



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Directorate F - Food and Veterinary Office

DG(SANCO) 2012-6481 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

HUNGARY

FROM 15 TO 24 MAY 2012

IN ORDER TO EVALUATE MEASURES IN PLACE FOR THE IDENTIFICATION OF
HAZARDS AND MANAGEMENT OF 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 Hungary from 15 to 24 May 2012.

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 1831/2003 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 at risk than others. 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 there is a control system in place focusing mainly on feed mills and intermediaries. However, although the system also covers some establishments supplying part of their production to the feed chain but whose main activity is not in the feed area, the competent authority is not yet in the position to ensure that all of these establishments are identified, registered and subject to official controls focusing on feed related matters. Moreover, there are some deficiencies in the reports on the official controls carried out. Finally, although many requirements along the chain are satisfactorily complied with, there are still some deficiencies in this respect, notably concerning HACCP-based procedures. Most recommendations of the previous report, relevant for the scope of this audit, remain not addressed.

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

Table of Contents

1 INTRODUCTION	1
2 OBJECTIVES	1
3 LEGAL BASIS	2
4 BACKGROUND	2
5 FINDINGS AND CONCLUSIONS	3
5.1 INFORMATION ON THE FEED SECTOR	3
5.2 OFFICIAL CONTROLS	3
5.2.1 <i>COMPETENT AUTHORITIES</i>	3
5.2.2 <i>ORGANISATION AND DELIVERY OF OFFICIAL CONTROLS</i>	4
5.2.3 <i>RECORDS OF OFFICIAL CONTROLS</i>	6
5.2.4 <i>VERIFICATION OF OFFICIAL CONTROLS</i>	7
5.2.5 <i>REGISTRATION AND APPROVAL</i>	7
5.2.6 <i>ACTIONS IN CASE OF NON-COMPLIANCE</i>	9
5.3 OFFICIAL CONTROLS ON REQUIREMENTS ALONG THE FEED CHAIN	10
5.3.1 <i>SOURCING AND LABELLING</i>	10
5.3.2 <i>FACILITIES AND EQUIPMENT</i>	11
5.3.3 <i>CROSS-CONTAMINATION, HOMOGENEITY AND UNDESIRABLE SUBSTANCES</i>	11
5.3.4 <i>TRACEABILITY</i>	12
5.3.5 <i>HACCP-BASED PROCEDURES</i>	13
6 OVERALL CONCLUSIONS	14
7 CLOSING MEETING	15
8 RECOMMENDATIONS	15
ANNEX 1 - LEGAL REFERENCES	17
ANNEX 2 – REQUIREMENTS CONCERNING THE MARKETING OF FOOD	18
1. BACKGROUND	18
2. FINDINGS	18
2.1 DECLARATION OF ADDITIVES	18
2.2 CLAIMS	19
2.3 TRUTHFULNESS OF LABELLING	20

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ABP	Animal by-products
Cross-contamination	Presence, due to production, of additives, medicines or ingredients in feedingstuffs which should not contain them
County DFCSAH	County Directorate for Food Chain Safety and Animal Health (<i>Megyei Mezőgazdasági Szakigazgatási Hivatal Élelmiszerláncbiztonsági és Állategészségügyi Igazgatósága</i>)
FVO	Food and Veterinary Office
HACCP	Hazard analysis and critical control points
HFSO	Hungarian Food Safety Office (<i>Magyar Élelmiszer-biztonsági Hivatal</i>)
NFCSO	National Food Chain Safety Office (<i>Nemzeti Élelmiszerlánc-biztonsági Hivatal</i>)
Report 2008/7720	Report of a mission carried out in Hungary from 1 to 5 September 2008 concerning feed safety

1 INTRODUCTION

The audit took place in Hungary from 15 to 24 May 2012.

The audit team, which comprised two auditors from the Food and Veterinary Office (FVO) and one national expert, was accompanied throughout the audit by a representative from the Ministry of Rural Development and representatives from the National Food Chain Safety Office (*Nemzeti Élelmiszerlánc-biztonsági Hivatal* – NFCSO).

An opening meeting was held on 15 May 2012 with representatives of the Ministry of Rural Development and representatives of NFCSO, 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. To that extent, the audit took account of the relevant requirements on:

- a) feed hygiene, as laid down by Regulation (EC) No 1831/2003 of the European Parliament and of the Council, 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;
- b) 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 of the 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 at risk than others (see section 4).

