EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6752 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SPAIN

FROM 19 TO 28 NOVEMBER 2013

IN ORDER TO EVALUATE MEASURES IN PLACE FOR THE IDENTIFICATION OF HAZARDS AND MANAGEMENT OF RISKS ALONG THE FEED CHAIN INCLUDING FOR OILS, FATS AND PRODUCTS DERIVED THEREOF

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 in Spain from 19 to 28 November 2013.

The overall objective of the audit was to evaluate whether the system for official controls was effective in verifying that operators along the feed chain identified hazards and managed properly the associated risks. In terms of scope, the audit focused on activities known, in the light of experience and past feed crises, to be more of a risk than others, including in particular those under the scope of Regulation (EC) No 225/2012. Moreover, the audit team also gathered information on the implementation of some requirements purely related to the marketing of feed.

Overall, the report concludes that the system of official controls cannot always ensure that operators along the feed chain identify hazards and manage properly the associated risks, since a) not all the identified risks affecting feed safety are considered when prioritising official controls b) it fails to detect shortcomings as regards identification of hazards linked to incoming materials or processes followed during handling of feed; notably, in one Autonomous Community, official controls were not able to detect and prevent the use of unsuitable materials and high risk production practices by food surplus recyclers, and c) cannot guarantee that the measures that operators put in place to minimise cross-contamination with coccidiostats or veterinary medicine products are effective.

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

Table of Contents

Abbreviations and definitions used in this report

Abbreviation	Explanation
CNCAA	National Animal Feed Coordinating Committee (*Comisión Nacional de Coordinación en Materia de Alimentación Animal)*
Cross-contamination	Presence, due to production, of additives, medicines or ingredients in feedingstuffs which should not contain them
FVO	Food and Veterinary Office
HACCP	Hazard analysis and critical control points
MAGRAMA	Ministry of Agriculture, Food and Environment (*Ministerio de Agricultura, Alimentación y Medio Ambiente)*
PCB	Polychlorinated biphenyls
Report 2011-8940	Report of an audit carried out in Spain from 08 to 18 February 2011 concerning feed safety

1 Introduction

This audit took place in Spain from 19 to 28 November 2013.

The audit team, which comprised 3 auditors from the Food and Veterinary Office (FVO) and a National Expert, was accompanied throughout the audit by a representative from the central competent authority, the Ministry of Agriculture, Food and Environment (*Ministerio de Agricultura, Alimentación y Medio Ambiente*-MAGRAMA*)*

An opening meeting was held on 19 November 2013 with the authority, 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 whether the system for official controls was effective in verifying that operators along the feed chain identified hazards and managed properly the associated risks.

The above was assessed against the following audit criteria:

- Regulation (EC) No 183/2005 of the European Parliament and of the Council.
- 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.
- Regulation (EC) No 882/2004 of the European Parliament and of the Council.

The audit also assessed the effectiveness of the corrective actions undertaken in response to the recommendations made following a previous FVO audit concerning feed safety (see section 4.2). Moreover, the audit team 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 and or products which, in the light of experience and past feed crises, are known to be more of a risk than others. (see section 4.1). The scope of the audit did not include the primary production of feed.

The itinerary for the audit included the following visits:

Visits/meetings		No	Comments
Competent Authority	Central	1	Opening and closing (de-briefing) meeting
	Regional	4	Meetings in the four Autonomous Communities visited
	Local	√	Discussions held in the course of visits to premises
Biodiesel plant		1	Placing on the feed market co-products from the refining process
Oleochemical plant		2	Placing on the feed market products derived from fats and oils
Fish oil manufacturer		1	Placing fish oil and fish meal on the market
Fat Blender		3	Placing on the feed market blends of oils
Approved Feed mills		5	Manufacturing compound feed using coccidiostats and/or veterinary medicines
Driers of feed		1	Drying cereals
Food surplus recyclers		2	De-packing and mixing food surplus to produce complementary feed

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

4.1 Rationale of the audit series

A previous series of audits carried out by the FVO in Member States in the area of feed safety was carried out between 2006 and 2011. After completion of the series, an overview report (reference DG(SANCO) 2012-6610 GR Final) summarising the main findings and conclusions was produced. Amongst others, this overview report noted that there were important deficiencies across the board on the implementation and official controls on procedures based on the hazard analysis and critical control points (HACCP) principles, an essential element for risk management at establishment level. The report is accessible at the following address:

http://ec.europa.eu/food/fvo/specialreports/overview_search_en.cfm

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 and/or products can be considered more of a risk than others, which resulted in the legislation being revised in some cases. In particular, Regulation (EU) No 225/2012 amending Annex II to Regulation (EC) No 183/2005

has introduced new requirements for establishments placing on the market, for feed use, products derived from vegetable oils and blended fats. These requirements concern the approval of these establishments, conditions for production, storage and transport, as well as the dioxin testing of fats, oils and products derived thereof.

For the above-mentioned reasons, a series of audits has started in 2012, focusing on some requirements of the legislation which concern the identification of hazards and the management of the associated risk.

4.2 Previous FVO audits

Report DG(SANCO)2011 – 8940 MR Final (hereafter: report reference) describes the results of a previous audit concerning feed safety carried out in Spain from 8 to 18 February 2011, and contains background information relevant to the current audit. This report made a number of recommendations to the competent authorities, who 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 is accessible at the following address:

http://ec.europa.eu/food/fvo/ir_search_en.cfm

4.3 Information on the feed sector

Report 2011-8940 provides an overview about the feed sector in Spain. In addition, the following information was provided by the competent authority about operators delivering their products or co-products to the feed chain.

The information contained in this section is to be limited to the types of establishments relevant within the scope of this audit (and which have not been covered by previous audits).

Type of establishment supplying the feed chain	Number
Processors of crude vegetable oils	20
Oleochemical manufacturers of fatty acids	16
Biodiesel plants	5
Fat blenders	11
Driers of feed (roughage)	194
Food surplus recyclers	7
Establishment placing on the market products destined for feed and products for other uses	27

5 Findings And Conclusions

5.1 Official control system

5.1.1 Competent authorities

Legal requirements

Article 4 of Regulation (EC) No 882/2004 lays down, amongst others, requirements for the designation of the responsible competent authorities and for their coordination and cooperation.

Findings

An overview of how control systems are organised in Spain is provided in the country profile, which is available at the following link:

http://ec.europa.eu/food/fvo/last5_en.cfm?co_id=ES

In summary, MAGRAMA is the central competent authority for feed. Its responsibilities include legislation, coordinating Autonomous Communities activities and interacting with the European Commission. It also interacts with representatives from the regions (officially known as Autonomous Communities) in the National Animal Feed Coordinating Committee (CNCAA), whose main tasks are follow-up and coordination with the said Autonomous Communities on the implementation of European Union and national rules on feed, proposing modifications necessary to achieve effective compliance with control objectives, advising Autonomous Communities, proposing studies and proposing coordinated control plans on animal feed and acting as forum for discussing any doubts as regards the implementation of feed legislation.

