the approval process of ABP plants [90]. In response to this recommendation, the CA advised the Commission that delays in approving establishments no longer exist.

A description of the approval procedure is included in report 7275/2004.

Observations:

- According to the CAs, the approval of ABP plants and premises has now been completed.
- Checklists and guidelines covering the controls required in biogas and composting plants have been issued by the CCA and were in use in the provinces visited. Checklists and guidelines for other ABP plants have not been issued by the CCA. The CCA stated that checks need to be based on specific assessments of each individual plant. The mission team saw an example of specific and comprehensive checklists in use at one of the ABP processing plants visited.
- The biogas plant visited which processed Category 2 and Category 3 ABP was equipped with a pasteurisation/hygienisation unit for the pre-treatment of Category 3 material and was operating in accordance with the requirements of Annex VI to Regulation (EC) No 1774/2002.
- One of the processing plants visited was approved for processing Category 1, 2 and 3 materials. In reality, it processed ABP as Category 1 on two lines using methods one and 5 (for blood meal) and the resulting material was incinerated. The mission team was informed by the CA that the plant would only be allowed to process ABP as Category 3 if modifications were made to the processing lines so that the approvals for Category 2 and Category 3 ABP were not valid [91].

Conclusion

Administrative provisions are in place to ensure that approval, authorisation and registration of ABP plants and premises, as applicable, can be carried out in accordance with EU requirements. However, some processing plants may be approved to process categories of ABP that they could not process according to EU requirements without modifications to equipment or layout of the plant.

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90 At that time there were many ABP plants (particularly biogas and composting plants) that had not been approved under Regulation (EC) No 1774/2002.

91 ***In their comments to the draft report the Austrian Authorities note that the approval for Category 3 pursuant to Art. 17 of Regulation (EC) No 1774/2002 has since been revoked, since all the material is processed together as Category 1 and then incinerated. There is no separate line for processing Category 3 material, and no such line has been operated in the past.***

2.2.2 List of approved plants

Legal basis

Art. 26(4) of Regulation (EC) No 1774/2002 requires that a list of approved plants is drawn, identifying the nature of their activities. Moreover, Regulation (EC) No 1192/2006 [92] sets out implementing rules regarding the afore-mentioned lists.

Audit findings

Observations:

- Lists of approved ABP plants are published on the internet. The lists also include premises operating under the derogations of Art. 23 of Regulation (EC) No 1774/2002. They can be found at:

http://www.bmgfj.gv.at

Conclusion

The lists of ABP plants and premises are published in accordance with Commission Regulation (EC) No 1192/2006.

2.2.3 Validation

Legal basis

Chapter V of Annex V to Regulation (EC) No 1774/2002 requires that CA must validate processing plants in accordance with the procedures laid down therein. Chapter II of Annex VI to Regulation (EC) No 1774/2002 also lays down specific requirements for the approval of biogas and composting plants used for processing ABP.

Audit findings

Observations:

- According to the CAs all processing plants have been subject to external validation. The mission team confirmed in the two processing plants visited that they have been validated within the last two years.
- The biogas plant visited was equipped with a hygienisation unit which treated Category 3 ABP for 60 minutes at a minimum temperature of 70 °C before it entered the biogas fermenting vessel.

Conclusion

Validation of processing plants has been done as required in Annex V (Chapter V) to Regulation (EC) No 1774/2002.

92 Commission Regulation (EC) No 1192/2006 of 4 August 2006 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards lists of approved plants in Member States; OJ L 273, 10.10.2002, p. 1.

2.3 ABP REQUIREMENTS ALONG THE CHAIN

2.3.1 Documents and records

Legal basis

Annex II to Regulation (EC) No 1774/2002 sets out the requirements for the collection and transport of ABP, including requirements for identification, records and the use of commercial documents.

Audit findings

The relevant recommendation of report 7275/2004 concerned ensuring that ABP was identified and accompanied by documents as required by Annex II to Regulation (EC) No 1774/2002 to ensure proper traceability of materials. In response to this recommendation the CCA indicated that they had increased checks on the marking, labelling and recording of ABP along the ABP chain; in addition the CCA indicated that random cross-checks were carried out on establishments of origin of ABP and ABP plants to verify the traceability of ABP.

Observations:

- In the food establishments visited, ABP were generally identified as required by Regulation (EC) No 1774/2002.
- In one of the slaughterhouses visited, bovine blood was dispatched to a processing plant as Category 1 material but the documentation accompanying this blood did not indicate the category of the blood. In addition the blood was marked as Category 3 material on dispatch from the slaughterhouse. Cross checks at the processing plant receiving the blood indicated that it was received as Category 3 material. The situation was further confused by the label marking the blood tanker being easily reversible (it referred to Category 1 material on one side and Category 3 material on the other side) [93].
- In another slaughterhouse visited Category 3 ABP were dispatched to a pet food plant with commercial documents that did not indicate that the materials were ABP [94].
- In an intermediate plant for bovine hides visited, two commercial documents accompanied some consignments of hides: one document indicated that the hides were fit for human consumption (for gelatine production) and the other document indicated that hides were ABP.
- In the milk processing plant visited, material considered as Category 3 ABP was stored separately from food product although it was not identified as Category 3 material. Commercial documentation accompanying the ABP from this plant did

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93 ***In their comments to the draft report the Austrian Authorities noted that it was clarified with the operator of the slaughterhouse that bovine blood can be classed as Category 3 material, provided that certain requirements are met (no contamination with specified risk material, negative result of a test for Bovine Spongiform Encephalopathy). The marking of vehicles has been changed so that plates can now only be labelled on one side and that only authorised persons can change them***.

94 ***In their comments to the draft report the Austrian Authorities stated that it had been explained to the people responsible at the slaughterhouse concerned that meat fit for human consumption that is no longer intended for human consumption must also be labelled as ABP and that the commercial documents must be drafted accordingly.***

not contain all the information required by Annex II to Regulation (EC) No. 1774/2002 [95].

- In the retail premises visited, ABP were identified and disposed of correctly but in one of the retail premises visited the commercial documents did not contain all the information required by Annex II to Regulation (EC) No 1774/2002.

Conclusion

EU requirements relating to commercial documentation and records for ABP, as laid down in Annex II to Regulation (EC) No 1774/2002 were not complied with in all cases; deficiencies were prevalent in relation to insufficient information included in the documentation and in some cases documentation did not indicate that the materials were ABP; in addition, it could not always be ensured that ABP was identified with the correct category status. This could affect the traceability of ABP and their flow in the authorised chains.

2.3.2 Former foodstuffs

Legal basis

Regulation (EC) No 197/2006 [96] lays down transitional measures for the collection, transport, treatment, use and disposal of former foodstuffs, but these do not apply to raw material of animal origin, whose collection must still comply with provisions on these areas laid down in Regulation (EC) No 1774/2002.

Audit findings

In Austria it is not permitted to dispose of former food stuffs to landfill sites.

Observations:

- In one of the retail premises visited, former foodstuffs and raw material of animal origin were both consigned as Category 3 returns to the distribution centre that supplied the premises. The mission team were informed that this material was then sent from the distribution centre to an ABP plant for disposal. In another retail premises visited, raw meat was consigned directly to a processing plant as Category 3 material while former food stuffs was consigned to a Category 3 intermediate plant.
- In the retail premises visited records were kept of consignments of former food stuffs dispatched.

Conclusion

The system for disposal of former foodstuffs including raw material of animal origin from retail premises was in line with EU requirements.

