EUROPEAN COMMISSION
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Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6737 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

AUSTRIA

FROM 22 TO 30 JANUARY 2013

IN ORDER TO EVALUATE MEASURES IN PLACE FOR THE IDENTIFICATION OF HAZARDS AND MANAGEMENT RISKS ALONG THE FEED CHAIN

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Austria, from 22 to 30 January 2013.

The overall objective of the audit was to evaluate the implementation of requirements aiming at ensuring the identification of hazards and management of risks along the feed chain, taking account of the relevant requirements on feed laid down by Regulation (EC) No 183/2005 and other related legislation and on official controls on the afore-mentioned legislation. In terms of scope, the audit focused on activities which, in the light of experience and past feed crises, are known to be more of a risk than others, including those falling under the scope of Regulation (EU) No 225/2012 concerning dioxins in fats, oils and products derived thereof. The audit also assessed the measures taken in response to the recommendations made following a previous FVO audit concerning feed safety.

Overall, the report concludes that the registration and approval process of feed establishments, including those whose main activity is not in the feed area, has been satisfactorily performed by the competent authority. Official controls are carried out regularly along the feed chain and their prioritisation is largely based on risk; although not all relevant risk criteria are always taken into account. There are some weaknesses in the implementation of official controls, in particular in relation to the targeting of official sampling to verify compliance with the maximum permitted levels of cross-contamination from coccidiostats, an area where feed operators are not able to prove that the measures they put in place are effective. Similarly, official controls are not always able to ensure that feed operators implement HACCP-based procedures that effectively manage all relevant risks.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
ABP	Animal by-products
AGES	Austrian Agency for Health and Food Safety (*Österreichische Agentur für Gesundheit und Ernährungssicherheit*)
BAES	Federal Office for Food Safety (*Bundesamt für Ernährungssicherheit*)
Batch	A batch is defined in Annex II to Regulation (EC) No 183/2005
Cross-contamination	Presence, due to production, of additives, medicines or ingredients in feedingstuffs which should not contain them
Dioxin-like PCBs	Dioxin-like polychlorinated biphenyls
Fat blending	Fat blending is defined in Annex II to Regulation (EC) No 183/2005
FVO	Food and Veterinary Office
HACCP	Hazard analysis and critical control points
MIK	Multi-annual national control plan (*Mehrjähriger Integrierter Kontrollplan)*
Products derived from vegetable oils	Products derived from vegetable oils are defined in Annex II to Regulation (EC) No 183/2005
RASFF	Rapid Alert System for Food and Feed
Report 2007-7500	Report of an audit carried out in Austria from 04 to 12 September 2007 concerning feed safety. The report is included in the annex to report DG(SANCO)/2007-7995 – Final

1 Introduction

The audit took place in Austria from 22 to 30 January 2013.

The audit team, which comprised of two auditors from the Food and Veterinary Office (FVO), was accompanied throughout the audit by members of the staff of the Austrian Agency for Health and Food Safety (*Österreichische Agentur für Gesundheit und Ernährungssicherheit – AGES*).

An opening meeting was held on 22 January 2013 with representatives of the Federal Ministry of Agriculture, Forestry, Environment and Water Management, the Federal Office for Food Safety (*Bundesamt für Ernährungssicherheit – BAES*) and AGES in the Federal Ministry of Agriculture, Forestry, Environment and Water Management, during which the audit objectives, itinerary, and the standard reporting and follow-up procedures were confirmed, and additional information required for the satisfactory completion of the audit was requested.

2 Objectives

The overall objective of the audit was to evaluate the implementation of the requirements concerning the identification of hazards and management of risks along the feed chain, including those falling under the scope of Regulation (EU) No 225/2012 concerning dioxins in fats, oils and products derived thereof. To that extent, the audit took account of the relevant requirements on:

- feed hygiene, as laid down by Regulation (EC) No 183/2005 of the European Parliament and of the Council, as amended by Regulation (EU) No 225/2012 and other relevant legislation laying down requirements concerning feed safety, notably Regulation (EC) No 1831/2003 of the European Parliament and of the Council, Directive 2002/32/EC of the European Parliament and of the Council and Regulation (EC) No 767/2009 of the European Parliament and of the Council;
- official controls on the above legislation, as laid down by Regulation (EC) No 882/2004 of the European Parliament and of the Council.

The audit also assessed the measures taken in response to the recommendations made following a previous FVO audit concerning feed safety (see section 4). Moreover, the audit also gathered information on the implementation of some requirements of Regulation (EC) No 767/2009 which are purely related to the marketing of feed; this information is presented in Annex 2.

In terms of scope, the audit focused on activities which, in the light of experience and past feed crises, are known to be more of a risk than others (see section 4).

The itinerary of the audit included the following visits:

Visits / Meetings	No	Comments
Central competent authority	√	Opening and closing meeting; meetings during visits to establishments (official controls in establishments under the scope of this audit are executed only by the central competent authority)
Fat blender	1	Mixing fats for feed and collecting used cooking oil for supplying biodiesel plants
Biodiesel plant	1	Supplying glycerol to the feed chain and fatty acids as technical non-feed grade fats
Food producer	1	One establishment supplying food and food co-products to the

		feed chain
Feed mills	3	Two approved and one registered feed mill
Plants dealing with feed and technical grade products	2	One plant processing limestone and clinoptilolite and one intermediate trading feed and technical non-feed grade materials
Dryer	1	Drying grains and mais
Oil and fat supplier	1	One operator under the scope of Regulation (EC) No 852/2004 supplying also the feed chain with fats

3 Legal Basis

The audit was carried out under the general provisions of European Union (EU) legislation and, in particular, Article 45 of Regulation (EC) No 882/2004.