Autonomous Communities are responsible for implementation of feed hygiene legislation and organising controls along the feed chain (with the exception of controls on imports and exports of feed). This includes the verification of the efficiency of official controls. The organisation of the said controls is reflected in regional (Autonomous Communities) feed control plans, which in theory follow the structure and content agreed upon in the CNCAA. Autonomous Communities are also in charge of the approval and registration of establishments.

Food establishments supplying co-products destined for feed are controlled by feed inspectors in all the Autonomous Communities visited.

In the four Autonomous Communities visited, the competent authorities are as follows:

- *Andalucía.* At central level feed control responsibilities are shared between the Directorate General for Agriculture and Livestock and the Agency for the Management of Agriculture and Fisheries. Implementation of the regional feed control plan is carried out mainly by Territorial Delegations (representations in each province of the regional central services) and to a lesser extend by officials from the Local Veterinary Units (*Oficinas Comarcales*).
- *Cataluña.* The regional control plan is designed at (regional) central level and implemented at territorial level.
- *Extremadura.* The regional control plan is designed and implemented at regional central level by officials from the Service of Food, Agricultural and Livestock Quality.
- *País Vasco.* The Directorate for Agriculture and Livestock, at central level, is responsible for the design, coordination and implementation of the regional control plan. One of the three provincial delegations is also responsible for implementing this plan on ten establishments located within its boundaries.

The coordination and cooperation between the MAGRAMA and the Autonomous Communities is ensured by regular meetings held (around 5 times per year) at CNCAA. Within each Autonomous Community coordination and cooperation is ensured by means of regular exchanges of information (by email or by telephone), access to internal documents and instructions available to all the officials involved in feed controls and joint inspections between official at central and territorial level, when applicable.

- The audit team noted that the competent authorities in charge of official controls have been designated. All officials met had a largely clear understanding of their tasks and activities and of the system in place for official controls on feed. This is in line with the requirements set out in Article 4 of Regulation (EC) No 882/2004.
- The audit team saw evidence of the following: a) minutes of the meetings between MAGRAMA and all the Autonomous Communities, b) several examples of exchange of information between the central level and the feed inspectors in the field in all the Autonomous Communities visited. This is in line with the requirements set out in Article 4 of Regulation (EC) No 882/2004.
- In *País Vasco*, it was decided that from 2013 onwards, 10 feed establishments located in one of the provinces were to be inspected by provincial inspectors (they were previously visited by feed inspectors at central (regional) level. The audit team noted that the provincial inspectors did not have the necessary information (for instance previous inspection reports, official sampling results) to adequately perform official controls in these establishments. This was explained by the fact that feed inspectors at central (regional) level had not communicated this information to the said provincial inspectors. This is not in line with the requirements set out in Article 4 of Regulation (EC) No 882/2004.

Conclusions

The requirements concerning designation of competent authorities and their coordination and cooperation are complied with except for a small number of feed establishments located in one of the Autonomous Communities visited. This largely allows to avoid gaps in the organisation of official controls along the feed chain.

5.1.2 Organisation and delivery of official controls

Legal requirements

Article 3 of Regulation (EC) No 882/2004 establishes, amongst 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 recommendations of report 2011-8940 concerned the prioritisation of official controls. In their response, the competent authority undertook to include all the relevant parameters in the said prioritisation.

The general principles supporting the organisation of official controls of feed remain as described in report 2011-8940.

The national feed control programme and specific guidelines approved at the CNCAA reflect the relevant legal requirements concerning the risk criteria that must underpin official controls. For this purpose, it indicates a number of criteria that the Autonomous Communities can use to risk-rate feed establishments. These documents state that several factors can be taken into account in this context, namely the type of establishment (approved or registered), the specific activities they carry out (including drying), the history of non-compliances and the reliability of own controls. As for sampling, the CNCAA has produced a document where it is explained which are the risks linked to the different types of feed materials, premixtures and compound feed; as regards sampling for assessing the effectiveness of the measures put in place by the operators to minimise cross-contamination with coccidiostats or veterinary medicines, there is no specific instruction detailing how to perform it. The number of inspections and samples are also influenced by other criteria such as the alerts generated in the Rapid Alert System for Food and Feed, the recommendations from the European Commission and the results of previous years' controls. In addition, Autonomous Communities can apply other risk criteria (different from those mentioned above) to account for regional or local particularities.

Each year Autonomous Communities work out the number of inspections and samples to be done taking into account amongst others, the volume of feed production, the number of feed establishments, the number of farm animals and the resources available to perform official controls. This information, coupled with the application of the risk criteria mentioned above, results in a concrete number of establishments to be visited. Autonomous Communities are allowed to select randomly a small percentage of their establishments to be controlled in order to avoid visiting every year only those establishments considered to be higher risk. Samples are usually taken in the course of inspection visits and the matrices from where these samples are taken are chosen following the afore-mentioned guidance document from the CNCAA. According to representatives from MAGRAMA met, samples for measuring residues of packaging material are not included in the national feed control plan because there is no official method to measure these residues. In addition, no tolerance for these types of residues has been set up at national level.

- According to the representatives from *Andalucía* met, the total number of inspections and samples is distributed to the Territorial Delegations (one per province) by the central (regional) services. Five per cent of this number can be chosen by each Territorial Delegation based on their own criteria. Each Delegation receives a list with the name of each establishment to be visited; sampling is normally done in those establishments. The audit team noted the following:
    - All the establishments visited were subject to regular inspections in accordance with the established frequency. Official controls visits were unannounced or announced at very short notice.
    - Most of the risk criteria contained in the guidance approved in CNCAA were followed when risk rating establishments. However, the reliability of own control system and, within the activities carried out in a feed establishment, the distinction between direct and direct drying are not taken into account. Therefore, the relevant recommendation of report 2011-8940 is not satisfactorily addressed.
    - The official sampling programme routinely covers the relevant undesirable substances and some prohibited materials, with an adequate targeting and distribution between feed materials, premixes and compound feed. However, samples for

assessing the effectiveness of the measures put in place by the operators to minimise cross-contamination with coccidiostats or veterinary medicines are not adequately taken, despite the fact that the said operators are not performing correctly their own tests in this area (see section 5.2.4).

- The laboratory analysing official samples can measure the levels of all the coccidiostats listed in Directive 2002/32 EC except one.