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95 ***In their comments to the draft report the Austrian Authorities stated that checks set out in new procedural instructions will ensure that containers are properly labelled and that the correct commercial documents are produced.***

96 Commission Regulation (EC) No 197/2006 of 3 February 2006 on transitional measures under Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards collection, transport, treatment, use and disposal of former foodstuffs; OJ L 32, 4.02.2006, p. 13.

2.3.3 Milk and milk products

Legal basis

Regulation (EC) No 79/2005 [97] sets out the conditions for the authorisation of the handling and use of milk and milk products defined as Category 3 material that have not been processed in accordance with Chapter V of Annex VII to Regulation (EC) No 1774/2002.

Audit findings

Observations:

- In the milk processing plant visited Category 3 material was consigned to a Category 3 ABP intermediate plant. Milk contaminated with antibiotic residues was consigned as Category 2 material to an approved biogas plant.
- No unprocessed products were consigned from the plant to farms. Processed whey was consigned directly from the milk processing plant to a limited number of pig farms authorised to feed whey. The mission team were informed that these farms were checked by the District Veterinary Authorities to ensure that there was minimal risk of epizootic disease spread form the farms and that animals could only leave these farms for slaughter. A list of these farms was kept at the plant and records were kept of each consignment dispatched.

Conclusion

The handling of ABP in the milk processing sector was in accordance with EU requirements apart from the deficiencies in identification and commercial documentation (see section 2.3.1).

3. RECOMMENDATIONS

1. To accurately reflect in the approvals of processing plants the category of material that they can handle according to Art. 13 and 17 of Regulation (EC) No 1774/2002.
2. To identify the category of ABP during their transport, as required by Chapter I of Annex II to Regulation (EC) No 1774/2002.
3. To ensure that commercial documents accompanying consignments of ABP fulfil the requirements set out in Chapter III of Annex II to Regulation (EC) No 1774/2002.

97 Commission Regulation (EC) No 79/2005 of 19 January 2005 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the use of milk, milk-based products and milk-derived products, defined as Category 3 in that Regulation; OJ L 16, 20.01.2005, p. 46.

EUROPEAN COMMISSION
HEALTH & CONSUMER DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO)/2007/7602 MR - FINAL

PILOT GENERAL AUDIT AUSTRIA – 2007

REPORT OF A SPECIFIC AUDIT

CARRIED OUT FROM 4 TO 12 SEPTEMBER 2007

IN ORDER TO EVALUATE THE

IMPLEMENTATION OF THE

PLANT PASSPORT SYSTEM, THE CURRENT SITUATION OF

ERWINIA AMYLOVORA (BURR) AND THE SYSTEM OF IMPORT

CONTROLS FOR PLANT HEALTH

PART B – SECTOR SPECIFIC ISSUES

Please note that factual errors in the draft report have been corrected. Clarifications provided by the Austrian competent authorities are included as footnotes, in bold, italic, type, to the relevant parts of the report.

INTRODUCTION

Definitions of terms used in this report are contained in Art. 2 of Directive 2000/29/EC.

In addition, the following terms are used in the report:

– Approved place of inspection – a place of destination approved by the responsible official body and the Customs authorities responsible for the area where that place of destination is located, as referred to in Art. 13c(2)(d) of Directive 2000/29/EC and Art. 1(2)(b) of Directive 2004/103/EC [98].

– Customs clearance – release of consignments into free circulation in the EU after the completion of Customs formalities.

– Inspection post – place at the point of entry or any other place close by, other than place of destination, designated by both Customs authorities and the responsible official body, as referred to in Art. 13c(2)(b) of Directive 2000/29/EC and Art. 1 of Directive 98/22/EC [99].

– Regulated articles – refers to those items for which a official phytosanitary certificate is required for import into the Community, which includes those items listed in Part B of Annex V to Directive 2000/29/EC.

1. IMPORT CONTROLS FOR PLANT HEALTH

1.1 IMPORT PROCEDURES

1.1.1 Notification of import

Legal Basis

Art. 13c(1)(c)(ii) of Directive 2000/29/EC establishes that importers or operators give, as soon as they are aware of the imminent arrival of consignments of regulated plants, advance notice thereof to the custom service and the official body of point of entry. The same article also establishes the information that must be provided, in order for the consignment to be placed under certain Customs procedures.

Art. 13(a) of Directive 2004/103/EC requires that importers shall notify the introduction of the products concerned sufficiently in advance to the relevant official body of destination.

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98 Commission Directive 2004/103/EC of 7 October 2004 on identity and plant health checks of plants, plant products or other objects, listed in Part B of Annex V to Council Directive 2000/29/EC, which may be carried out at a place other than the point of entry into the Community or at a place close by and specifying the conditions related to these checks; OJ L 313, 12.10.2004, p. 16.

99 Commission Directive 98/22/EC of 15 April 1998 laying down the minimum conditions for carrying out plant health checks in the Community, at inspection posts other than those at the place of destination, of plants, plant products and other objects coming from third countries; OJ L 126, 28.04.1998, p. 26.

Audit findings

Art. 27 of the Plant Protection Law requires that importers provide notification of import to BAES, 'in-time', which, according to BAES and the Customs service, is in practice 24 hours in advance of arrival of the consignment. The notification also acts as an application for the import checks to be carried out; if no notification is provided, then the import checks cannot be performed.

Art. 27 of the Plant Protection Law and Artt. 14 and 18 of the Customs Code transposes the requirements of Art. 13c(1)(c)(i) regarding the type of information that must be provided by importers in order for a consignment to be placed under a Customs procedure.

- The mission team visited Vienna airport and one place of destination. In both places, records showed that the advanced notification had been provided, as required. In addition the information provided by importers was in line with the requirements of Art. 13c(1)(c)(i) of Directive 2000/29/EC.

Conclusions

The system of import controls in Austria requires the provision of notification of import, in line with relevant Community legislation.

1.1.2 Customs supervision

Legal Basis

Art. 13(1) of Directive 2000/29/EC establishes that imported regulated articles shall, from the time of their entry, be subject to supervision by Customs and the responsible official body until all of the import checks have been completed.

Audit findings

The cooperation between the Customs service and the plant health services has been established in Customs legislation and Artt. 23, 32 and 33 of the Plant Protection Law. Art. 33 establishes that every consignment declared to contain regulated articles must be inspected and approved for entry by the plant health service before the consignment may clear Customs controls.

The import controls for plant produce are carried out by the Customs service on behalf of BAES. Customs officers also perform checks of arriving passengers at all international airports on behalf of BAES (see section 1.7 below). On completion of the checks, the approval for entry is given by endorsing the original phytosanitary certificate with by Customs, together with the number of the Air Way Bill, date and name and signature of the Customs officer.

- The mission team visited Vienna airport and examined entry records. It was noted that the plant health check had been carried out for all consignments declared to contain regulated articles, before Customs clearance.

Conclusions

There is adequate cooperation between BAES and Customs. Customs supervision and procedures are in accordance with the relevant Community legislation.

1.1.3 Registration

Legal basis

Art. 13c(1)(b) of Directive 2000/29/EC requires that importers, whether or not producers, of regulated plants must be included in an official register of a MS under an official registration number.

Art. 1(3) of Directive 92/90/EC [100] requires that responsible official bodies list those importers that are able and willing to comply with the obligations included in Art. 2 of the said Directive, in an official register under a unique number.

Audit findings

All importers and agents acting on their behalf are obliged to register in a national register under a unique number. At the time of the mission, there were 238 registered importers and agents.

Information about plant health requirements, including any changes, is sent directly to registered importers by email.

- The mission team noted that BAES has established a harmonized procedure for the registration of importers in line with Art. 1(3) of Directive 92/90/EC and that the obligations for importers are identical to those established by Art. 2 of the said Directive; an annual check of records had also been carried out at each of the registered importers.