The itinerary for the audit included the following visits:

Visits / meetings		No	Comments
Competent authority	Central	2	Opening and closing de-briefing meeting
	Regional	2	Meetings in two counties visited
	Local	√	Discussions held in the course of visits to premises
Feed mill		2	Approved establishments using coccidiostats, premixtures and manufacturing medicated, compound and complementary feed
Manufacturer of mineral feed		1	Manufacturing both mineral additive and technical grade products
Feed dryer		1	Drying and pelleting lucerne
Crude oil producer		1	Manufacturing vegetable oil, and delivering sunflower and rape seeds cakes and meal to the feed chain
Food operator		1	Manufacturing pasta and supplying its co-products to the feed chain
Chemical industry plant		1	Producing starch, ethanol and sugars and delivering their co-products to the feed chain
Trader		1	Dealing both with feed-grade and technical-grade materials
Farm / user		1	Pig farm receiving food co-products for feeding purposes

3 LEGAL BASIS

The audit was carried out under the general provisions of European Union 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)/2008/7720 – MR Final (hereafter: report 2008-7720) describes the result of a previous audit concerning feed safety in Hungary carried out from 1 to 5 September 2008, and contains background information relevant to the current audit. This report made a number of recommendations to the competent authority, 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. This report was published as part of the Report on a General Audit carried out in 2008 (reference number DG(SANCO)/2009-8346) and is accessible at the following address:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2359#

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 addition, 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 at risk than others and, in some cases, this has resulted in the legislation being amended (e.g. approval of establishments operating in the oil and fat chain). For these reasons, a new series of audits is being rolled out as of 2012, focusing on some key 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

Report 2008/7720 provides an overview about the feed sector in Hungary. According to the information provided by NFCSO, the number of operators delivering their co-products to the feed chain is presented in the following table (the information is limited to establishments relevant for the scope of this audit and which have not been covered by previous audits):

Type of establishments	No. of operators	Nature of feed material
Feed material dryers (including production of pellets)	26	Grass and crops
Producers of crude vegetable oil	13	sunflower and/or rape seed cakes or meal
Establishments manufacturing or handling both feed grade and technical grade products	15	mineral feed, corn gluten feed and dried distillers grains with solubles
Fat blenders	7	fat of vegetable or animal origin
Dairy plants	5	cheese whey

In addition, there are 94 operators (mostly farms) collecting surplus of food at plants (pasta, wafers, ice creams) and/or food co-products (bran, flour, yeast) to be used as feed.

Apart from the above, no other information concerning these types of co-products and their quantities placed into the feed chain or on the main use of co-products and the species to which they are destined, is available. The competent authority stated that, if necessary, such information could be collected and analysed on an *ad-hoc* basis.

5.2 OFFICIAL CONTROLS

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 coordination and cooperation.

Findings

NFCSO representatives noted that some structural changes of the competent authorities responsible for official controls along the feed and food chain took place at the beginning of 2012. The Agricultural Office (the former competent authority on feed) and the Hungarian Food Chain Safety Office (the former competent authority on food) became NFCSO, which took responsibilities of both consolidated bodies and started its operation in March 2012. According to the NFCSO representatives met, the consolidation did not affect organisation of official controls on feed. NFCSO is the single competent authority responsible for official controls on feed and in establishments delivering their co-products to the feed chain covered by the scope of this audit.

There is dual subordination of county officials which, for professional issues, are vertically directly related to NFCSO, and at the same time they are employees of County Government Offices linked directly to the Ministry of Public Administration and Justice.

Observations:

- The audit team noted that the competent authority is designated, and that officials met were aware of their duties and responsibilities.
- The audit team noted that although food inspectors carry out controls in food establishments or in animal by-products (ABP) plants, they do not pass to feed inspectors information that some of these entities also supply their co-products to the feed chain (see section 5.2.3).

Conclusions

The requirements laid down in Article 4 of Regulation (EC) No 882/2004 are largely complied, with, although there are communication gaps in the cooperation between inspectors from different units within NFCSO (see section 5.2.3).

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 of report 2008/7720 concerned the organisation of official controls. In response to this recommendation, the central competent authority undertook to modify the system for the organisation of official controls and the way these are recorded.

According to NFCSO there is a tool for risk-based prioritisation of official controls both for inspection and sampling activities. The lists with all registered and approved feed operators are used for establishing a target group of operators to be checked every year. During the inspection visit an individual risk assessment of each operator is carried out. Several factors (production type, risk related to material and products used, production volume and history of non-compliance) are taken into account in order to obtain a score which is used to rank operators. Top ranked operators are subject to official controls. To ensure that none of the lower ranked operators remain uncontrolled, a minimum inspection frequency is fixed for each type of operator. The frequency ranges from one visit every year to one every five years. Apart from inspection visits there is also a sampling plan which is executed separately. This plan contains the number of samples to be collected annually from each type of establishment; the sampling frequency varies from one to several samples to be taken every year in each establishment. While the individual assessments for operators are made by local inspectors, the general annual programmes for inspections and sampling are prepared at the central level.