A full list of the legal instruments referred to in this report is provided in Annex 1 and refers, where applicable, to the last amended version.

4 Background

Report DG(SANCO)/2007-7500 – MR Final (hereafter: report 2007-7500) describes the results of a previous audit concerning feed safety carried out in Austria from 04 to 12 September 2007, and contains background information relevant to the current audit. This report made a number of recommendations to the competent authorities, which subsequently informed the Commission services of actions that had been or would be taken aimed at addressing the recommendations made; where appropriate, both the relevant recommendations and the afore-mentioned actions are outlined in section 5. The report which is included in the annex to report DG(SANCO)/2007-7995 – Final is accessible at the following address:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2056

FVO audits on feed safety in Member States have shown important deficiencies across the board on the implementation and official controls on procedures based on the hazard analysis and critical control points (HACCP) principles. In parallel, a number of past feed safety crises (e.g. dioxins in fatty acids or in dried food co-products) were linked to poor hazard identification and risk management measures by the feed operators concerned. These crises have also shown that some activities can be considered more of a risk than others, resulting in some cases, in the legislation being revised. In particular, Regulation (EU) No 225/2012 has amended Annex II to Regulation (EC) No 183/2005 and introduced additional requirements for:

- approval of some categories of establishments placing on the market, for feed use, products derived from vegetable oils and blended fats;
- production, storage and transport, and;
- dioxins testing of oil, fats and products derived thereof.

For all the afore-mentioned reasons, a series of audits has been rolled out since 2012, focusing on some requirements of the legislation concerning key areas where hazards have been identified and, therefore the consequent risks have to be managed.

5 Findings And Conclusions

5.1 Information on the feed sector

Currently there are 195 approved and registered feed producers in Austria and 1,400 non-producers (mainly primary producers, traders and transporters); in addition there are about 700 food producers placing surplus food and food co-products in the feed chain.

Some 160 companies are active in drying feed materials and 15 companies are active in the placing of surplus food (bakery products) in the feed chain; one of these companies also dries the surplus food while all others unpack bread and send it directly to farmers. According to the competent authority, only one of the food surplus recyclers uses mechanical means to remove packaging from the bakery products.

There is only one fat blender in Austria as well as one plant producing fats of animal origin for feed and one biodiesel plant supplying glycerol to the feed chain. No oleochemical plants exist currently in Austria which manufacture products for the feed chain.

About 30 companies are known to the competent authority for handling and storing feed grade and technical non-feed grade materials.

The annual production of compound feed for farmed animals in Austria is approximately 1,200,000 tonnes of which about 40% is destined to poultry, 40% to bovines and 20% to pigs. About 43,725 tonnes of co-products from the food industry are supplied to the feed chain.

The production of medicated feed is carried out directly on the farms with the use of small mixers. According to the competent authority, the requirements for feed mills in order to produce medicated feed are so demanding that these operators are not willing to manufacture such feed. Currently, there is only one establishment in Austria producing medicated feed.

5.2 Official control systems

5.2.1 Competent authorities

Legal requirements

Article 4 of Regulation (EC) No 882/2004 lays down, among others, requirements for the designation of the responsible competent authorities and for their co-ordination and co-operation.

Findings

The competent authority for official controls in commercial feed producers and establishments placing feed on the market is BAES which was established in the organisational structure of AGES. BAES makes use of AGES, in particular its Institute of Animal Nutrition and Feedingstuffs for the delivery of official controls. In practical terms, the Institute of Animal Nutrition and Feedingstuffs of AGES is the organisational unit for planning and carrying out the official controls in the name of BAES.

The on-farm mixing, use and storage of feed is under the responsibility of the provincial authorities.

- The audit team noted that the responsibilities were clearly defined and all members of staff of AGES met were aware of their tasks and duties in relation to feed controls.
- The audit team noted that within AGES, there were members of staff responsible to monitor and co-ordinate official control activities and sampling in order for the planned arrangements to be achieved.

Conclusions

The requirements for the designation of competent authorities and for their co-ordination and co-operation laid down by Article 4 of Regulation (EC) No 882/2004 are satisfactorily complied with.

5.2.2 Organisation and delivery of official controls

Legal requirements

Article 3 of Regulation (EC) No 882/2004 establishes, among others, that official controls are to be carried out regularly, on a risk basis and with appropriate frequency, taking particular account of identified risks that may influence feed safety. For context, the relevant requirements applicable along the feed chain are laid down by Regulation (EC) No 183/2005, Directive 2002/32/EC, Regulation (EC) No 1831/2003 and Regulation (EC) No 767/2009.

Findings

The relevant recommendation in report 2007-7500 concerned sampling for dioxins. In the submitted action plan, the competent authority undertook to continuously monitor the collection of samples during the year and adjust sampling when required.

The multi-annual national control plan (*Mehrjähriger Integrierter Kontrollplan* - MIK) covering the years 2011 - 2015 is the basis for official controls in feed. MIK establishes the risk-based approach for official inspections and sampling. Based on MIK, AGES prepares an annual control plan for feedingstuffs, which includes details about the risk categorisation of establishments, the number of inspections to be carried out, the estimated number of follow-up controls and the samples to be taken and analysed. The frequency of inspections in a given feed establishment depends on its risk scoring, which is calculated on the basis of several risk factors. For feed producers, the foreseen frequency ranges from one every two years to two per year; for non-producers, this ranges from once per year to once every three years.