- During the visit to Vienna airport, the mission team was shown the import procedure which includes a check to confirm that the importer is registered. The Customs officers met by the team stated that if the importer is not registered with the plant health service then the consignment would either be held pending registration, or would be refused entry.

Conclusions

All importers are registered and their obligations are in accordance with relevant Community legislation.

1.2 POINTS OF ENTRY, INSPECTION POSTS AND APPROVED PLACES OF INSPECTION

1.2.1 Points of entry

Legal basis

Art. 13c(4), paragraph 2, of Directive 2000/29/EC requires that MS forward to the Commission and the other MS, the list of places designated as points of entry.

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100 Commission Directive 92/90/EEC of 3 November 1992 establishing obligations to which producers and importers of plants, plant products or other objects are subject and establishing details for their registration; OJ L 4, 8.01.1993, p. 22.

Point 1(c) of the Annex to Decision 2004/4/EC [101] establishes that the points of entry authorised for the introduction of relevant potatoes and the name and address of the responsible official body in charge of each point shall be notified to the Commission.

Audit findings

Nine points of entry have been defined for the import of regulated articles in the Ordinance 186 of 30 April 2004. The list of points of entry has been provided to the Commission and the other MS. BMLFUW informed the mission team that, in order to be designated as a point of entry, there must be an inspection post (see section 1.2.2 below).

The principal point of entry for Austria is Vienna airport; limited imports also take place at Linz airport. Austria has a short border with Lichtenstein, but BMLFUW informed the mission team that no imports of regulated plant material take place across this border. Austria has also a border with Switzerland; BMLFUW informed the mission team that the checks are performed according to the Agreement on Trade in Agricultural Products referred to in Decision 2002/309/EC [102].

BMLFUW informed the mission team that two points of entry have been authorised for imports of potatoes originating in Egypt, however such imports have never occurred.

Conclusions

Austria has designated points of entry and provided a list of these to the Commission and the other MS, in line with the relevant Community legislation.

1.2.2 Facilities and equipment for inspection at or near the point of entry

Legal Basis

Art. 13c(2)(b) of Directive 2000/29/EC establishes that identity and plant health checks must (with certain specific exceptions) be made by the official body of point of entry in connection with the Customs formalities, either at the same place as those facilities, on the premises of the official body of point of entry or at any other place close by and designated and approved by the Customs authorities and by the responsible official body.

The minimum conditions for carrying out plant health checks at such places are established by Directive 98/22/EC.

Audit findings

In order for a point of entry to be designated for the purposes of Directive 2000/29/EC, it must include an inspection post at or nearby the point of entry, which meets the minimum conditions established in Directive 98/22/EC. BMLFUW stated that each of the nine points of entry complied with this provision and that the four main points of entry to Austria (Vienna, Linz, Salzburg and Graz) have official BIPs for plant health.

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101 Commission Decision 2004/4/EC of 22 December 2003 authorising Member States temporarily to take emergency measures against the dissemination of *Pseudomonas solanacearum* (Smith) Smith as regards Egypt; OJ L 002, 6.01.2004, p. 50.

102 Council Decision 2002/309/EC, Euratom of 4 April 2002 on the conclusion of seven Agreements with the Swiss Confederation; OJ L 114, 30.04.2002, p. 1.

- The mission team visited the official inspection post in Vienna airport. This is a dedicated room, equipped with inspection tables, adequate lighting and suitable equipment for the inspection and sampling of consignments, including stereo microscopes. There is also access to a dedicated refrigerated store, where non-compliant or infested consignments may be stored pending destruction (see section 1.8 below).

- The Customs officers, who are responsible for performing checks of plant produce, had access to administrative facilities, including fax and computers at their nearby office. However, this did not include an up-to-date list of interceptions (see sections 1.3.3 and 1.8 below) or access to EUROPHYT. The BAES inspector met by the mission team carried a laptop computer, printer and technical information, including relevant legislation and written guidelines with him.

- BAES informed the mission team that an inspector has been trained to audit facilities and procedures at the point of entry, including an assessment of the checks performed by authorised Customs officers. One check had been performed at Vienna airport in 2007.

Conclusions

The facilities and equipment, at or nearby the point of entry, for carrying out import checks comply, with the exception of an up-to-date list of interceptions, with the minimum conditions established in Directive 98/22/EC.

1.2.3 Inspection posts other than at or near the point of entry

Legal basis

Directive 2004/103/EC establishes the procedures and conditions for carrying out checks at a place other than the point of entry into the Community or a place close by.

Audit findings

Six places have been approved as places of destination. There are minimum requirements for such inspection posts, which are in-line with the requirements of Directive 2004/103/EC.

- The mission team visited one place of destination (see section 1.4 below) and noted that it included a suitable area for inspection and separate storage for imported consignments until checks have been completed and the consignments are cleared into free circulation.

Conclusions

The inspection posts other than at or near the point of entry in Austria, comply with the requirements established in Directive 2004/103/EC.

1.3 IMPORT CHECKS

1.3.1 Documentary checks

Legal Basis

The requirement for document checks to be carried out is laid down in Artt. 13(1)(ii) and 13a(1)(b)(i) of Directive 2000/29/EC. The requirements for phytosanitary certificates are laid down in Artt. 13a (3), 13a (4)(b), (c) and (d) of the said Directive.

Audit findings

The Customs service performs documentary checks for all consignments of regulated articles at the point of entry. BAES performs an additional document check for all consignments consisting of plants for planting.

Electronic certification is not recognised by Austria.

BAES informed the mission team that all phytosanitary inspectors had been given guidelines on the requirements relating to additional declarations during training courses held in 2005 and 2006.

- The mission team observed documentary checks being performed at the point of entry. It was noted that the officers had received guidance on the requirements for certificates, including additional declarations, and appeared to be familiar with its use.

- The phytosanitary certificates had been endorsed with an entry stamp, including the entry number, Air Way Bill number, date and identity of the Customs officer. In the event that the consignment had been intercepted, the phytosanitary certificate had been cancelled with a red triangular stamp.

Conclusions

Documentary checks are carried out in line with the relevant Community legislation.

1.3.2 Identity checks

Legal Basis

The requirement for, and objective of, identity checks to be carried out are laid down in Art. 13a(1)(b)(ii) of Directive 2000/29/EC.

Audit findings

The Customs service is responsible for performing the identity checks of plant produce; these are carried out at the same time as the plant health checks. BAES also performs the identity checks of plants for planting at the same time as the plant health checks.

The mission team observed checks being performed by the Customs service; the officers demonstrated identity checks. Each officer had access to technical literature and was able to identify plant produce.

Conclusions

Identity checks are carried out for each consignment of plants and plant produce at the same time as the plant health checks, in line with the relevant Community legislation.

1.3.3 Plant health checks

Legal Basis

The requirement for, and objective of, plant health checks is laid down in Artt. 13(1)(i) and 13a(1)(iii) of Directive 2000/29/EC. Art. 13a(1)(a) states that the formalities referred to in Art. 13(1) shall consist of meticulous inspections by the responsible official body on at least each consignment, or in the case of a consignment which is composed of different lots, each lot declared to consist of, or to contain, relevant plants.

Phytosanitary procedure PM3/65 [(103)] of the European and Mediterranean Plant Protection Organisation, establishes guidelines for the sampling of consignments.

Art. 2(1)(g) and (i) of Directive 2000/29/EC establishes conditions for the delegation of tasks and the qualifications of staff performing official checks.