Observations:

- Annual control programmes for inspection and sampling were produced regularly, and individual assessments for establishments were carried out and used for prioritisation of

controls. However, the audit team noted that lists of registered and approved feed operators used for targeting official controls contained mainly feed mills, intermediaries and only few operators acting in the field of food, ABP and chemicals which also delivered their products into the feed chain (see section 5.2.5).

- Operators acting in areas other than feed production are subject to other, sector specific controls, e.g. food establishments are checked by food inspectors. The audit team noted that food inspectors were not instructed to verify if the establishment is registered as a feed operator when placing its co-products into the feed chain. The check-lists used for food establishment controls did not foresee such verification (see section 5.2.3).
- Inspectors met followed both programmes for inspection and sampling. The audit team noted that although local inspectors, depending on the local situation, could optimise (reduce or increase) the frequency of controls or number and scope of samples, they rather stick to the frequencies set out in the programmes.
- In the establishments visited, which were manufacturing, respectively, mineral feed and crude oil, an official met did not consider taking official samples for dioxins as these were not foreseen in the sampling programme for such establishments.
- In one of the approved feed mills visited the official met collected official samples from archive samples kept by the operator.
- According to representatives of the competent authority, inspections and sampling are not announced; however, the audit team noted that some inspectors notified operators prior to their visits. The announcements varied from a few hours to a few days. The inspectors met explained that they announced their visit in order to make sure that operators will be present in establishments.
- The audit team noted that sourcing of feed material was rarely verified by inspectors during inspection visits; as a consequence some operators and transporters remained not registered (for inspection reports see section 5.2.3, for registration see section 5.2.5, for safe sourcing of feedingstuffs see section 5.3.1).
- The officials met stated that in all cases HACCP-based procedures had been assessed before approval for feed establishments was granted, moreover the procedures were also regularly verified by feed inspectors during inspection visits. However, on the basis of the discussion held with the inspectors, the audit team noted that they had difficulties to assess HACCP-based procedures (see section 5.3.5).
- The audit team noted that food inspectors carrying out controls in food establishments paid very little attention to food co-products supplied for feeding purposes, and considered these co-products as waste (see section 5.2.3). This resulted in the absence of official controls on this feed.
- In the establishments visited, officials carrying out controls overlooked a number of basic non-compliances which were identified by the audit team (see section 5.3), although some of the shortcomings had been in place during the last inspection visit.

Conclusions

There is a system for official controls which mainly focuses on feed mills and intermediaries (albeit they overlook some basic shortcomings – see section 5.3); however, some establishments supplying part of their production to the feed chain, but whose main activity is not in the feed area, are still not subject to official controls concerning feed (see section 5.2.5). Therefore, the requirements for

official controls laid down by Article 3 of Regulation (EC) No 882/2004 are not met and the relevant recommendation of the previous report has not been satisfactorily addressed.

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

According to NFCSO inspection and sampling guides have been issued. The competent authority organised regular training sessions which covered also preparation and execution of official controls and sampling. Non-compliances found during inspection visits are reported quarterly by county inspectors to the central office.

Observations:

- All inspections were documented in reports accompanied with check-lists. However, the audit team noted that most of the inspection reports contained only very general information concerning the scope of the visits and provided limited feedback on elements checked during the inspection. In addition, other than check-lists filled-in with “yes/no” options there was no or very little assessment concerning the level of compliance of the establishments controlled.
- There is a unique check-list for all kinds of feed establishments, therefore each inspector has to decide which sections and/or questions are relevant for a particular type of activity. However, the audit team noted that although the check-list could be used without major modification for controls on primary feed producers or feed mills, it was not designed for checks of operators acting in sectors other than the feed sector and supplying their co-products for feeding purposes.
- Check-lists used by food inspectors in food establishments do not consider co-products of food production as feed materials but as waste. This resulted in a lack of official controls on these products (see section 5.2.2).
- The feed inspectors met stated that they did not record in the inspection reports shortcomings and requests for corrective actions as these are communicated verbally to operators (concerning judgements on non-compliances see section 5.2.6). The audit team noted that there were many cases when time lapse between inspections was two or three years.
- The audit team noted that although inspectors claimed to carry out verification on feedingstuffs suppliers and transporters, this was not recorded in their inspection reports.

Conclusions

Requirements for documented procedures for carrying out official controls are largely complied with. However, reports on the official controls carried out lacked information on the result of the official controls and, where necessary, the actions that the concerned operator is to take; therefore, the relevant requirements laid down by Article and 9 of Regulation (EC) No 882/2004 are not complied with.