MIK also establishes the distribution of sampling locations in the annual programme; for that, it specifies that 48% of the samples must be taken at feed producers, 25% at traders, the same percentage at agricultural holdings and 2% at entry points and border inspection posts. The annual control plan establishes the number of samples to be taken for a specific commodity and the analytes to be determined in each of the commodities based on known possible hazards. A member of staff in AGES is responsible for monitoring the execution of the sampling programme. The competent authority stated that the decision on the analytes to look for in a sample is taken by the said member of staff who reviews the progress of the sampling programme for each type of analysis, unless, the sample was taken to investigate a suspicion, in which case the accompanying documents state the analysis requested.

In relation to the organisation and delivery of official controls, the audit team made the following observations.

- All operators met in the establishments visited confirmed to the audit team that official controls are always carried out unannounced.
- The audit team noted that in 2012, the execution of official inspections largely met the planned arrangements.
- Some differences observed in 2011 in the frequency of official controls in the feed establishments visited (compared to their risk categorisation), were attributed, according to the representatives of AGES, to the fact that it is only as of 2012 that the frequency model of official controls based on risk categorisation of the establishments is fully in place. Prior to

that and since 2007, prioritisation of official controls was based on risk but no frequency of official controls was set for a certain risk category of establishments.

- The audit team noted that the operators' own-checks and the history of non-compliances are not taken into account in the frequency of official controls. The competent authority stated that nevertheless all high-risk operators and producers are inspected at least once a year in addition to any possible follow-up activities.
- The audit team noted that the risk factors taken into account for prioritising official controls on transporters of feed considered only risk factors that would apply if they transported solely feedingstuffs (e.g. the cross-contamination with fish meal or with coccidiostats along with some other risks); risks arising from possible transport of other commodities than feed (e.g. organic fertilisers and soil improvers or animal by-products (ABP) and their derived products) were not taken into account. In this respect, during a visit to a feed mill, the audit team noted that a vehicle, which was unloading Ca-Na-Phosphate to the feed mill, was marked with a label "CAT 1 Material – Only for destruction" as this is foreseen by the ABP legislation for vehicles transporting Category 1 ABP or derived products. The said transport company was registered as a transporter of feedingstuffs.[1]
- The audit team noted that the sampling programme in place is executed largely according to the planned arrangements concerning commodities to be tested, number of samples to be taken and analytes to be determined with only minor fluctuations over or below the targets set[2].
- The audit team noted that for cross-contamination testing the official sampling did not focus on the first batch produced after a batch with the substance under investigation. In a feed mill visited, the audit team noted that the official sample for cross-contamination of coccidiostats was taken after the production of at least seven batches without coccidiostat. According to the competent authority, random sampling is also applied for testing for cross-contamination of active substances (e.g. coccidiostats).
- In relation to the presence of packaging material in feed materials (surplus food), the competent authority stated that there is a zero tolerance in Austria for packaging material residues. The audit team noted that the annual control plans for 2012 and 2013 and in particular the sampling sections did not make reference to analyses for residues of packaging material in feed. The competent authority stated that these analyses are covered by the analyses done for the presence of constituents of animal origin or botanical impurities, which are both microscopic methods. The audit team saw examples of samples taken from surplus bakery products, however, since the declaration on the laboratory results referred to "Constituents of animal origin" as a laboratory method and the result referred to "Absence of constituents of animal origin under microscopical examination" it was not possible to verify that indeed packaging material was the focus of the analysis. The audit team noted also that the annual plan did not contain any provisions for targeting feed materials from food surplus recyclers for the presence of packaging materials.

Conclusions

There is a risk-based official control plan in place since 2012 which considers several risk factors for the risk categorisation of the establishments and the determination of the frequency of official

1 In their response to the draft report, the competent authorities noted that the Federal Ministry of Health (responsible for ABP) was at the time of the audit informed of the audit team's findings and instructed the local veterinary authority to check the transport company. According to the competent authority, the check revealed that the company has certified quality systems in place with documentation of freight activities, cleaning and disinfection and that Category 1 material had not been transported for very long, however, the relevant marking had not been removed.

2 In their response to the draft report the competent authorities noted that in accordance to the risk-based annual sampling plan, testing is also carried out for prohibited substances and maximum permitted levels for carry-over of coccidiostats.

controls, which provides for official controls to be carried out in a reasonable amount of time to all feed operators. Nevertheless, the reliability of operator's own checks or previous history of non-compliances are not taken into consideration. In relation to official controls in transporters, important risk factors that arise from activities outside the feed chain (e.g. transport of ABP and derived products) are not taken into account for prioritising the official controls as required by Article 3 of Regulation (EC) No 882/2004.

Although official sampling is largely carried out in accordance with the planned arrangements, there is a lack of targeting in relation to the cross-contamination of coccidiostats. As regards residues of packaging material in feed materials, the absence of specific reference to this type of analysis in the sampling plan and the way the laboratory results are given (presence or absence of constituents of animal origin) do not ensure that official controls verify the absence of packaging materials in order to ascertain compliance with the requirements laid down in Article 6 of Regulation (EC) No 767/2009.

5.2.3 Records of official controls

Legal requirements

Articles 8(1) and 9 of Regulation (EC) No 882/2004 lay down, respectively, requirements for documented procedures and for drawing up reports on official controls.

Findings

The competent authority prepared several checklists to be used in official controls in the different types of feed establishments.

In all establishments visited the audit team focused on official controls carried out in the last two years.