Audit findings

Plant health checks are performed at the point of entry, by Customs officials for all plant produce and by BAES inspectors for plants for planting. BFW informed the mission team that their inspectors would perform the checks of any regulated forestry plants or wood, however, there have been no imports of such material into Austria. Following completion of the checks, the BAES inspector sends details to the nearest office to the consignment's destination to enable post-entry 'monitoring' inspections to be carried out.

The checks at Vienna airport are carried out at one inspection post (see section 1.3.3 below). Between December 2006 and September 2007, the Customs service had inspected 146 consignments of plant produce. During the same period, BAES had inspected 11 consignments (36 from March 2004 to January 2007) consignments of plants and other objects.

According to BAES, the intensity of inspection is a minimum of 5% but may be higher depending on the outcome of a risk assessment, which should be performed before carrying out each check. This assessment considers primarily the interceptions by Austria and other MS.

- The mission team noted at Vienna airport that:
  - The BAES inspectors and the Customs officers were aware of relevant harmful organisms and carried appropriate sampling and inspection equipment.
  - The Customs officers carried out a plant health check of a consignment of orchid cut flowers from Thailand. 5% of the consignment was inspected.

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103 Phytosanitary Procedures, Sampling of consignments for visual phytosanitary inspection, PM3/65, European and Mediterranean Plant Protection Organisation, EPPO Bulletin, 36(1), p. 195, April 2006.

– The way that the check of the flowers (for the presence of *T. palmi*) was performed meant that the check was not meticulous.

– The officers met did not appear to be aware of the need, or method, for carrying out risk assessments and neither did they have details of interceptions in Austria or the other MS. The officers stated that cut flowers of *Rosa* from India were a priority for inspection and 8% of each consignment was inspected, although the officers were unable to explain why.

Once the plant health check has been completed, the consignment is permitted to clear Customs. In the event that the consignment moves to another MS in transit, a copy of the phytosanitary certificate is endorsed with the stamp of the plant health service to indicate that the certificate is a true copy and also that the import checks have been completed.

- The Customs officers met by the team stated that they had attended a two day induction training course on plant health. The first day covered administrative issues. The second day covered technical issues, including pest biology, identification and inspection techniques.

Conclusions

Plant health checks are performed for each consignment of regulated articles however, the observed check was not meticulous, as required by Art. 13a(1)(a) of Directive 2000/29/EC.

The actual level of sampling applied (5%) does, according to EPPO Phytosanitary Procedure PM3/65, provide an appropriate probability for finding harmful organisms when inspecting small lots.

The Customs officers met by the team were not fully competent with respect to the performance of the plant health check and the use of risk assessments. The training provided for them was focused more on administrative issues than on the performance of checks or on pest biology. These factors mean that the officers cannot be considered to have the qualifications necessary, for the proper application of Directive 2000/29/EC, as required by the third indent of Art. 2(1)(i) of the said Directive.

1.3.4 Reduced frequency of checks

Legal Basis

Art. 13(a) paragraph 2 of Directive 2000/29/EC permits the possibility for a reduced frequency of identity and plant health checks to be carried out for certain commodities, which are determined in accordance with Regulation (EC) No 1756/2004 [104].

Audit findings

BMLFUW stated that a reduced frequency of plant health checks is not applied in Austria.

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104 Commission Regulation (EC) No 1756/2004 of 11 October 2004 specifying the detailed conditions for the evidence required and the criteria for the type and level of the reduction of the plant health checks of certain plants, plant products or other objects listed in Part B of Annex V to Council Directive 2000/29/EC; OJ L 313, 12.10.2004, p. 6.

- The mission team noted that data is provided annually to the Commission on the number of consignments of commodities, which have been determined in accordance with Regulation (EC) No 1756/2004 as being eligible for reduced checks, imported in Austria.

Conclusions

Austria does not implement a reduced frequency of checks. Data on the imports of eligible consignments is provided to the Commission in line with the relevant Community legislation.

1.3.5 Fees for import checks

Legal basis

Art. 13d of Directive 2000/29/EC establishes the requirement for MS to ensure the collection of fees to cover the costs of performing the documentary, identity and plant health checks. Art. 13d(2) of the said Directive permits MS to collect the fees established in Annex VIIIa to the said Directive, or to set the level of their fees on the basis of a detailed cost calculation. Art. 13d(3) Directive 2000/29/EC of requires that MS communicate to the Commission the method for calculating the fees.

Audit findings

BMLFUW informed the mission team that Austria does not charge the standard fees in Annex VIIIa to Directive 2000/29/EC. The level of import fees is determined by BAES and BFW, on a cost recovery basis and is subject to approval by BMLFUW and the Ministry of Finances. In accordance with an agreement between BMLFUW and the Ministry of Finances, the fees are collected by the Customs service. In the case of inspections at place of destination, the fees are collected directly by BAES. The level of the fees is the same for both BAES and BFW and is published in the official journal online.

At the time of the mission, the method of calculating the fees had not been communicated to the Commission, however this was done immediately after the mission.

In 2006, a total of €167,722 was collected on behalf of BAES for inspections under Directive 2000/29/EC. A total of €1,000 was collected by BFW for forestry related inspections excluding wood packing material, and a total of €120,000 including wood packing material.

Conclusions

Austria collects fees to recover the costs of performing the import checks for plant health.

1.3.6 Checks for prohibited and non-declared items

Legal Basis

Art. 13b, paragraph 1 of Directive 2000/29/EC requires that MS shall ensure that consignments or lots imported from third countries, which are not declared to contain

regulated plants, are also inspected if there is a serious reason to believe that regulated plants are present.

The second paragraph of the above article requires that MS ensure that import checks and/or official measures are carried out if a Customs inspection reveals that a consignment or lot contains prohibited or non-declared regulated items.

Audit findings

The checks that are carried out are based primarily on the information contained in the phytosanitary certificate. The Customs service does perform additional checks of consignments for their own purposes. No specific instructions or guidance have been issued on this subject.

- The Customs officers met by the mission team reported that they had not found any prohibited or non-declared regulated articles during their routine inspections, however, they stated that if they did, the consignment would be held and the Customs provisions would be applied.

Conclusions

No systematic checks are performed for the presence of prohibited or non-declared regulated items.

1.4 IMPLEMENTATION OF DIRECTIVE 2004/103/EC

Legal Basis

Directive 2004/103/EC establishes conditions for performing identity and plant health checks at places other than at the point of entry or nearby. The said Directive includes a procedure for moving consignments, for which an identity or plant health check has not been carried out, within and between MS and establishes a template for the Plant Health Movement Document, that in accordance with Art. 13(3)(c) of Directive 2004/103/EC, should accompany such movements.

Art. 6 of Directive 2004/103/EC requires that, where applicable, MS shall ensure cooperation between their own official bodies and Customs services and with the equivalent bodies in the other MS.

The above Directive also establishes the minimum conditions for places of inspection (see section 1.2.3 above).

Audit findings

Directive 2004/103/EC is implemented in Austria for six importers of seeds. This was introduced in order to reduce the length of time that consignments were being held at the point of entry, while the seeds were tested. In agreement with Customs, BAES has approved six places of destination for receiving consignments of imported seeds. In 2006, a total of 15 consignments were imported by these approved places of destination.

A bilateral agreement has been established with Germany in order to facilitate movements from Hamburg. Movements are accompanied by a Plant Health Movement Document issued in Hamburg.

The registration of places of destination is done by the provincial plant protection service – the details are sent to AGES who decide if a control should be done or not; the PPPS are responsible for performing an annual documentary check.