- According to the representatives from *Cataluña* met, the total number of inspections and samples is distributed to the different Territorial Services. Inspectors based in these Services chose the establishments to visit taking into account their type of activity and history of non-compliances. As a result of those parameters, establishments are classified as high risk (must be inspected once a year), medium risk (to be inspected once every two years), low risk (to be inspected every four years-for instance producers of low risk feed materials-) and "others" (five per cent of which must be inspected every year-for instance, transporters-). The audit team noted the following:
  - Official controls visits were unannounced or announced at very short notice.
  - Aside from the type of activity, the rest of the risk criteria contained in the guidance approved in CNCAA were not taken into account when feed establishments were rated. Therefore, the relevant recommendation of report 2011-8940 is not satisfactorily addressed.
  - All the establishments visited were subject to regular inspection in accordance with the established frequency. However, two food surplus recyclers were receiving materials which could not be considered feed and were also using high risk production practices to obtain compound feed (see section 5.2.6). These establishments had been rated as low risk by the competent authorities and were therefore inspected, for feed purposes,[1] only once every four years. This does not meet the requirements laid down in Article 3 of Regulation (EC) No 882/2004.
  - The official sampling programme routinely covers the relevant undesirable substances and some prohibited materials, with an adequate targeting and distribution between feed materials, premixes and compound feed. However, samples for assessing the effectiveness of the measures put in place by the operators to minimise cross-contamination with coccidiostats or veterinary medicines are not adequately taken, despite the fact that the said operators are not performing correctly their own tests in this area (see section 5.2.4). In addition, official samples taken at the food surplus recyclers did not cover the risk posed by high risk producing practices (see section 5.2.6). This is not in line with Article 3 of Regulation (EC) No 882/2004.
  - The laboratory performing analysis on official samples can only measure the level of four (out of eleven) coccidiostats appearing on Directive 2002/32 EC.
- According to the representatives from *Extremadura* met, inspection and samples are performed by officials working at the regional central office. The audit team noted the following:
  - All the establishments visited were subject to regular inspection in accordance with the established frequency. Official controls visits were unannounced or announced at very short notice.
  - All the major risk criteria contained in the guidance document approved by CNCAA are used for the prioritisation of official controls. However, within the activities

1 These establishments were inspected once a year according to the animal by-products control plan.

carried out in a feed establishment, the distinction between direct and direct drying is not taken into account. This largely meets the requirements laid down in Article 3 of Regulation (EC) No 882/2004.

- The official sampling programme routinely covers the relevant undesirable substances and some prohibited materials, with an adequate targeting and distribution between feed materials, premixes and compound feed. However, samples for assessing the effectiveness of the measures put in place by the operators to minimise cross-contamination with coccidiostats or veterinary medicines are not adequately taken, despite the fact that the said operators are not performing correctly their own tests in this area (see section 5.2.4). This is not in line with Article 3 of Regulation (EC) No 882/2004.
- The laboratory performing analysis on official samples can only measure the level of four (out of eleven) coccidiostats appearing on Directive 2002/32 EC.

- According to the representatives of *País Vasco* met, with the exception of some feed establishments located in one of the provinces, inspections and sampling are performed by officials at regional central level. The audit team noted the following:
  - All the establishments visited were subject to regular inspection in accordance with the established frequency. Official controls visits were unannounced or announced with a very short notice.
  - Of all the risk criteria included in the guidance approved in CNCAA , the following were considered by the competent authorities from *País Vasco:* the activity of the establishment, non-compliance detected in the last two years, establishments which were at the origin of RASFF notifications and establishments (other than distributors) which start off their activities. The rest of risk criteria contained in the said document were not taken into account when feed establishments were risk-rated. Therefore, the relevant recommendation of report 2011-8940 is not satisfactorily addressed.
  - The official sampling programme routinely covers the relevant undesirable substances and some prohibited materials, with an adequate targeting and distribution between feed materials, premixes and compound feed. The example seen concerning the sample taken for assessing the effectiveness of the measures put in place by the operators to limit cross-contamination with coccidiostats or veterinary medicines was adequately targeted for measuring the situation in only one of the two production lines (see section 5.2.4). This is not in line with Article 3 of Regulation (EC) No 882/2004.
  - The laboratory performing analysis on official samples had a limit of detection for one coccidiostat that was 50 times higher than the lowest limit for that substance appearing on Directive 2002/32 EC.

Conclusions

Establishments to be inspected are targeted based on general risk factors. However, certain criteria are not fully taken into account in this exercise, amongst others, the reliability of operators' own controls and, in the case of *Cataluña,* the risk posed by the quality of material received in food surplus recyclers. These limitations do not allow competent authorities to prioritise their inspections taking into account all the relevant risks linked to operators' activities and operations affecting feed safety.

Official sampling is carried out following a risk-based approach linked to each type of raw material, premixture and compound feed handled in feed establishments. However, this sampling programme does not adequately cover the risk posed by cross-contamination with coccidiostats or veterinary medicines. Moreover, laboratories analysing official samples are not always capable to measure the relevant levels of all the coccidiostats used in the production of feed. In Addition, in *Cataluña* the sampling programme does not cover the risk posed by certain production practices carried out in food surplus recyclers (see section 5.2.6).

Overall, the system of official controls (inspection and sampling) does not enable competent authorities to fully assess the level of compliance of feed establishments with all the relevant legal requirements.

5.1.3 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

According to the representatives of all the Autonomous Communities visited, either a copy of the inspection report is left to the operator after the inspection or a summary with the main points checked and the non-compliances found is drafted after the visit and subsequently sent to the operator.

- The audit team noted that documents covering sampling and inspection establishments are available to feed inspectors. All the officials met were aware of their existence and were making use of them. This is in line with Article 8(1) of Regulation (EC) No 882/2004.
- In most of the establishments visited, the audit team noted that check-lists used by feed inspectors contained enough information and additional comments to know what particulars had been checked and on what basis a specific requirement had been considered satisfactorily complied with. In most of the Autonomous Communities visited, these lists included comprehensive sections covering cross-contamination, homogeneity and HACCP requirements. In addition, in two of the Autonomous Communities visited, the specific requirements contained in Regulation (EU) No 225/2012 had been included in the said lists. This is in line with Article 8(1) of Regulation (EC) No 882/2004.
- In the establishments visited, the audit team noted that reports of inspections were always made available to operators either directly at the end of the visit or at a later stage. This is in line with the requirements of Article 9 of Regulation (EC) No 882/2004.

Conclusions

Feed inspectors can avail of guidelines for performing inspections and sampling. This enables them to carry out these controls in a systematic way. In addition, the reports produced following those inspections include the necessary information to ascertain on which basis it is concluded that a requirement is fulfilled or not. As regards official reports, a copy of these was always given to operators; this gives the latter the necessary information to take adequate corrective actions when non-compliances are found during official controls.

5.1.4 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

Competent authorities performing official controls should meet a number of operational criteria so as to ensure that they are achieving the objectives of Regulation (EC) No 882/2004.

- The audit team noted that in all the Autonomous Communities visited the verification of the effectiveness of official controls consisted in a combination of a) reviewing, by a senior official, of inspection reports and other relevant documentation and b) carrying out joint inspections with members of the hierarchy or arranging for inspectors to inspect establishments located in different Territorial Delegations (other than their own).
- The audit team noted that the system for verification of official controls was not able to detect that official controls repeatedly missed certain non-compliances by feed operators; for instance, the adequateness of operators' arrangements to measure their cross-contamination, hazards identification in feed mills or the quality of incoming material and production practices in food surplus recyclers (see section 5.2.6).

Conclusion

There is a system in place for assessing the effectiveness of official controls, but it is not always capable of detecting problems affecting the quality of official controls in a timely fashion. This affects negatively the effectiveness of the said system.

5.1.5 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. Article 19 of this Regulation lays down requirements for the list of these establishments.

Findings

The relevant recommendation from report 2011-8940 concerned the registration and approval of feed establishments and their inclusion in a national list. In their response the competent authority undertook to complete the registration and approval process and include establishments in the national list.