- In all establishments visited, the audit team noted that official controls were always documented and copies of reports of the official controls were always given to the operator irrespective of the presence of shortcomings or not.
- As regards the quality and content of the reports, the audit team noted that there were significant differences between the reports seen concerning the information included and the level of details of the checks carried out. Although some reports of the official controls carried out in the establishments visited were very detailed, the majority of them contained only limited information on the checks carried out and their outcome. In this respect, the audit team noted also that the checklists sometimes attached to the reports, did not provide any additional information that could be useful for subsequent official controls since their contents was limited to the ticking of the yes/no boxes adjacent to the questions.
- Most of the non-compliances stated on the reports seen during the visits to feed establishments concerned labelling issues such as absence of certain information or problems with declaration of ingredients[3]. The audit team noted that in these cases, non-compliances were only stated on the reports without any explicit requests as to the actions the operators are to take. The competent authorities stated that this is because labelling issues are considered low severity non-compliances and the measures catalogue foresees for those cases only a warning letter without fee (see section 5.2.6). According to the competent authority, if they imposed a corrective action request and a deadline for remedy of the non-

3 In their response to the draft report the competent authorities noted that the reason why not all measures are included in the report of the official control is because it is not possible to adequately check or assess on-the-spot certain shortcomings. Therefore, the establishments concerned are sent a separate letter pointing out the shortcomings and asking to remedy them.

compliance, according to national rules, they would need to introduce an administrative fee which is not in line with the softer approached aimed for such non-compliances.

Conclusions

Official controls were always documented and a copy of the report of an official control was always left with the operator. However, reports do not always include details on the control methods applied, their outcome and the actions the feed operator is to take to address any non-compliances as required by Article 9 of Regulation (EC) No 882/2004.

5.2.4 Verification of official controls

Legal requirements

Article 8(3)(a) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to verify the effectiveness of official controls that they carry out.

Findings

According to the competent authority, all newly appointed inspectors undergo an intensive mentoring programme whereby experienced s guide and train the newcomers. In addition, according to the competent authority, within ISO/IEC 17020 every inspector is shadowed by another inspector during an official control once every three years. Every five years, the inspector supervisor of AGES accompanies an inspector for an on-site supervision during an official control.

- The audit team saw evidence of the training sessions that the newcomers have to complete before starting carrying out official controls on their own.
- The audit team saw reports prepared by the supervisor, in which were presented to the supervised inspector the weaknesses identified on his performance of official control as well as the points deserving more attention for improvement.

Conclusions

There is a satisfactory system in place for internal supervision for verification of effectiveness of official controls, therefore, the requirements of Article 8(3)(a) are met.

5.2.5 Registration and approval

Legal requirements

Articles 9 and 10 of Regulation (EC) No 183/2005 lay down, respectively, requirements for the registration and approval of feed establishments by the competent authorities, including those for which approval is required under Regulation (EU) No 225/2012; Article 19 lays down requirements for the list of these establishments.

Findings

The relevant recommendation made in report 2007-7500 concerned the registration of feed establishments. In response to this recommendation the competent authority indicated that efforts would focus on raising awareness of feed operators about registration and on checking the lists of suppliers of feed operators during official controls.

A list of feed establishments in Austria is maintained by BAES and is publicly available on the internet site of BAES. The inclusion in this list requires the operator to pay an annual fee payment

that covers its registration and official control expenses; the level of this fee ranges from approximately 50 to 1,250 Euro and depends on the risk categorisation of the establishment and the activities carried out. According to the competent authority, Austria decided not to have double listings, therefore, food operators supplying the feed chain who are already registered in the list of food operators maintained by the provincial authorities are not obliged to be registered also in the list of feed operators; they are only obliged to notify their activity as supplier of feed to BAES.

The following observations were made in relation to registration and approval of establishments.

- The audit team noted that all establishments visited were approved or registered as required.
- The audit team noted that only some of the food operators supplying food co-products to the feed chain were included in the list of feed establishments. According to competent authority officials met, food operators are mostly not willing to be registered in the list of feed establishments because of the additional cost arising through the annual fee for the registration in the register of feed establishments.
- Food establishments placing food co-products in the feed chain are known to the competent authority. The audit team noted that these establishments underwent a risk assessment and categorisation by AGES and are included in the annual control programme, however, since they do not appear on the list of feed establishments publicly available on BAES website, feed operators need to obtain this information by querying AGES on a case by case basis.
- The two food establishments visited were also registered in the list of feed establishments. The food operators met stated that their customers (feed mills) requested them to apply for registration in the list of feed operators in order to comply with the requirement of sourcing only from registered feed establishments.
- As regards establishments requiring approval under Reg. (EU) No 225/2012 the audit team noted that both plants visited requiring approval under the provisions of the said Regulation were approved and included in the list of feed establishments.
- Feed establishments having also drying facilities are known to the competent authority. The audit team noted that the competent authority avails of information for every dryer concerning the type of drying and the fuel used. The drying activity is not included in the list of activities of the relevant operators.

Conclusions

The requirements of Articles 9 and 10 of Reg (EC) No 183/2005 are largely met; the relevant recommendation in report 2007-7500 has been addressed. However, the requirement of Article 19 concerning the making available to the public of the lists of registered feed establishments is not fully complied with, since the complete list of food operators supplying co-products to the feed chain is not be made available to the public (information on the registration of some of these operators is only given on a case by case basis following specific queries to AGES).

5.2.6 Actions in case of non-compliance

Legal requirements

Article 54 of Regulation (EC) No 882/2004 lays down requirements for action where non-compliance is identified.

Findings

AGES developed a document called "measures catalogue" which classifies the different possible non-compliances in feed establishments into severity groups. Depending on the severity group, the catalogue contains information on the measures to be taken in case of non-compliance, the percentage of follow-up activities in that case and the measures to be taken in case of repeated non-compliance. The measures included in the catalogue range from written warning to the issuance of an administrative order and confiscations up to legal proceedings for repeated non-compliance[4].