- The mission team visited one approved place of destination, which receives seed imported via Hamburg in Germany. The importer was obliged to provide advanced notification of import. When consignments arrive from Hamburg, the consignment is opened and inspected by the Customs service, then BAES takes a sample for testing. The container is re-sealed by Customs, pending the results of the analysis. The importer had been approved as a place of destination since June 2005.

Conclusions

The system for carrying out identity and plant health checks at places other than at or near the point of entry is in line with Directive 2004/103/EC.

1.5 CONTROLS ON WOOD PACKAGING MATERIAL AND OTHER OBJECTS

Legal Basis

Annex IV Part A Section I, point 2 includes wood packaging material and other objects originating in certain countries.

The list of non regulated plants that may be subject to supervision in accordance with Art. 13 (3) of Directive 2000/29/EC, includes wood in the form of dunnage, spacers, pallets or packaging material, which are actually in use in the transport of objects of all kind.

Audit findings

Controls on wood packaging material are performed inland by inspectors from BFW after the consignment has cleared Customs controls. The checks target high risk commodity/origin combinations established following a risk assessment carried out by BFW, and are carried out according to guidelines issued by BFW.

BFW informed the mission team that they attempt to carry out controls at least once every year at all importers of stone, metal ware, electrical items, furniture and motor components from third countries. In 2006, BFW performed 1,000 checks of wood packaging material.

The Customs service informed the mission team that they had been provided with information about the plant health requirements relating to wood packaging material. If Customs detect wood packaging material that does not bear the mark defined in ISPM 15 [105], then BFW or BAES is informed.

- The mission team observed inspections of wood packing material by BFW at an importer situated in south west Austria. It was noted that checks had been carried out at least once every month between May and November. BFW informed the mission

105 International Standards for Phytosanitary Measures Publication N° 15, Guidelines for Regulating Wood Packaging Material Moving in International Trade, Food and Agriculture Organisation, Rome, March 2002.

team that checks are not necessary in the winter due to the very low temperatures and snow cover.

- The importer informed the mission team that he is obliged to notify BFW of each import; he had been provided with information on the marking requirements [106].

Conclusions

BFW systematically controls wood packing material in imported consignments.

1.6 IMPORTS FOR TRIALS OR SCIENTIFIC PURPOSES

Legal Basis

Directive 95/44/EC [107] establishes the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Directive 2000/29/EC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections.

Art. 1 of Directive 95/44/EC establishes an application procedure to be complete prior to the introduction. Art. 2 of the said Directive establishes the process to approve applications, monitor approved activities, including the quarantine facilities and procedures, including the termination of approved activities. Art. 3 of the said Directive requires that a list of imports for trial or scientific purposes is submitted to the Commission each year.

Part 1 of the Annex to Directive 95/44/EC includes details of quarantine measures to be applied; Part 2 of the Annex contains a template for the Letter of Authority.

Audit findings

BAES informed the mission team that there is only very limited activity that requires authorisation in accordance with Directive 95/44/EC; the two principal facilities are AGES and the Federal Forest Service laboratory, which were both visited by the mission team.

The procedure for importing material under Directive 95/44/EC is harmonised. BAES has responsibility for authorising imports from third countries, and their supervision from point of entry to the approved facility. It is also responsible for authorising movements between MS. In all cases, the Letter of Authority is issued by BAES. The relevant PPPS is responsible for approving the facility.

In the case of imports from third countries, the importer must apply to BAES for approval of activities. An inspection is carried out of the premises by the PPPS in accordance with guidelines and a checklist established by BAES.

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106 ***In their response to the draft report, the Austrian Authorities noted that there is no general provision on the declaration of every consignment containing wood packaging material. In practice all big consignments are notified to BFW***.

107 Commission Directive 95/44/EC of 26 July 1995 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections; OJ L 184, 3.08.1995, p. 34.

- The mission team met the inspectors responsible for carrying out the pre-approval inspections; they had all attended a specific training course offered by BAES and appeared to be familiar with the requirements for quarantine facilities.

- The mission team visited the AGES and Federal Forest Service laboratories; neither worked, at the time of the mission, with live organisms listed in Part I section I of Annexes I and II to Directive 2000/29/EC, however both laboratories had suitable equipment, facilities and expertise available.

Conclusions

The procedures and conditions for importing and working with harmful organisms, plants and other objects are in accordance with Directive 95/44/EC.

1.7 PERSONAL USE CONCESSIONS

Legal Basis

Art. 13b(3) of Directive 2000/29/EC provides that MS may establish exemptions for small quantities of plants, plant products and foodstuffs, providing there is no risk of harmful organisms spreading in the Community, and that they are intended for use by the owner or recipient for non-industrial and non-commercial purposes.

Audit findings

A passenger baggage allowance, for personal use, of 3kg of regulated articles (except seeds) has been established by Art. 11 of the Plant Protection Ordinance. BAES, in cooperation with the Customs service carried out risk assessment for orchid cut flowers carried by passengers arriving from Thailand, Malaysia and Singapore. These were found to present a risk for the introduction of *T. palmi* and subsequently, the import by passengers, of orchid cut flowers originating in these three countries, is prohibited. Publicity material has been published, however this is mainly aimed at arriving passengers who have had their flowers seized [108]. The Customs service performs systematic controls of arriving passengers for the presence of plant material in passenger baggage at all international airports in Austria.

Conclusions

Austria has implemented a passenger baggage allowance, which has been adapted to take account of risk.

1.8 NOTIFICATION OF INTERCEPTIONS AND ACTION TAKEN

Legal Basis

Directive 94/3/EC [109] establishes a procedure for notification of interception of harmful organisms or consignments presenting an imminent phytosanitary danger. Art. 2(1) of the

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108 ***In their response to the draft report, the Austrian Authorities noted that travel agencies and airlines are informed by press releases about phytosanitary restrictions.***

109 Commission Directive 94/3/EC of 21 January 1994 establishing a procedure for notification of interception of a consignment or a harmful organism from third countries and presenting an imminent phytosanitary danger; OJ L 32, 5.02.1994, p. 37.

said Directive requires that notifications be sent within two working days and preferably more rapidly in the case of a refusal. Art. 2(2) of the said Directive requires that, immediately on receipt of a notification, MS shall send the information to its own entry points. Art. 5 of the said Directive states that MS should preferably make use of the network established by the Commission.

Point 1(e) of the Annex to Directive 98/22/EC requires that the responsible official body in charge of the inspection posts shall have an up-to-date list of relevant interceptions. Indent 7 of Point 1 of the Annex to the said Directive establishes that MS should adapt their established programme of plant health checks as quickly as possible in such a way as to meet actual needs, in the light of new plant health risks or any changes in the quantity/volume of the plants, plant products or other objects offered for introduction at the inspection posts.

Art. 13c(7) of Directive 2000/29/EC specifies action that should be taken immediately following an interception.

Audit findings

BAES informed the mission team that action is always taken following an interception. Consignments are immediately held, pending confirmation of the interception by AGES or the inspector. The action is based on oral notification; written notification is only normally provided if the importer refuses to cooperate.

Austria uses EUROPHYT, the European Commission's rapid alert system for plant health, to notify interceptions to the Commission and other MS.

- The mission team noted that:
  - The time taken to notify interceptions, between September 2006 and September 2007 was 7-14 days.
  - No interceptions had been recorded in the cargo terminal at Vienna airport.
  - The Customs service did not have an up-to-date list of relevant interceptions.
  - The inspection post at Vienna airport had access to an on-site incinerator.

Conclusions

Action is always taken following an interception or non-compliance in accordance with Art. 13c(7) of Directive 2000/29/EC.

Austria uses the network established by the Commission to make and distribute notifications, however the time taken to notify interceptions is more than two working days.