MAGRMA maintains a national list of establishments to which all the Autonomous Communities upload the new registered or approved establishments. The information available in this list includes the different activities for which an establishment is registered or approved, which is mainly based on the type of product (i.e. additives, premixtures, compound feed or feed materials) produced, stored, placed on the market or transported. The activity of drying is not included in the information contained in the said list. As regards food establishments sending co-products for feed, these are

included in a separate list (the food establishment list).

According to the representatives from all the Autonomous Communities visited, establishments applying for registration and having to comply with the requirements of Annex II to Regulation (EC) No 183/2005 are required to submit, among other things, their HACCP plans in order to be registered. In addition, only one Autonomous Community envisages to carry out an inspection of the said establishments before granting the registration.

- The audit team noted that al the establishments visited were approved or registered, as applicable. In addition, all the Autonomous Communities visited had a good knowledge of those establishments requiring reinforced dioxin monitoring testing or approval under Regulation (EU) 225/2012. This is in line with requirements of Article 9 and 10 of Regulation (EC) No 183/2005.
- The audit team noted that all the establishments contained in the list which each Autonomous Community maintains were also included in the national list. This is in line with the requirements of Article 19 of Regulation (EC) No 183/2005. However, in the food establishments list, the activity of sending co-products for feed cannot be seen by the public yet; only competent authorities have access to it.[2]
- The audit team noted that the number of establishments approved and registered in *Andalucía* has significantly increased. This is in line with the requirements of article 19 of Regulation (EC) No 183/2005. Therefore the relevant recommendation of report 2011-8940 has been satisfactorily addressed.
- The audit team noted that in three of the Autonomous Communities visited a pro-active approach had been followed to find feed establishments requiring registration or approval. For instance, a) in *Extremadura* the competent authority requested all the feed mills to provide the list of suppliers to find out if the latter were registered or approved as applicable, b) in *Cataluña* the competent authority sent more than 5000 letters to inform food establishments sending co-products for feed about their obligation to register as feed operators and c) In *País Vasco* letters were also sent to the association of producers of cider. This is in line with the requirements of Article 9 and 10 of Regulation (EC) No 183/2005.
- The audit team noted that in *Cataluña* some food establishments sending co-products (intended to be used as feed materials) to two food surplus recyclers were not registered as feed establishments. This is not in line with the requirements of Article 9 of Regulation (EC) No 183/2005.

Conclusions

All the establishments visited were approved or registered and this facilitates checks on the traceability of the products these establishments place on the market, as well as the organisation of official controls on the said establishments. However, in *Cataluña,* despite the proactive approach taken by competent authorities to identify and register or approve (as applicable) those operators active in the feed chain, there is still a number food establishments sending co-products for feed which are not yet registered; this does not allow competent authorities to ensure that all the products intended for use in feed comply with the relevant legal requirements.

The information on the lists of establishments available to the public largely allows to know for which specific activities these establishments were approved or registered. This enables other

2 According to MAGRAMA , this information is planned to be made available to the public by the end of 2013.

operators and competent authorities to know if establishments are only placing on the market products covered by the activities for which they have been specifically approved or registered, as applicable.

5.1.6 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

The relevant recommendation of report 2011-8940 concerned actions to be taken when non-compliances were detected. In their response the competent authority undertook to further improve the situation in this regard.

Regulation (EC) No 882/2004 states that when competent authorities identify non-compliances, they shall take action to ensure the operator remedies the situation.

- In all the Autonomous Communities visited, the audit team saw some examples of shortcomings detected during official controls, deadlines proposed and follow-up activities that resulted in operators remedying the said non-compliances in a largely timely fashion. However, the audit team noted the following:
    - In *Extremadura* the competent authority detected in 2009 a non-compliance related with HACCP in a small feed mill; despite several warning letters sent to the operator over the following years, the said establishment did not correct the deficiencies until 2012. This shows that the relevant recommendation of report 2011-8940 remains unaddressed.
    - In *Andalucía* official controls detected some shortcomings regarding homogeneity and cross-contamination in a feed mill in 2009 (see section 5.2.4). The owner of this establishments was given verbal and writing warnings to solve the deficiencies but these were not yet corrected at the time this audit was carried out. This shows that the relevant recommendation of report 2011-8940 remains unaddressed.

Conclusions

Non-compliances detected during official controls are largely followed up but measures designed to rectify them are not always enforced efficiently. This does not always allow competent authorities to ensure that suitable corrective actions are taken in a timely manner.

5.2 Official controls on requirements along the feed chain

5.2.1 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 this Regulation indicates that the requirements set out in its Annex II shall be met for operations other than those regarding primary production; amongst others, these requirements concern the labelling on whether products

are intended for feed or other purposes.

Specific labelling requirements are laid down for feed materials and for compound feed by, respectively, Articles 16 and 17 of Regulation (EC) No 767/2009, and for feed additives and premixtures by Article 16 of Regulation (EC) No 1831/200.

Findings

- Official controls largely include a verification on whether the suppliers of feed materials, premixtures and additives of the feed establishments inspected are registered or approved as required. This is in line with the requirements of Article5(6) of Regulation (EC) No 183/2005.
- Except in the two food surplus recyclers visited, where a number of suppliers (food establishments) were not registered, the audit team noted that in the rest of establishments, those suppliers checked were approved or registered, as applicable. This is in line with the requirements of Article5(6) of Regulation (EC) No 183/2005.
- The audit team noted that in two of the three establishments visited handling both products intended for feed and for other uses, the latter were not specifically labelled as such. This is not in line with the requirements of Article 5(2) of Regulation (EC) No 183/2005.
- The audit team noted that, with the exception of the food surplus recyclers and one oleochemical plant, incoming and outgoing products found in the establishments visited were correctly labelled as feed. This is in line with the requirements of Article 15 of Regulation (EC) No 767/2009 and Article 16 of Regulation (EC) No 1831/2003.

Conclusions

In most cases, official controls pay attention to the sourcing and labelling requirements applicable to feed received or delivered from traditional feed establishments. However, this is not always the case as regards a) incoming material received by the food surplus recyclers and b) the labelling of those products destined for other uses handled in establishments also handling products intended for feed. This makes it more difficult for competent authorities to detect any potential diversion into the feed chain of products not suitable to be used as feed.

5.2.2 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 concern some of the requirements at the level of facilities and equipment, production, storage and transport.

Findings

- The audit team noted that feed inspectors pay attention during official controls to the infrastructural and organisational requirements in feed establishments. This is in line with the requirements of Article 5(2) of Regulation (EC) No 183/2005
- The audit team noted that in those establishment handling both feed and products intended for other uses, cross-contamination was not possible since the same product is sold either as feed grade or technical grade depending of the demand of each one of them. Feed inspectors met were aware of the requirements on the separation of these two types of products. This is

in line with the requirements of Article 5(2) of Regulation (EC) No 183/2005.