- In relation to follow up activities, the audit team noted that the measures catalogue foresees the percentage of follow-up controls to be carried out depending on the severity of the non-compliance. This ranges from zero for labelling issues to 100% for severe non-compliances with in-between steps at 10% and 50% depending on the severity.
- A rapid alert system for food and feed (RASFF) notification was sent to the competent authority from another Member State informing them about a delivery to an Austrian feed operator of a fishoil-based complementary feed (97% fish oil and 3% rapeseed oil) with dioxine levels exceeding the maximum permitted levels in complementary feed (had it been pure fishoil without the 3% addition of rapeseed oil the dioxine levels would have been far below the maximum permitted level). The audit team noted that the competent authority took immediate action from the very first day of receiving the RASFF notification requesting recall actions from the company. An administrative fine was also imposed on the feed operator.

Conclusions

The requirements of Article 54 on actions to be taken in case of non-compliance are largely complied with.

5.3 Official controls on requirements along the feed chain

5.3.1 Sourcing and labelling

Legal requirements

Article 5(6) of Regulation (EC) No 183/2005 requires feed business operators to source and use feed only from registered and/or approved establishments. Article 5(2) of the said Regulation indicates that the requirements set out in its Annex II shall be met for operations other than those regarding primary production; these requirements foresee, among others, that the intended use of a product for feed or other purposes shall be clearly indicated on the label.

The labelling of feed materials and compound feed placed on the market must identify them as such, as laid down by Article 15 of Regulation (EC) No 767/2009; for feed additives and premixtures, the same principle is laid down by Article 16 of Regulation (EC) No 1831/2003.

Findings

- In all feed mills visited, the audit team noted that the operators were actively verifying the registration of their suppliers as feed operators prior to purchasing any feedingstuffs. All suppliers checked by the audit team were included in the list of feed establishments. However, in one of the feed mills visited which also produced custom made formulas for

4 In their response to the draft report the competent authorities noted that the catalogue does not take court cases into account; however, when repeated shortcomings are identified, the competent district authority is informed that there is a suspicion of law breaches and that authority can then institute administrative criminal proceedings.

farmers, the audit team noted that the operator accepted and used an additive (steatite) supplied by a farmer without any labelling and indication of its origin.

- Concerning food operators placing food co-products in the feed chain, the feed mill operators met stated that it is burdensome to obtain information about such operators if they are not on the list of feed establishments as AGES needs to be contacted to provide them with a written confirmation about the supplier's registration (see section 5.2.5). A feed mill operator met stated that it is not easy either to find the information about registration of feed operators in other Member States due to, in many cases, language limitations.
- The audit team noted that all suppliers of feed checked in the feed mills visited were registered/approved as feed establishments.
- In the bio-diesel plant visited supplying glycerol to the feed chain, the audit team noted that only semi-refined (degummed) oil was used in the production of bio-diesel, which was sourced from an attached oil seed crusher registered as a feed establishment.
- Labelling of feedingstuffs are part of official controls. The audit team noted that several non-compliances recorded in reports of official controls concerned labelling issues including the requirement for labelling as feed material see sections 5.2.3). In a feed mill visited, the audit team noted that in a report of an official control, amongst other labelling issues, a non-compliance was stated about a product that was not labelled as feed material; other labelling issues identified concerned for example absence of target species, absence of additive codes, wrong classification of a product as a premix although it was produced only with feed materials etc..
- The audit team noted that with only one exception the products and raw materials seen were labelled as “feed materials” or as being “feed grade”.

Conclusions

Official controls take account of the relevant requirements concerning sourcing of feed materials and are largely able to ensure that operators source feed materials only from registered establishments, as laid down by Article 5(6) of Regulation (EC) No 183/2005 and that feed materials are labelled as such as such as laid down by Article 15 of Regulation (EC) No 767/2009.

5.3.2 Infrastructural and organisational requirements

Legal requirements

Article 5(2) of Regulation (EC) No 183/2005 indicates that the requirements set out in its Annex II shall be met for operations other than those regarding primary production; among others, these requirements concern separation between products intended for feed and products not intended for use in feed during production, storage and transport.

Findings

- The checklists prepared by the competent authority to be used during official controls in the different types of establishments contain points in relation to measures put in place to avoid cross-contamination of feed with other materials. The audit team noted that official controls usually include the verification that facilities and equipment comply with the applicable requirements of Regulation (EC) No 183/2005.
- In the establishments visited handling both feed and technical non-feed grade products, there was, when required, an adequate separation between the products of different grades.

- In the food establishment visited supplying food co-products to the feed chain, the audit team noted that there was a clear separation of the materials intended for feeding and the waste material, which was placed in colour-coded containers.
- In the fat blender visited the audit team noted that the tanks for the technical fats were on one side of the plant and had a separate pipe system. It was also noted that the competent authority verified the complete separation between the feed and technical part of the plant during the pre-approval official control as required by Regulation (EU) No 225/2012.
- In a feed mill visited, the audit team noted that bags of coccidiostats and premixtures for laying hens were stored next to each other, together with other feed materials. The operator stated that construction works which started recently are currently ongoing in the storage facility and for that reason they moved the bagged ingredients temporarily to that location.

Conclusions

Official controls are largely able to ensure that feed establishments comply with the requirements laid down in Article 5(2) of Regulation (EC) No 183/2005 concerning facilities and equipment.

5.3.3 Dioxins and dioxin-like PCBs monitoring

Legal requirements

Article 5(2) of Regulation (EC) No 183/2005 indicates that the requirements set out in its Annex II shall be met for operations other than those regarding primary production; these requirements concern, among others, monitoring of dioxins at establishments placing on the market fats, oils or products derived thereof.