The Customs service at Vienna airport do not have access to the up-to-date list of notifications and do not adapt their inspections in light of the interceptions, as required by Point 1 of the Annex to Directive 98/22/EC.

2. THE PLANT PASSPORT SYSTEM

2.1 PROCEDURES

2.1.1 Registration

Legal basis

Art. 6(5) of Directive 2000/29/EC requires that all producers of products, which must be accompanied by a plant passport when moved within the EU, must be officially registered. Art. 6(6) of the said directive, and Directive 93/50/EEC [110] extend this obligation to producers, collective warehouses or dispatching centres of potatoes for consumption and *Citrus* fruits.

Directive 92/90/EEC establishes the procedures for registration, the obligations for registered establishments and the official checks that must be carried out.

Audit findings

BMLFUW stated that the PPPS of each province has responsibility for registering relevant establishments in a provincial register. These registers are compiled by BMLFUW to form a national register. Establishments must apply to the relevant PPPS for registration; a fee is payable for this. The PPPS then carries out an on-site inspection to verify the information provided and to confirm that the establishment can comply with the obligations. If the outcome is successful, the establishment is registered. The validity of registration is unlimited, providing that the obligations are complied with. The registration number given to each establishment is unique.

In 2006, the number of registered establishments in Austria was 1,390.

The PPPS perform documentary checks at least once every year at all registered establishments; 1,393 such checks were performed in 2006.

- The registration process and compliance with the obligations, was evaluated in two provinces and at a nursery in Upper Austria.

- The mission team noted that the obligations imposed on registered premises are identical to those contained in Directive 92/90/EEC. The person responsible in the nursery had been informed of, and had complied with, these obligations. A detailed plan of the premises was available, which allowed the PPPS to identify every tree.

Conclusion

The registration of establishments, their obligations and the checks performed are in line with Community legislation.

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110 Commission Directive 93/50/EEC of 24 June 1993 specifying certain plants not listed in Annex V, Part A to Council Directive 77/93/EEC, the producers of which, or the warehouses, dispatching centres in the production zones of such plants, shall be listed in an official register; OJ L 205, 17.08.1993, p. 22.

2.1.2 Authorisation to issue plant passports

Legal basis

Art. 2(2) of Directive 92/105/EEC [111] provides that producers may, permit producers to issue the plant passport under the control of the responsible official body. The same Directive also establishes the procedure and requirements that have to be satisfied in order for a plant passport to be issued.

Audit findings

Establishments must apply to the PPPS for authorisation to issue plant passports. A pre-authorisation check is carried out to ensure that the establishment and in particular the person responsible, is able to comply with the obligations and carry out the necessary checks prior to issuing plant passports. A fee is payable (usually €100 – €250) for the authorisation.

946 establishments were authorised to issue plant passports in 2006. 322 of these were approved to issue replacement plant passports and 469 of these were authorised to issue plant passports for protected zones. 45 fruit tree nurseries had been authorised to issue a plant passport in Upper Austria and 60 in Lower Austria; most of these establishments have a growing area of less than 5 ha.

AGES has provided guidelines for inspection as well as datasheets on relevant harmful organisms to the PPPS.

- The mission team noted that the persons responsible for issuing plant passports at the places visited by the mission team were aware of the procedures and requirements that must be met before a plant passport is issued. The producers had also received written guidelines for checks relevant to their production.

Conclusion

The system of authorisation to issue plant passports is in line with Community legislation.

2.2 USE OF PLANT PASSPORTS

Legal basis

Directive 92/105/EEC establishes requirements for the standardisation of plant passports, including their format.

Art. 10 of Directive 2000/29/EC establishes the procedures and requirements that have to be met in order for a plant passport to be issued.

111 Commission Directive 92/105/EEC of 3 December 1992 establishing a degree of standardisation for plant passports to be used for the movement of certain plants, plant products or other objects within the Community and establishing the detailed procedures related to the issuing of such plant passports and the conditions and detailed procedures for their replacement; OJ L 4, 8.01.1993, p. 22.

Audit findings

Plant passports, including replacement plant passports, are issued by establishments that have been authorised for this purpose. The format of the plant passport is approved by the PPPS as part of the pre-authorisation check. Authorisation is valid for an indefinite period, subject to compliance with the obligations for registered establishments and the appropriate official examinations being completed.

- The mission team noted that in Upper Austria, authorisation to issue plant passports for *E. amylovora* protected zones is valid for a period of one year.

- The mission team visited a place of production that had been authorised to issue plant passports for *E. amylovora* protected zones. The team noted that the plant passports issued by this nursery consisted of a label, attached to individual plants, and an accompanying document (invoice). The accompanying document did contain the elements required by the Community legislation. An example of the label issued by the nursery did not contain certain necessary elements, in particular, the mark "EU plant passport", the EU MS code, the code identifying the responsible official body and the registration number of the establishment. It was not possible to examine an actual label as these could only be printed following completion of a sale in the nursery's computer system.

The PPPS of the two provinces visited stated that no plant passports had been replaced in their provinces.

Conclusion

The system for authorising establishments to issue plant passports is in line with Community requirements, however the plant passports issued by one establishment visited, which consisted of an accompanying document and label, did not comply fully with the format established in Directive 92/105/EEC.

The system for replacing plant passports is not in line with Art. 10(3), third indent of Directive 2000/29/EC, which establishes that "the replacement passport may be prepared *only* by the responsible official body of the area in which the requesting premises are situated".

2.3 PROTECTED ZONES

Protected zones are areas of the Community, where favourable conditions for the establishment of the disease exist, but which have been established to be free from the organism in line with Art. 2(1)(h) of Directive 2000/29/EC.

Directive 2001/32/EC [112] recognises part of Austria, consisting of Burgenland, Carinthia, Lower Austria, Styria, Vienna and the Lienz district of Tirol, as a protected zone for *E. ammylovora* until 31 March 2008. The situation of this protected zone is covered in detail in section 3 below.

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112 Commission Directive 2001/32/EC of 8 May 2001 recognising protected zones exposed to particular plant health risks in the Community and repealing Directive 92/76/EEC; OJ L 127, 9.05.2001, p. 38.

2.4 BUFFER ZONES FOR *ERWINIA AMYLOVORA*

Legal basis

Art. 5(2) of Directive 2000/29/EC requires that the introduction of plants or other products listed in Annex IV B into a protected zone, be authorised only if certain requirements are met. Point 21 of Part B of Annex IV to Directive 2000/29/EC establishes additional requirements that have to be met in order to introduce host plants into protected zones for *E. amylovora*; these include the establishment of buffer zones.

Audit findings

E. amylovora is considered to be established in all provinces, except for the protected zone. In Upper Austria, 22 establishments have been authorised to issue plant passports valid for *E. amylovora* protected zones. The authorisation system is based on three levels of administration: the province (through the PPPS), the district, and the municipality. There is one specialist in each municipality responsible for identifying trees with visual symptoms, and one specialist in each District who is responsible for inspecting symptomatic trees and confirming if the disease is present.

Establishments must apply to the PPPS for authorisation, every year. The PPPS determines a buffer zone in line with the requirements of point 21 of Part B of Annex IV to Directive 2000/29/EC. An official decision describing the buffer zones is issued by the District and sent to the relevant municipality.

The PPPS performs two inspections of host plants in the places of production, the first in early summer and the second in early autumn. During the second inspection, a sample is taken from each field in the place of production to be tested for latent infection.

During the year, the district expert carries out a visual inspection of at least 40 host plants, within 500 m around each place of production and a random inspection in the surrounding 50 km^2. The PPPS grants authorisation to issue plant passports for the protected zone for the year following the year of application if no evidence of infection was found in the place of production or the surrounding 500 m zone.