- The audit team noted that in the two food surplus recyclers visited, material not suitable for feed was received and processed to obtain compound feed (see section 5.2.6). This was overlooked by the feed inspectors at the said plants. This is not in line with the requirements of Article 5(2) of Regulation (EC) No 183/2005

Conclusions

Except in the case of food surplus recyclers in *Cataluña*, official controls pay attention to infrastructure and organisational requirements, thus largely ensuring that there is no cross-contamination between feed and products intended for other uses.

5.2.3 Dioxin 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, amongst others, dioxin monitoring arrangement for fats, oils or products derived thereof.

Findings

Annex II to Regulation (EC) No 183/2005 requires that processors of crude vegetable oils analyse, for dioxins and dioxin-like PCB, 100 % of incoming crude coconut oil as well as 100 % of the batches of certain products derived from vegetable oils. The above-mentioned Annex requires that biodiesel plants analyse amongst other things, 100 % of the incoming batches of crude coconut oils and products derived from vegetable oils except glycerol, lecithin and gums.

According to the information provided by the operator of the Biodiesel plant visited, a) the plant processes (physical refining) vegetable oils and subsequently transforms the fully refined oil in biodiesel and b) fatty acids from the refining process and glycerine from the biodiesel process are sold as feed materials; fatty acids from the biodiesel process are re-utilised on site. The audit team noted the following:

- Fatty acids from the refining process were sold for feed in 2012. A sample of every truck of this product was taken, and a pooled sampled comprised of these individual samples was sent to the laboratory to analyse for dioxins and dioxins-like PCB. The product was dispatched as feed material without knowing the result of the test, which was sent to the customers once the result from the laboratory was available. The results thereof seen by the audit team were compliant. The operator explained that these tests were performed in the context of their own controls and not because they were required to do so under Regulation (EU) No 225/2012. He added that their interpretation of the said legal text is that the term "production of biodiesel" comprised both processing of crude oil (i.e. refining) plus the methyl esterification (i.e. the chemical reaction that produces the actual biodiesel) and therefore the legal requirements concerning processors of crude vegetable oils (i.e. the need of testing the fatty acids derived from this process if sold for feed) were not applicable to them. The audit team noted that the competent authorities shared the approach followed by the operator.

Annex II to Regulation (EC) No 183/2005 requires that oleochemical plants analyse among other things, 100 % of the incoming batches of crude coconut oils and products derived from vegetable oils except glycerol, lecithin and gums. They must also analyse 100 % of the batches of products

derived from the processing of the products mentioned above, except glycerol, lecithin and gums. The audit team noted the following:

- In one of the oleochemical plant visited, crude oils were refined and the following derived products were placed on the market as feed: hydrogenated fatty acids, lauric acids and acid oils; 100 % of the batches of these products were tested for dioxins and dioxins-like PCB. As for the incoming product, every batch of imported crude coconut oil was tested for dioxins and dioxins-like PCB; the company considers as batch the entire vessel (ship) and takes a representative sample from all compartments of the ship (a pooled sample is analysed from a 5000 tonne boat). The laboratory results seen of both incoming and outgoing products showed always compliant levels of dioxins and dioxins-like PCB. The competent authority has classified this plant as oleochemical due to its activity of hydrogenation of fatty acids.
- In another oleochemical plant visited, soap stocks and gums derived from the refining of vegetable oils were received and treated on site. The treatment consisted in extracting the fatty acids contained in these products by mixing them with sulphuric acid after which a deodorising process took place in order to eliminate other impurities. The said incoming materials were not always accompanied by an analysis of dioxins and dioxin-like PCB since, according to the owner, he receives these products globally labelled as "gums" and these are exempt from the dioxin testing according to the relevant legislation. The audit team noted that the competent authorities agreed with this approach[3].
- In the above-mentioned plant, the product contained in a 700 tonne tank was considered a batch; this tank was sampled and this sample was sent to a laboratory for analysing dioxins and dioxin-like PCB (the results thereof seen by the audit team were always compliant). After the tank, the product was sent to the deodoriser, where it was subject to a combination of vacuum pressure and temperature. However, no dioxin tests were carried out on the product exiting the deodoriser (see section 5.2.6).

Annex II to Regulation (EC) No 183/2005 requires that fat blenders analyse for dioxins and dioxin-like PCB, 100 % of incoming batches of certain commodities or that they analyse 100% of the blended fats intended for feed. The audit team noted the following:

- In two of the fat blenders visited, 100 % of both incoming and outgoing products were analysed for dioxin and dioxin-like PCB. The results thereof seen by the audit team were always compliant.
- One category 3 processing plant visited was sending fat as raw material for feed. This establishment was taking a sample per 2000 tonnes produced and analysing it for dioxins and dioxin-like PCB (the results thereof seen by the audit team were compliant). The customers of this fat received the product along with an statement from the company saying that the fats had been analysed in a representative way and that all the relevant aspects of Regulation (EU) No 225/2012 were complied with. The feed inspector met at the establishment said that she was not aware of the said statement. During an inspection performed in November 2013, the same feed inspector found out that this establishment was purchasing Category 3 fat and mixing it with that produced in his own plant. A comprehensive report was produced as a consequence; in this report the establishment was requested to apply for the approval as a fat blender and to start the dioxin testing regime applicable to these types of plants.

3 According to several technical manuals seen, gums and soap stocks are two different products derived from different steps of the refining of oils. The former results from the removal of phospholipids from the crude oil by mixing it either with water or an acid and the latter results from the removal (during chemical refining) of fatty acids by mixing the crude oil with an alkaline salt.

Annex II to Regulation (EC) No 183/2005 requires that certain operators of fish oil analyse, for dioxins and dioxins-like PCB, 100 % of fish oil if produced from products derived from crude fish oil other than refined fish oil. They shall also analyse one representative analysis per 2000 tonnes of certain type of fish oil. The audit team noted the following:

- The operator of fish oil visited was producing around 3000 tonnes of fish oil per year and was analysing the oil for dioxins and dioxins-like PCB once a year. This was detected by feed inspectors, who requested the operator to adjust the frequency of analysis to the production of 2000 tonnes.

Annex II to Regulation (EC) No 183/2005 requires that producers of Category 3 animal fats carry out one representative analysis per 2000 tonnes of animal fat products. The said Annex also requires that producers of compound feed for food producing animals analyse, for dioxins and dioxin-like PCB, 100 % of incoming batches of certain commodities (including fats not subject to a representative analysis of 2000 tons) and 1% of the final feed containing any of those commodities. These establishments can avail of a derogation allowing them not to test the said 1% if they can demonstrate that the incoming batches of the above-mentioned commodities have already been analysed (at an early stage of production, processing or distribution) for the presence of dioxins and dioxin-like PCB and the result thereof is acceptable. In the feed mills receiving oils, fats or products derived thereof visited, the audit team noted the following:

- In one feed mill, consignments of fat arrived either accompanied with a laboratory result for dioxins and dioxin-like PCB (from a producer of animal fats) or with a statement from the supplier saying that the establishment was registered in accordance with Regulation (EC) No 183/2005. The audit team noted that there was no link between the analysis and the batch of fats received. The operator stated that they did not analyse for dioxins and dioxins-like PCB 1% of the final feed containing the said fats. These shortcomings were overlooked by the feed inspectors at the plant.
- In one feed mill, a consignment of animal fat was received from a producer of animal fats along with a laboratory result obtained five months prior to to despatch of the consignment. The operator at the feed mill confirmed that he did not have any evidence, aside from a verbal statement from the said provider, showing that the laboratory result covered the consignment received.[4] The operator also stated that they did not analyse for dioxins and dioxin-like PCB i.e. 1% of the final feed containing the said fats. These shortcomings were overlooked by the feed inspectors at the plant.
- In one feed mill visited, eight consignments of protected fat for ruminants were received in 2013 without any dioxin tests.[5] The operator also stated that they did not analyse for dioxins and dioxin-like PCB 1% of the final feed containing the said fats. These shortcomings were overlooked by the feed inspectors at the plant
- In one feed mill visited, the operator showed the audit team documents accompanying consignments of fats coming from a producer of animal fats. In the said documents there was an invoice and a laboratory report for dioxins and dioxin-like PCB but it was not possible to know if the laboratory results corresponded to the consignment sent. The operator also stated that they did not analyse for dioxins and dioxin-like PCB i.e. 1% of the final feed containing the said fats. These shortcomings were overlooked by the feed inspectors at the plant.

4 The audit team visited the said provider of fat. According to the volumes of production and sells and the definition of a batch seen in that plant, it is theoretically possible that consignments belonging to the same batch (analysed for dioxins and dioxins-like PCB) were dispatched over a period of several months.

5 These results were made available to the audit team after the audit; they were complaint with the relevant legal limits.

Annex II to Regulation (EC) No 183/2005 requires that where a feed business operator mandates a laboratory to perform an analysis, he shall instruct the laboratory to communicate the results of that analysis to the competent authority in case the said results are non-compliant. The audit team noted the following:

- The producer of Biodiesel, the fish oil operator, one oleochemical plant and one fat blender visited had an agreement with a laboratory whereby any non-compliant result of dioxins had to be communicated to the relevant competent authority.
- One oleochemical plant and one fat blender visited did not have any such agreement. This was overlooked by the feed inspectors at those plants.
- One fat blender visited did not have any such agreement with a laboratory; this was detected by the feed inspector during the last inspection to the establishment.

According to the competent authorities from the different Autonomous Communities visited, the turnaround time for dioxin results varied from two weeks two one month and a half.

Conclusions

Competent authorities have largely a good knowledge of the processes and risks associated with biodiesel, oleochemical and fat blending operations. However, official controls are not in a position to ensure that the obligations of producers of compound feed for food producing animals concerning dioxin testing are met, since neither the said producers nor the competent authorities have found a way to establish a clear link between each consignment of fats received and the accompanying laboratory results for a representative analysis of 2000 tonnes. In addition, these official controls cannot always ensure that feed establishments mandate the laboratories to report any non-compliant result to the relevant competent authority. These shortcomings compromise the adequate functioning of the system of official controls.

5.2.4 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, amongst 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

Cross-contamination

Annex II to Regulation (EC) No 183/2005 states that technical or organisational measurements must be taken to avoid or minimise any cross-contamination and errors. There must be sufficient and appropriate means of carrying out checks in the course of manufacture.

- The audit team noted that feed inspectors pay attention to the requirements regarding cross-contamination with coccidiostats or veterinary medicines. Comprehensive check-lists covering this point are used during inspections.
- According to the operator of one feed mill visited, several types of antibiotics are used for the production of medicated feed; cross-contamination tests are carried out once a year and the results have always deemed compliant. The audit team noted that a) the measures put in

place by the operator to minimise cross-contamination consisted in flushing (30 kg of barley), specific order of manufacturing different types of feed (sequencing) and physical automatic cleaning of the line, b) in 2012 oxitetracycline was used as a tracer to measure the level of cross-contamination and the results were either considered compliant (as in the results seen) or not depending on the absolute amount of the oxitetracycline measured in the clean feed produced immediately after the one containing the said antibiotic, c) the feed mill manufacturers feed containing at least three different antibiotics, but only one has been used for measuring cross-contamination and d) the cross-contamination occurring in the part of the circuit after the mixer is not measured, since the samples for this measurement are taken only immediately after the mixer. Official controls did not detect these shortcomings; in addition, no official sample to assess cross-contamination was taken in this establishment.

- According to the operator of one feed mill visited, several types of antibiotics and coccidiostats are used for the production of feed and the last cross-contamination tests were performed in 2009. He stated that cross-contamination in his plant is under control since, there are no rejections at farm level of milk from the animals fed with his feed. The audit team noted that a) the measures put in place by the operator to minimise cross-contamination consisted in flushing (with 100 kg of material) and sequencing and b) the cross-contamination test in 2009 consisted in a inhibition test, which is a procedure not valid for coccidiostats; this was overlooked by feed inspectors, who, during the last inspection visit, considered that the requirements concerning cross-contamination were adequate. An official sample to measure cross-contamination was taken in this establishment by feed inspectors; this sample only covered the line manufacturing pelleted feed but not the one manufacturing meal. The results of this sample were not made available to the provincial inspectors. In addition, the limit of detection of the laboratory where this sample was processed could not detect the levels required by the relevant legislation (see section 5.1.2).
- According to the operator of one feed mill visited, several types of antibiotics are used for the production of medicated feed for pigs; a test for measuring cross-contamination is undertaken annually. The audit team noted that a) the measures put in place by the operator to minimise cross-contamination consisted in sequencing and this was observed in the examples seen b) zinc oxide was used as a tracer to measure cross-contamination and only three samples (subsequently pooled in one) for this measurement were taken when loading the truck with the final product; no other antibiotic was used in 2012 and 2013 to measure this parameter; this was overlooked by the feed inspectors at the establishment, who confirmed that no official samples to assess cross-contamination were taken in this site and c) a threshold level of 5 % carry-over was set up by the operator to decide if the cross-contamination was acceptable or not (the result of the last test seen was 4.38%).
- According to the operator of one feed mill visited, coccidiostats were used for the production of compound feed for poultry and a test for measuring cross-contamination is done every fifteen days. The audit team noted that a) the operator used sequencing and automatic physical cleaning of the line as measures to minimise cross-contamination b) the procedure for measuring cross-contamination (obtained from the laboratory processing the samples) included the use of micro tracers; however, the operator confirmed that the samples for measuring cross-contamination are taken from feed produced without any added substance and c) a result of a cross-contamination test seen (dated November 2013) measured the level of this parameter by the amount of micro tracer detected. These shortcomings were first detected by the feed inspectors at the plant in 2009 but they were

still on-going at the time the audit was performed. The said inspectors confirmed that no official sample to measure cross-contamination was taken in this establishment.[6]

- According to the operator of one feed mill visited, several types of antibiotics and coccidiostats are used for the production of feed; a test for measuring cross-contamination is undertaken annually. The audit team noted that a) the operator used sequencing as a measure to minimise cross-contamination and b) zinc oxide is used as a tracer to measure cross-contamination and samples for this purpose are taken only immediately after the mixer; no other veterinary medicines or coccidiostats are used for this test. This was overlooked by the feed inspectors at the establishment, who stated that an official sample to assess cross-contamination (with a coccidiostat) was taken in this establishment in 2011; however, the audit team noted that the batch previous to the one from which this sample was taken did not contain any coccidiostat.