Findings

- Both the fat blender and the biodiesel plant visited are approved in accordance with the requirements of Regulation (EU) 225/2012. The audit team noted that a pre-approval official control was carried out in both plants and official control reports were prepared. It was noted that in the case of the fat blender the competent authority requested the operator to arrange with the laboratory used for dioxins testing to directly inform the competent authority in case of non-compliant results. The approval was granted after the operator met the requested arrangement with the laboratory.
- In the fat blender visited, the operator stated that dioxin and dioxin-like polychlorinated biphenyls (dioxin-like PCBs) testing on every batch (before placing on the market) was introduced since the beginning of 2011. According to the operator the maximum batch size is 135 tonnes which is the maximun capacity of one tank. The audit team noted that all batches are analysed and there is a system in place to withhold batches as long as the laboratory results for dioxins testing are not available.
- The fat blender operator stated that some of the customers (feed mills) require the certificate of analysis to be attached to the accompanying documents on delivery, while some others do not. The operator stated that for those who do not request it, this is forwarded by email once a month. In a feed mill visited, the audit team confirmed that the operator received the certificate of analyses from the said fat blender not attached to the deliveries but every few weeks by email.
- The day prior to the visit to the fat blender, the operator's own checks identified a batch with dioxin levels exceeding the maximum permitted limits. The audit team noted that the competent authority was immediately notified of the case. Investigations carried out to

identify the source of contamination revealed that this originated in a load of fatty acids of plant origin from another Member State. A RASFF notification was immediately released by the competent authority. The audit team could not find the said supplier on the list of registered or approved operators of the Member State of origin; the operator could only be found on the list of approved oleochemical plants in accordance to Regulation (EC) No 1069/2009 of the European Parliament and of the Council [5].

- In the bio-diesel plant visited, the audit team noted that two samples per year are tested for dioxins and PCBs, heavy metals, salmonella and pesticides. One to two samples of glycerol per month are tested for methanol. The said biodiesel plant supplies only glycerol to the feed chain.
- The laboratories used by both operators for the dioxin and dioxin-like PCBs analyses were accredited.

Conclusions

Official controls are largely able to ensure that feed establishments comply with the requirements for dioxin and dioxin-like PCBs monitoring as laid down in Annex II to Regulation (EC) No 183/2005.

5.3.4 Cross-contamination, homogeneity and undesirable substances

Legal requirements

Article 5(2) of Regulation (EC) No 183/2005 indicates that the requirements set out in its Annex II shall be met for operations other than those regarding primary production; these requirements concern, among others, cross-contamination, homogeneity as well as undesirable substances. In particular, Directive 2002/32/EC sets out maximum permitted levels for undesirable substances in feed.

Findings

- Both approved feed mills visited used production sequencing to minimise cross-contamination of coccidiostats in feed for non-target species. In one of the two, the computerised control system did not allow specific formulas to be produced after the production of feed with coccidiostats; in the other one, the feed that could be produced after the use of coccidiostats was established in the work instructions, but the system allowed the production of any formula thereafter. In the said feed mill, the audit team verified however, that in the last three months prior to the audit the sequencing was followed as described in the work instructions.
- The audit team noted that, the approved feed mill operators neither could prove that the measures they have in place to minimise cross-contamination are effective nor could demonstrate what was the level of the coccidiostat in the first batch produced without coccidiostat. In none of the two was the cross-contamination assessed for the coccidiostats used; the only cross-contamination studies were carried out with a micro-tracer in 2003 and 2004 together with the homogeneity tests. There was no information demonstrating that the behaviour of this micro-tracer resembled the behaviour of the coccidiostats used. It was also noted that none of them was taking targeted samples to assess the level of cross-contamination. This was overlooked by officials controls. This, in conjunction with the lack

5 In their response to the draft report the competent authorities noted that the Austrian company acquired the product in question from a registered company (intermediary) in another Member State and therefore it was not the responsibility of the Austrian operator to to verify the registration/approval of the original supplier.

of targeting of official sampling for cross-contamination (see section 5.2.2) does not allow to verify whether the maximum permitted levels in non-target feed are met or not by feed operators.

- The audit team noted that all three feed mills visited had previously homogeneity tests carried out by AGES in 2003 or 2004. The results at that time were satisfactory for the three of them. Since then, only one of them carried out an in-house homogeneity test in 2008 using micro-tracer, however, according to the competent authority, the number of samples taken and analysed (less than 10) was not adequate to provide reliable results. One of the feed mills visited had fluctuations and non-compliances as regards the composition of feed produced and analysed, however, this had not triggered an investigation on the performance of the mixer by the operator. The audit team noted that the need to verify the performance of the mixers at regular intervals was not described in the internal procedures of the feed mills visited. Official controls had not identified the shortcomings noted by the audit team both as regards inadequate number of samples and absence of procedures for verification of homogeneity.
- According to the competent authority, since 2005, a feed ingredients monitoring programme covering undesirable substances is in place financed by the Association of Feed Business Operators. About 150 samples per year are tested; sampling and analysis of the samples is carried out by AGES. Apart from this feed ingredients monitoring programme, the audit team noted that operators carry out their own monitoring programmes on undesirable substances. The audit team noted that only some operators assessed the ingredients or the products and prepared the own-checks plan taking account of the identified risks. In the other operators visited, although sampling for undesirable substances was carried out, the operators were not always able to explain why some specific analyses were carried out in some products (see section 5.3.6). This was overlooked by official controls. For the operators it was important to demonstrate that their monitoring system in place fulfils the requirements set by the feed assurance certification schemes.
- In the dryer visited, according to the operator's own-check programme, several samples were due to be analysed for dioxins on a yearly basis. The audit team noted that, contrary to the planned arrangements, only one sample was analysed in the last two years (see section 5.3.6). This was overlooked by official controls.