In the event that infected plants are found in the 500 m zone, or in the place of production; authorisation to issue plant passports will be withdrawn and a new application for authorisation will not be considered for two growing seasons. Any infected trees found elsewhere in the buffer zone are destroyed by the district authorities.

- The mission team visited one place of production that had been authorised to issue plant passports for *E. amylovora* protected zones and noted that two official checks had been carried out at optimal times. The authorisation was valid for one year only.

- The mission team visited one place of production, where infected trees had been found in the surrounding 500 m zone. It was noted that authorisation to issue plant passports valid for protected zones had been withdrawn for 2007 and 2008.

Conclusion

The process for authorising establishments to issue plant passports for protected zones for *E. amylovora* and the system of buffer zones in Austria are in compliance with Community legislation.

2.5 IMPORTS FROM THIRD COUNTRIES

Legal basis

Art. 10(2) of Directive 2000/29/EC, requires that plants or plants products listed in Part A of Annex V to the said Directive may not be moved within the EU, unless they are accompanied by a plant passport.

Audit findings

Importers of plants listed in Part A of Annex V to Directive 2000/29/EC must be registered and authorised to issue plant passports to accompany the plants from point of entry to place of destination.

Conclusions

Plant passports are issued, and accompany, plants for planting listed in Part A of Annex V to Directive 2000/29/EC, from the point of entry, in line with the relevant Community legislation.

2.6 OFFICIAL EXAMINATIONS

Legal basis

Art. 6(5) of Directive 2000/29 requires MS to carry out official examinations (plant health checks), in accordance with the provisions of points (a) to (c) of the said article.

Art. 4 of Directive 92/90/EEC requires that MS shall examine records and other documents (documentary checks) in order to ensure compliance with Art. 2(2)(b) of the said Directive.

Audit findings

BMLFUW stated that checks are carried out by PPPS in all establishments that handle plants that must be accompanied by plant passports, including garden centres. The PPPS stated that they perform checks of documents, including the plant passports issued and received, by all registered establishments, at least once every year. The PPPS visited also informed the mission team that it is an obligation for registered establishment, to notify the PPPS of any non-conformities that they are aware of.

The PPPS of lower Austria (protected zone for *E. amylovora*) stated that they pay particular attention during the documentary checks, to the validity of plant passports for host plants introduced from outside the zone. If the passport is not valid, then the plants will be destroyed or the owner will be obliged to move them outside of the protected zone. If the plants originate in another MS, an official notification of interception is sent via BMLFUW.

- It was noted by the mission team during the site visits, that the official documentary and plant health checks had been performed, at appropriate times, by the PPPS. An inspection report had been provided after each inspection, which was signed by the PPPS inspector and the responsible person of the establishment.

- The inspectors met by the mission team had attended a one-day induction course provided by AGES; none had attended refresher training at AGES [113], however they reported that there is exchange of information at biannual meetings between the PPPS, BMLFUW and AGES.

- The inspectors met by the mission team stated that authorisation to issue plant passports for *Prunus* plants was not suspended following occurrences of Plum pox virus on a place of production. The advice provided by AGES also does not require that authorisation be withdrawn following an occurrence of plum pox.

Conclusions

Official documentary and plant health examinations are carried out, at appropriate times, in line with Community legislation.

The action taken following an outbreak of Plum pox virus is not in line with Art. 11(1) of Directive 2000/29/EC, since establishments are allowed to issue plant passport for host plants although the conditions for doing so, contained in point 16 of Part A of Section II of Annex IV to Directive 2000/29/EC, have not been complied with.

2.7 OCCASIONAL CHECKS

Legal basis

Art. 12(1) of Directive 2000/29/EC requires that MS shall organise official checks to ensure compliance with the said Directive, in particular its Art. 10(2). It further establishes that the checks should be random, but must be regular in places authorised to issue plant passports, and may be regular in other registered premises.

Audit findings

BMLFUW informed the mission team that occasional checks are carried out by each PPPS, based on their own risk assessments and priorities. In 2006, a total of 2,250 occasional checks were carried out. The risk assessment is based on notifications of outbreaks and interceptions in Austria and other MS, the climate of the province and the volume of high-risk plants traded by premises in the province.

- The mission team noted that occasional checks had been carried out at the premises visited.

- The PPPS of Lower Austria informed the mission team that monitoring inspections are carried out for all imported plants for planting, within three weeks of import.

Conclusions

Occasional checks are carried out at both registered and authorised establishments, in-line with Community legislation.

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[113] ***In their response to the draft report, the Austrian Authorities noted that refresher training is provided by AGES given the available resources and depending on the actual demand.***

2.8 EXEMPTIONS FROM THE SYSTEM

Legal basis

Artt. 6(7) and 10(2) of Directive 2000/29/EC permit exemptions from the system, subject to certain conditions being met.

Findings

BMLFUW stated that exemptions may be granted to all establishments, whose entire production is sold to non-professional final consumers on the local market, which is defined as the whole of Austria. The exemption does not apply to host plants of *E. amylovora*.

Conclusions

The exemption of all establishments from the system is not fully in accordance with Community legislation, since Art. 6(7) of Directive 2000/29/EC stipulates that the exemptions should apply only to "*small* producers or processors….." Further, the extent of the 'local market' means that it may be difficult, in the absence of plant passports, for PPPS, which only have competence within their own province, to trace the source of plants in the event of an outbreak, or to ensure that plants are not moved outside the local market.

3. PROTECTED ZONE FOR *ERWINIA AMYLOVORA*

E. amylovora is included in Part A of Section II of Annex II to Directive 2000/29/EC; its host plants are listed in Part A of Annex V to the said Directive, and specific requirements which must be complied with in order for a plant passport to be issued, are included in point 9 of Part A of Section II of Annex IV to the said Directive. The disease is established in all provinces of Austria, except for the protected zone.

3.1 SURVEYS FOR *ERWINIA AMYLOVORA*

Legal basis

Art. 2(1)(h) of Directive 2000/29/EC requires that MS shall conduct regular and systematic surveys for the presence of the organism in respect of the protected zone that has been recognised. The same article requires that the survey takes into account scientific and statistical principles. Detailed rules for performing the surveys for protected zones are included in Directive 92/70/EEC [114].

Audit findings

Each PPPS is responsible for organising surveys in its province. AGES is responsible for performing laboratory analysis and compiling data supplied by the various PPPS in an annual report. It also provides advice to the PPPS. The AGES laboratory is accredited to 17025 ISO for microbiological and molecular genetic tests. The analyses for *E. amylovora* are performed according to EPPO protocol PM 7/20(1). AGES is studying the

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114 Commission Directive 92/70/EEC of 30 July 1992 laying down detailed rules for surveys to be carried out for purposes of the recognition of protected zones in the Community; OJ L 250, 29.08.1992, p. 37.

scientific basis for sampling for latent infection, it also participates in the EU project DIAGPRO for diagnosis of *E. amylovora*. Specialists from AGES frequently attend training, workshops and conferences, in particular those organised by EPPO.

AGES informed the mission team that it develops an annual plan of sampling. The samples included in this plan are analysed free of charge. The actual number of samples taken by each province is shown in the following table. The mission team was informed that, inside the protected zone, only symptomatic or suspicious samples are taken.