Homogeneity

Annex II to Regulation (EC) No 183/2005 states that operators shall demonstrate the effectiveness of mixers with regard to homogeneity.

- The audit team noted that feed inspectors pay attention to the requirements regarding homogeneity. Comprehensive check-lists covering this point are used during inspections.
- The audit team noted that a) in four of the five the feed mills visited homogeneity was measured at least once a year b) in some cases, analytical constituents were used to measure these parameters and c) most of the values obtained were below the limit set by the feed operators (usually between 10 and 15 % expressed as coefficient of variation).
- In the feed mill producing feed with coccidiostats for poultry (see above) the same procedure was used to assess cross-contamination and homogeneity. The operator stated that each week a homogeneity test was carried out. The only result available (dated November 2013) also considered the homogeneity as satisfactory. These shortcomings were first detected by the feed inspectors at the plant in 2009 but they were still on-going at the time the audit was performed (see footnote 6).

Undesirable substances and other contaminants

Annex II to Regulation (EC) No 183/2005 states that the presence of prohibited material, undesirable substances and other contaminants shall be monitored and appropriate control strategies to minimise the risk posed by the above-mentioned materials shall be put in place.

- The audit team noted that feed inspectors pay attention to the requirements regarding the obligation of operators to monitor and control the risks related to contaminants. Check lists used by feed inspectors contained questions covering this topic.
- According to the operator of one feed mill visited, sampling for monitoring the level of contaminants in feed materials is done as a part of a project where several feed establishments carry out this sampling collectively. The results thereof are communicated to each member and to the relevant competent authority. The audit team noted that a high number of samples were taken and the results seen were compliant.
- In the rest of the feed mills visited, the audit team noted that samples for measuring the level of undesirable substances were limited and were not correlated to specific risks linked to each type of feed materials received. For instance, in one feed mill the presence of heavy metals was considered a hazard equally applicable to all types of incoming materials without

6 During the final meeting, the relevant competent authority showed the audit team an official inspection report to this establishment where it was indicated that these deficiencies (cross-contamination and homogeneity) had to be rectified within fifteen days of the inspection date.

any justification for this approach. As a result, feed with a high content of minerals (the type of feed where contamination with these substances most frequently occur) was not specifically targeted when sampling for these contaminants. In another feed mill, no samples were taken for measuring the level of dioxins in the the kaolinitic clay received (despite this risk having been clearly documented in the scientific literature) and this was not justified by the operator with an analysis from the supplier or any other kind of supporting information. The deficiencies above were not detected by feed inspectors at these establishments.

- In the feed establishments handling oils or products derived thereof visited, the audit team noted that samples for measuring undesirable substances were largely linked to the risks associated with the feed materials received and final products produced. For instance, most of the these establishments included dioxins and, where relevant, also pesticides in their own sampling plan. The results thereof seen were compliant.
- In one food surplus visited, the audit team saw a pile of incoming material at the intake bay. In this pile there were food surplus products (mainly bakery products, chocolates, candies and pizzas) along with some urban solid waste not suitable for feed; for instance, adhesive tapes rolls, empty tooth paste tubes and numerous plastic bags. According to the operator of this plant, samples for assessing residues for packaging material in the final product were taken and the level found was around 0.4 % . The audit team noted that in the final product, some residues of packaging material were clearly visible to the naked eye. The above deficiencies were overlooked by feed inspectors.
- In another food surplus visited, the audit team saw a pile of incoming material at the intake bay. In this pile there were food surplus products (mainly bakery products, chocolates and biscuits) along with some urban solid waste not suitable for feed; for instance, there were cardboard rolls, empty plastic containers and broken wooden pallets. In the final product, some residues of packaging material were clearly visible to the naked eye. The above deficiencies were overlooked by feed inspectors.

Conclusions

Official controls are not in a position to ensure that the requirements concerning cross-contamination are fully complied with at establishment level. In particular, these controls cannot guarantee that the measures which operators implement to minimise cross-contamination with coccidiostats or veterinary medicines are effective, because a) feed inspectors largely fail to detect that operators' arrangements for measuring cross-contamination are poorly designed or executed and b) official sampling for this purpose is rarely performed or it is performed incorrectly. This affects negatively the ability of competent authorities to ensure that the feed for non-target species always complies with the maximum permitted levels of coccidiostats or veterinary medicine products.

As regards homogeneity, official controls can largely ensure compliance with the requirements related to this aspect.

Concerning undesirable substances and other contaminants, official controls cannot always ensure that certain feed operators monitor and control the relevant contaminants as a) they fail to detect that operators' sampling plans in feed mills are generic and do not consider the different risks linked to different feed materials, and b) they are not able to detect that food surplus recyclers do not have adequate measures in place to ensure that no unsuitable material for feed is processed along with food surplus products. This does not allow competent authorities to fully guarantee that feed placed on the market is always sound, genuine and of merchantable quality.

5.2.5 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

Annex II to Regulation (EC) No 183/2005 states that feed business operators shall take adequate measures to ensure effective tracing of the products.

- The audit team noted feed inspectors do pay attention to the requirements regarding the obligation of operators taking adequate measures to ensure effective tracing of the products. Check lists used by feed inspectors contained questions covering this topic.
- In all the feed establishments where this was checked, the audit team noted that a) samples for all the ingredients and final products were adequately kept and b) practical exercises showed that the traceability system was able to trace products backwards and forward.

Conclusions

There is a system in place that ensures compliance with requirements related to traceability.

5.2.6 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 feed inspectors pay attention to the requirements regarding the HACCP-based procedures. Check lists used by feed inspectors contained questions covering this topic.
- According to the operator of one food surplus recycler visited, solid and liquid material was received from different types of food establishments, the latter in different types of containers. The liquid surplus was destined for pigs and the solid material for petfood. The audit team noted the following:
    - Incoming material is taken from the pile at the intake bay (see section 5.2.4) to be processed for removing packaging material. This processing consists of shredding, drying and sieving. Drying was applied to the material coarsely shredded (before the removal of packaging material); it took place in a direct drying apparatus, where the product was subject to a decreasing range of air temperature, starting at 500ºC and finishing at 85ºC; however, the possible risks of dioxins or polycyclic aromatic hydrocarbons formation during this drying was not assessed by the operator. After drying, further shredding and sieving was carried out; as a consequence, the remaining residues of packaging material were reduced to a very small size, enough to go through a one millimetre sieve.
    - Liquid products arrive in cans, plastic containers, tetra-packs or glass containers; they are then crushed to recover the liquid contents. The liquid is separated from the

crushed solid material through filtering and decantation. The HACCP manual described the hazard of residues in the extracted liquid product, which is controlled by means of a critical control point consisting in a three millimetres mesh plus a decanting device. However, the operator did not have evidence that these measures were effective in removing all the small pieces of crashed glass from the liquid since there was no analytical result for this.