Conclusions

Official controls can not always ensure that all relevant requirements laid down by Article 5(2) of Regulation (EC) No 183/2005 are met by feed operators; in particular, as regards minimisation of cross-contamination from the use of coccidiostats, both the arrangements put in place by feed operators and the way official controls are targeted are not adequate to verify whether the maximum permitted levels set out by Directive 2002/32/EC in non-target feed are met[6] (see section 5.2.2). As regards homogeneity, official controls overlook flaws in the design or implementation of measures related to the verification of the effectiveness of mixing operations. Finally, in some cases, official controls do not identify that the monitoring of undesirable substances carried out by feed operators does not take account of all relevant hazards because of weaknesses in the risk assessment carried out as part of their HACCP-based procedures (see section 5.3.6).

6 In their response to the draft report the competent authorities noted that targeted monitoring of cross-contamination with coccidiostats is not compatible in practice with the requirement that inspections be conducted unannounced, since compound feeds are usually supplied in bulk immediately after production and are therefore generally not kept in storage; it is thus therefore unlikely for inspectors to find products which have been produced immediately after a flushing batch following production of a feed containing a coccidiostat.

5.3.5 Traceability

Legal requirements

Article 5(2) of Regulation (EC) No 183/2005 indicates that the requirements set out in its Annex II shall be met for operations other than those regarding primary production; these requirements concern, among others, records for traceability and the keeping of samples.

Findings

- The audit team noted that official controls in feed establishments include verification of traceability.
- In all places visited, backward and forward traceability was possible as regards the origin of almost all products used in a formulation (for exception see section 5.3.6) and the destination of the finished product.
- In all places visited the operators kept samples of feed materials, liquid materials and finished products for at least six months. However, in the approved feed mills visited the audit team noted that no samples were kept of the additives used; this was overlooked by the official controls.

Conclusions

With the exception of the requirement of keeping samples of ingredients used in the production, in particular feed additives, official controls are largely able to ensure that feed establishments meet the requirements concerning records for traceability and the keeping of samples laid down by Article 5(2) of Regulation (EC) No 183/2005.

5.3.6 HACCP-based procedures

Legal requirements

Articles 6 and 7 of Regulation (EC) No 183/2005 lay down requirements for feed business operators concerning procedures based on the HACCP principles.

Findings

- The audit team noted that official controls verify the existence and implementation of HACCP-based procedures.
- In all establishments visited, HACCP-based procedures were in place.
- In an approved feed mill visited, the audit team noted that the hazard analysis was comprehensive and assessed also the ingredients used for the production of feed.
- In two of the three feed mills visited, the audit team noted that the different hazards that could arise from ingredients used in the production were not analysed in the HACCP study. The hazard analysis considered only the production steps and the possible hazards that could be observed at these specific steps. As a result, the operators could not establish a risk-based own-checks programme; this was overlooked by official controls (see section 5.3.4).
- In the food establishment visited, the HACCP plan also considered the products destined to the feed chain. The audit team noted that no own-checks sampling plan was established for the feed materials as, according to the operator, most of the feed materials are of food quality and as such are covered by the quality and safety measures in place for food.

- In the dryer visited, the audit team noted that the HACCP-based procedures were focusing mainly in delivering a quality product as regards the humidity content; only humidity was monitored and recorded although increased temperature could be a risk for the safety of the product in terms of dioxin levels. In this respect, although the HACCP-based procedures were prescribing several samples per year for dioxins testing as verification of the correct drying, the audit team noted that in the last two years, only one sample was analysed (see section 5.3.4). These weaknesses were overlooked by the official controls.
- In an approved feed mill visited, the audit team noted that the HACCP-based procedures did not accurately reflect the activities carried out in the feed mill as there was no reference to the production of custom-made formulations for farmers who can supply ingredients as well. As a result, the risks arising from such supplied ingredients were not taken into account. In the said feed mill, the audit team noted that bags without any labels were stored and were to be used in the production. According to the operator these bags contained talc (Steatite) and were delivered by a farmer to be used in his own formulations (see section 5.3.1). These weaknesses were overlooked by the official controls.

Conclusions

The procedures based on the HACCP principles laid down by Articles 6 and 7 of Regulation (EC) No 183/2005 are largely in place. However, official controls are not in a position to ensure that all relevant risks have been identified and that they are adequately managed by the feed operators, because there are several flaws in the design of HACCP-based procedures and the risk assessment carried out on ingredients used for the production of feed.

6 Overall Conclusions

The registration and approval process of feed establishments, including those whose main activity is not in the feed area, has been satisfactorily performed by the competent authority. Official controls are carried out regularly along the feed chain and their prioritisation is largely based on risk; although not all relevant risk criteria are always taken into account. There are some weaknesses in the implementation of official controls, in particular in relation to the targeting of official sampling to verify compliance with the maximum permitted levels of cross-contamination from coccidiostats, an area where feed operators are not able to prove that the measures they put in place are effective. Similarly, official controls are not always able to ensure that feed operators implement HACCP-based procedures that effectively manage all relevant risks.

7 Closing Meeting

A closing meeting was held on 30 January 2013 with representatives of the Federal Ministry of Agriculture, Forestry, Environment and Water Management, BAES and AGES. At this meeting, main findings and preliminary conclusions of the audit were presented by the audit team. The central competent authority did not indicate any disagreement with these. During the meeting, additional information as requested by the audit team was provided by the competent authorities.