Table 3.1: Number of samples planned and tested in 2005 – 2006 *(source: AGES)*

Province of protected zone	Number of samples planned by AGES	Number of samples taken in 2005	Number of samples taken in 2006
Burgenland	50	78	67
Karinthia	150	19	49
Lower Austria	150	194	97
Styria	300	85	37
Tyrol (Lienz district only)	100	47	65
Vienna	50	48	39
TOTAL	**700**	**348**	**289**

In some provinces, the number of samples taken was significantly below the number planned. The overall number of samples analysed for the protected zone as a whole was much less than planned. The PPPS met by the mission team stated that the sampling plan from AGES was not used to plan their inspections.

The mission team evaluated the survey performed in Lower Austria for visual symptoms. 59 fixed observation points have been established, which are inspected twice every month during the growing period by 16 district observers, who report the results to the municipal specialist. In addition to compiling the reports from the districts, the municipal specialist also carries out monitoring inspections at least two times a year, for visual symptoms within the municipality. 2,290 suspected cases were identified in 2007, of which, 1,772 were confirmed by AGES to be *E. amylovora* (see section 3.2 below).

The PPPS is responsible for coordination at provincial level, supporting the experts, and for transmission of the data to the national level. The results of the survey have been submitted to the Commission every year.

Conclusions

The survey consists of sampling and inspections, at appropriate times, for visual symptoms. The sampling plan takes into account relevant scientific and statistical principles in line with Community requirements, however the plan is not fully implemented by the PPPS.

3.2 SITUATION AND CONTROL OF *ERWINIA AMYLOVORA* IN THE PROTECTED ZONE

Legal Basis

Art. 2(1)(h) of Directive 2000/29/EC states that a harmful organism is considered to be established if it is known to occur and if either no official measure has been taken with

the view to its eradication or such measures have proven, for a period of at least two successive years, to be ineffective.

3.2.1 Situation of *Erwinia amylovora* in the protected zone

Audit findings

There has been a significant increase in the occurrence of the disease since 2004, especially in 2007 in the protected zone. This is reflected by the number of positive samples reported by AGES (710, 550 and 2,148 in 2005, 2006 and 2007, respectively) and the number of confirmed outbreaks in the two provinces of the protected zone visited by the mission team as detailed in the following table.

Table 3.2: Number of confirmed outbreaks of *E. amylovora* 2004 – 2007 *(source: AGES)*

Province	Number of confirmed outbreaks			
	2004	2005	2006	2007
Lower Austria	569	441	211	1772
Styria	40	17	3	723

The PPPS of Lower Austria informed the mission team that, in 2007, the dramatic increase in the number of outbreaks was caused by unusual climatic conditions during blossom time. In 2007, the outbreaks in this province were concentrated in two areas, the first close to the Danube River, and the other in the area bordering the Alps. In this second area, the majority of infected trees were a traditional variety of high stem pear trees, known to be highly susceptible to the disease, which are widely planted in the provinces visited.

3.2.2 Control measures

BMLFUW stated that since 2004, all outbreaks in the protected zone have been eradicated in the same year as the outbreak. Each province is responsible for deciding and implementing control measures, which are based on provincial laws. The control measures are also financed by the provinces; the costs for Lower Austria in 2006 were €200,000, and for 2007 (up to September) were estimated to be €1,500,000. Other control measures include a prohibition on the introduction of beehives into the protected zone unless it can be proved that they originate in the protected zone.

Following confirmation of an outbreak, the administration of the district issues an official control order. This includes the demarcation of an 'infected zone' which consists of a three km radius area around the focus. It is forbidden to move host plants from this zone and to move beehives from 15 March to 30 June, except if the bees are prevented from flying for 48 hours after arrival. The district expert is responsible for supervising and verifying the control measures which are either pruning or destruction of the tree. The control measures are paid by the province and are carried out by specialists selected by the expert. The expert performs a follow-up inspection four weeks after the measures have been carried out, and again, one year later. The owner may claim compensation in certain cases.

- The mission team visited an outbreak site in Lower Austria. The owner had noted symptoms of infection in June 2007 on three pear trees. He stated that he was aware of the disease as a result of media coverage, and had reported the symptoms to the expert, who confirmed the outbreak two days later. By observing the neighbouring area, including the wild host plants, the expert discovered 6 further outbreaks:

  – The control measures were given orally to the owner. The PPPS explained that a written order is issued by the District Authorities only if the oral instructions are not complied with.

  – The measures were to prune the infested branches, and because new symptoms appeared after, to fell the trees. The branches were destroyed by incineration and the trunks were dried, under cover, for use as firewood.

  – The owner stated that he will receive €25 compensation for each tree destroyed.

The PPPS of lower Austria stated that no outbreaks of *E. amylovora* had been found in nurseries and, if such an outbreak was found, then the infected trees would be destroyed. Should this case arise an infested zone would be designated and measures would be decided on a case by case basis, with the help of AGES.

Conclusions

There have been a significant number of outbreaks found in the protected zone each year and although stringent eradication measures have been taken following each outbreak, the disease is commonly, and increasingly, found in the protected zone each year. The increase in prevalence has continued over a period of at least four years; the eradication and containment measures taken have therefore proved, for a period of at least two successive years, to be ineffective. The protected zone, at least in the two provinces visited, does not satisfy the requirements for such zones contained in Art. 2(1)(h) of Directive 2000/29/EC.

3.3 TRANSIT THROUGH THE PROTECTED ZONE

Legal basis

Directive 93/51/EEC [115] describes the conditions to be fulfilled when products originating from outside a protected zone are moved through a protected zone.

Audit findings

It is not known if such movements take place, and if so how many. The PPPS stated that this would be difficult to determine. No information on this topic has been provided to producers of host plants, or other stakeholders.

115 Commission Directive 93/51/EEC of 24 June 1993 establishing rules for movements of certain plants, plant products or other objects through a protected zone and for movements of such plants, plant products or other objects originating in and moving within such a protected zone; OJ L 205, 17.08.1993, p. 24.

Conclusion

No specific measures are in place to ensure that any transits of *E. amylovora* host plants through the protected zone, are in accordance with Directive 93/51/EEC.

4. RECOMMENDATIONS

The Single Authority of Austria is recommended to ensure that:

1. Plant health import checks are carried out meticulously, as required by Art. 13a1(a) of Directive 2000/29/EC.

2. The inspection posts, particularly at Vienna airport, have access to an up-to-date list of notifications and that the inspections are adapted in light of the interceptions, as required by Item 1 of the Annex to Directive 98/22/EC.

3. Staff performing official checks have the qualifications necessary for the correct application of Directive 2000/29/EC, as required by Art. 2(1)(i) third indent, of the said Directive.

4. Notifications of interception are made within two working days, or preferably sooner in the case of a rejection, as required by Art. 2(1) of Directive 94/3/EC.

5. The label used for plant passport contains all the information requested by Art. 1(3) of Directive 92/105/EEC.

6. Plant passports are only issued for those plants that comply with the special requirements laid down in Part A and B of Annex IV to Directive 2000/29/EC, and in particular following an occurrence of Plum pox virus, point 16(b)(bb) of Section II, Part A of Annex IV to the said Directive.

7. Those producers and processors exempted from the plant passport system comply with all of the requirements in the first indent of Art. 6(7) of Directive 2000/29/EC.

8. The measures taken, following an occurrence of *E. amylovora* in the protected zone and the status of the protected zone are reviewed, in light of the continued and increasing level of the organism in that zone, to ensure that it complies with Art. 2(1)(h) of Directive 2000/29/EC.

9. Controls may be carried out to ensure that the requirements of Directive 93/51/EEC are met in cases where host plants of *E. amylovora* are moved through the protected zone.

The Single Authority in Austria is advised to:

10. Issuing instructions or guidelines for performing checks for the presence of non-declared or prohibited items in consignments.

11. Review the definition of 'local market' for plant passport purposes.