- The above-mentioned deficiencies were overlooked by feed inspectors at the plant, who stated that the official samples taken at this establishment were analysed for mycotoxins, heavy metals, pesticides and coccidiostats, but not for assessing the presence of residues of packaging materials or other prohibited material.

- According to the operator of another food surplus recycler visited, solid and liquid material was received from different types of food establishments. The liquid surplus was destined for pigs and the solid material for farm animals. There is a general contract with suppliers whereby only material suitable for food can be sent for processing. Excess packaging material results in a reduction of the price paid to the food establishment supplying the product, but only occasionally in its rejection. The audit team noted the following:
  - Incoming material is taken from the pile at the intake bay (see section 5.2.4) in order to remove the packaging material. This processing consists of shredding, drying and sieving. Material coarsely shredded was subjected to indirect drying at low temperatures. It was subsequently finely grounded and sieved.
  - Liquid products arrive in several types of containers including glass; they are then crushed to recover the liquid contents. The liquid is separated from the crushed solid material by decantation. However, the operator could not demonstrate the effectiveness of this measure because there were no analytical results for that purpose.
  - The above-mentioned deficiencies were overlooked by the feed inspectors at the plant, who confirmed that no samples for assessing the presence of packaging materials or other prohibited material (for instance glass) had been taken in this establishment.
- In most of the feed mills visited, the audit team noted that they have implemented generic HACCP-based procedures which did not fully take into account the risks derived from the the incoming materials; there was no clear link between the risk assessment reflected on their HACCP plan and the intensity of sampling for some undesirable substances. As a consequence, the said sampling was poorly targeted (see section 5.2.4). Official controls overlooked these deficiencies.
- In the file of one direct drier examined, the audit team noted that no chemical hazards were identified from the type of fuel or the type or drying used. This was overlooked by feed inspectors, who were not clear on the distinction between direct and indirect drying.
- According to the operator of one oleochemical plant visited, the risk of dioxin concentration during the deodorisation step was ruled out due to the low working temperature (around 105ºC); however, the said operator did not provide any evidence supporting such risk management decision. The audit team noted that the competent authority did not require him to provide such evidence.
- The audit team noted that in most of the establishments handling oils and products derived thereof visited (i.e. refineries, fat blenders and oleochemical manufacturers) comprehensive and fit for purpose HACCP plans were in place and implemented.

Conclusions

Except in those establishments handling oils and products derived thereof, official controls cannot always ensure that feed establishments comply with the requirements on procedures based on HACCP principles, since there are deficiencies in their design and implementation, in particular as regards the identification of hazards linked to incoming materials or processes followed during handling of feed. This situation was observed also in feed mills, but it was of particular importance in food surplus recyclers, where the competent authorities overlooked that these operators follow high risk production practices.

6 Overall Conclusions

The system of official controls cannot always ensure that operators along the feed chain identify hazards and manage properly the associated risks, since a) not all the identified risks affecting feed safety are considered when prioritising official controls b) it fails to detect shortcomings as regards identification of hazards linked to incoming materials or processes followed during handling of feed; notably, in one Autonomous Community, official controls were not able to detect and prevent the use of unsuitable materials and high risk production practices by food surplus recyclers, and c) cannot guarantee that the measures that operators put in place to minimise cross-contamination with coccidiostats or veterinary medicine products are effective.

7 Closing Meeting

A closing meeting was held on 28 November 2013 with the representatives of the central competent authority. 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 major disagreement with these. During the meeting, additional information as requested by the audit team was provided by the central competent authorities.

8 Recommendations

The competent authorities of Spain are invited to provide details of the actions taken and planned, including deadlines 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 compliance with the requirements of Article 3 of Regulation (EC) No 882/2004, in particular as regards: a) taking into account all the relevant risks (including the reliability of feed operators' own-checks) linked to activities and operations when risk-rating, inspecting and sampling feed establishments, and b) ensuring that official sampling for analysing cross-contamination with coccidiostats in feed for non-target species is able to cover all the substances included in Directive

N°.	Recommendation
	2002/32 EC.
2.	To ensure that the system for assessing the effectiveness of official controls is able to detect in a timely manner shortcomings in the quality of the these controls, as laid down by Article 8(3)(a) of Regulation (EC) No 882/2004.
3.	To ensure that non-compliances detected during official controls are always rectified in a timely manner, as laid down by Article 54 of Regulation (EC) No 882/2004 .
4.	To ensure that the labelling of products clearly indicates whether they are intended for feed or for other purposes, as laid down by Article 5(2) of Regulation (EC) No 183/2005 and Annex II to the said Regulation.
5.	To ensure that requirements laid down by Article 5(2) of Regulation (EC) No 183/2005 and Annex II to the said Regulation are complied with in that a) producers of compound feed for food producing animals follow the relevant dioxin monitoring arrangements and b) feed establishments mandate laboratories to report any non-compliant result to the relevant competent authority.
6.	To ensure that feed operators meet the requirements of Article 5(2) of Regulation (EC) No 183/2005 and Annex II to the said Regulation related to performing appropriate checks to measure cross-contamination with coccidiostats or veterinary medicines in feed for non-target species and ensuring that measures implemented by these operators to minimise the said cross-contamination are effective.
7.	To ensure that the requirements of Article 5(2) of Regulation (EC) No 183/2005 and Annex II to the said Regulation concerning monitoring of undesirables substances and other contaminants, are complied with by feed establishments, especially as regards the presence of materials not suitable to be used as feed in food surplus recyclers.
8.	To ensure that feed operators comply with the requirements concerning procedures based on the HACCP principles, as laid down by Articles 6 and 7 of Regulation (EC) No 183/2005, in particular as regards the identification of hazards linked to incoming materials or processes followed during handling of feed.

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=2013-6752

Annex 1 - Legal References

Legal Reference	Official Journal	Title
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. 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
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. 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

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

Verification of compliance with feed marketing rules forms part of feed controls. Feed inspectors are instructed to pay attention to these requirements during routine inspections to feed establishments. Most Autonomous Communities visited avail of specific check-lists for this purpose.

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

According to MAGRAMA, the declaration of the amount of the salt rather than that of the trace element entails a twofold problem: on the one hand, it makes difficult for farmers to work out the amount of trace elements contained in the feed, and on the other hand, the analytical techniques available only allow to measure the level of the trace element and not that of the salt. This is why MAGRAMA (pending the development of Community codes of good labelling) agrees with keeping the amount of trace element on feed labels.

- In the feed establishments visited, the labels examined by the audit team showed the amount of trace element added along with the name of the salt containing such trace element. However, the amount of the said salt was not mentioned. This was not considered non-compliance by the feed inspectors met.

2.2 Claims

Legal requirements

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

Findings

According to the information provided by MAGRAMA, claims found during inspection in the different Autonomous Communities can be sent to CNCAA where it will be decided if they are substantiated or not.

- The audit team did not find any claims on the labels checked in the feed establishments visited.

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

According to MAGRAMA this area is also part of the general controls of labelling and checked always along with claims.

- The audit team did not find any misleading information on the labels checked in the feed establishments visited.