8 RECOMMENDATIONS

The competent authorities of Austria are invited to provide details of the actions taken and planned, including deadline for their completion, aimed at addressing the recommendations set out below within 25 working days after receipt of the report.

N°.	Recommendation
1.	To ensure that all risk criteria referred to in Article 3 of Regulation (EC) No 882/2004 are taken into account for prioritising official controls, such as the reliability of operator's own checks or previous history of non-compliance, and in the case of transporters, the particular risks arising from activities outside the feed chain such as transport of ABP and derived products.
2.	To ensure that official sampling takes account of the risk criteria laid down by Article 3 of Regulation (EC) No 882/2004, notably the possible presence of residues of packaging material and of residues of coccidiostats in feed for non-target species.
3.	To ensure that reports on official controls include details on the control methods applied and the results of the official controls and where appropriate, the actions that the business operator concerned is to take in case of non-compliance, as required by Article 9 of Regulation (EC) No 882/2004.
4.	To ensure that the national list of registered establishments, in particular food operators supplying food co-products to the feed chain is made available to the public as required by Article 19 of Regulation (EC) No 183/2005.
5.	To ensure that operators maintain and implement adequate procedures to demonstrate compliance with the requirements for homogeneity laid down by Article 5(2) of Regulation (EC) No 183/2005 and set out in its Annex II.
6.	To ensure that operators keep samples of all ingredients used in the production, in particular additives, as laid down by Article 5(2) of Regulation (EC) No 183/2005 and set out in its Annex II.
7.	To ensure that feed business operators make further progress concerning the design and implementation of the HACCP-based procedures required by Articles 6 and 7 of Regulation (EC) No 183/2005, so that all relevant risks are adequately controlled.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6737

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Dir. 2002/32/EC	OJ L 140, 30.5.2002, p. 10-22	Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement
Reg. 1831/2003	OJ L 268, 18.10.2003, p. 29-43	Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 183/2005	OJ L 35, 8.2.2005, p. 1-22	Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene
Reg. 767/2009	OJ L 229, 1.9.2009, p. 1-28	Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC
Reg. 1069/2009	OJ L 300, 14.11.2009, p. 1-33	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

Annex 2 - Requirements concerning the marketing of feed

1. Background

Regulation (EC) No 767/2009, which applies from September 2010, has resulted in a major recast of the legislation concerning the placing on the market and use of feed. The FVO is gathering information on a selected number of key requirements which are solely related to feed marketing in an attempt to establish the level of implementation of this Regulation in Member States.

2. Findings

Official controls on requirements of Regulation (EC) No 767/2009 are an integral part of official controls. Activities in the annual control plan for feed are classified either as safety related or as quality and fraud related. The controls on the requirements of Regulation (EC) No 767/2009 fall under the quality and fraud related activities. In 2011, some 1403 products were controlled for labelling and marketing requirements out of which 381 were non-compliant. In 2012, some 1539 products were controlled out of which 308 were found non-compliant.

2.1 Declaration of additives

Legal requirements

Article 15(f) of Regulation (EC) No 767/2009 lays down general mandatory labelling requirements for feed additives. These requirements are further specified in Chapter I of Annexes VI and VII to this Regulation.

Findings

In February 2012, AGES wrote to the Commission a letter explaining that the Austrian competent authorities are in favour of indicating on the labels the amount of the trace elements rather than the amount of the chemical compound. In the said letter it is explained that the calculation of the amount of trace element from the chemical compound is not feasible with a reasonable effort and, is impossible to carry out routinely during official controls. In addition, it is explained that there are currently no analytical methods available for routine determination of the chemical compounds.

- The competent authority stated that the Guidelines for labelling of feed materials and compound feed issued by the German competent authorities as well as the EU Code of good labelling practice for compound feed for food producing animals are used to assist in the implementation of the Regulation (EC) No 767/2009. As regards the labelling of trace elements, the audit team noted that both documents refer to the amount of trace elements rather than the amount of compounds.
- In the establishments visited, the audit team noted that feed was labelled with additives declared as the amount of active substances.
- In the feed mills visited the operators stated that in their views, the only way to ensure correct use of the products by the farmers is to provide them with information that is understandable for them; in the case of the trace elements this is the amount of trace elements in the product.

2.2 CLAIMS

Legal requirements

Article 13 of Regulation (EC) No 767/2009 lays down the conditions which have to be met for claims to be used.

Findings

According to the competent authorities, controls on the labelling of feed are integral part of the official controls carried out in feed establishments and special attention is paid towards disease-related claims.

- The competent authorities stated that official controls check on the presence of claims for all types of feedstuffs.
- The audit team saw examples where the competent authority had requested operators to remove from labels disease related claims. During the audit, the audit team did not see any labels containing claims related to curing of diseases or to productivity and performance.
- The audit team noted that the websites of the operators visited did not include any claims on their products. In only one case, the audit team noted that zeoliths were attributed mycotoxin binding capabilities.
- The audit team noted however, that advertisement brochures which the operators give to their customers contained a number of claims; these brochures were not publicly exposed and were provided to the audit team on request.

2.3 TRUTHFULNESS OF LABELLING

Legal requirements

Article 11(1) of Regulation (EC) No 767/2009 prescribes that labelling of feed shall not mislead the user.

Findings

- In all establishments visited, the audit team noted that none of the labels or packaging examined contained any indications attributing special characteristics to a product that could mislead the customers.
- The audit team noted that the competent authority took actions in cases where certain information (e.g. the target species) was missing from the labels.
- All official samples of feeds are accompanied to the laboratory in AGES by the label of the product sampled. Labels are then reviewed in light of the results of the analyses on the contents and incorrect information on composition are identified and acted upon.