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 NFCSO verification of official controls is carried out regularly in accordance with the rules established by each County Government Office. In the field of feed, internal supervision is carried out by heads of the County Directorates for Food Chain Safety and Animal Health, who checks the content of inspection reports and go together with feed inspectors for joint inspection visits. The frequency and the number of inspectors covered every year by such supervision are set individually by each County Government Office in their internal control procedures.

According to NFCSO, with the exception of statistics reports delivered by county directorates on monthly or quarterly basis, which indicate the number of inspections carried out and samples taken, the central office does not carry out other verification of official controls on feed ¹.

Observations

- In the county directorate visited, the official met stated that each feed inspection report is subject to regular scrutiny, individual supervision of feed inspectors takes place every three years and that the results of individual supervision were discussed with the inspector in the course of joint inspections. Moreover, the county feed inspector, who was in charge of verification on sampling carried out by district inspectors, indicated that he focused this on the scope of analyses, type of product, type of establishment and turnover time elapsed between sampling and delivery of results. However, the audit team noted that there were no records showing that these internal supervision activities had been carried out.

Conclusions

The requirement laid down by Article 8(3)(a) of Regulation (EC) No 882/2004 are not met, given that there are no records concerning the implementation of the procedures for verifying the effectiveness of official controls.

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; Article 19 lays down requirements for the list of these establishments.

Findings

The relevant recommendation of report 2008/7720 concerned the registration and approval of feed establishments. In response to this recommendation, the central competent authority undertook to carry out the registration and approval of feed establishments in line with the requirements of Regulation (EC) No 183/2005.

¹ In their response to the draft report the competent authority noted that NFCSO carries out also audits covering additional topics. In particular in 2012 NFCSO carried out an audit covering implementation of the monitoring programme and the use of the Online Inspection Module which contains all information on on-the-spot inspections.

National lists of approved and registered feed establishments and representatives of third country feed producers are publicly available at:

http://www.nebih.gov.hu/szakteruletek/szakteruletek/elelmszer_takarmanybiztonsag/szakteruletek/takarmany_letesitmeny

In October 2011 the competent authority requested all county directorates to verify whether the feed companies acting under their territories are accurately registered on the list. This check is still pending. According to NFCSO all feed producers are automatically classified as feedingstuffs transporters.

Observations:

- The operators acting in the food sector, along the ABP chain or in the chemical / industrial sector met stated that they are registered because as big scale operators they were aware of this requirement and took the initiative to fulfil it. According to the competent authority operators supplying part of their production to the feed chain but whose main activity is not in the feed area are registered. However, the audit team noted that the competent authority could not provide any evidence in order to support this assertion (e.g. there has not been any initiative in order to check the destination of food co-products at small/medium scale operators, and there has not been any exchange of information with inspectors carrying out official controls at this level).
- According to NFCSO, there are 26 operators drying feed material in the country. However, in one of the establishments visited, the person responsible for purchase of grains from primary producers stated that in a 25 km radius neighbourhood there are approximately 50 agricultural holdings using their own drying facilities.
- The audit team noted that some suppliers and transporters of the feed operators visited were not registered; this had been overlooked during official controls (see section 5.2.2).
- In one of the feed mills visited the audit team noted that the feed mill received fat of animal origin from a company which was not registered as a feed operator. In the document which accompanied the consignments the fat was specified as industrial fat and its origin was not mentioned. The competent authority immediately investigated the case and established that the fat supplier acted as a trader of various goods including feed grade materials and chemicals but without its own storage facility. At least from 2006 the trader was not registered as feed a operator and therefore was excluded from official controls. According to the competent authority the trader supplied the fat also to another feed mill in this county and, taking into account the quantities, possibly to other counties. The fat originated from a Category 3 processing plant, which dispatched the product with a proper commercial document which subsequently was altered by the trader.
- In one of the counties visited the audit team noted that a dairy plant dispatched cheese whey to farms for feeding purposes. According to the county official met this plant received a permit for supplying the whey as feed material but was not listed on the list of feed operators. The official stated that during inspection visits, none of the food inspectors have ever focussed neither on the registration issue nor on the hygiene requirements for the whey dispatched from this plant for feeding purposes; feed inspectors did not control the plant either.
- The audit team noted that one of the feed operators visited was registered as a third country representative. The operator stated that he had stopped importing feed materials few a years ago and since then acts as a supplier of feed additives originating from Member States. The

operator had been recently subject to an inspection visit but the issue of inaccurate registration had been overlooked.

- The lists of feed operators contain fields for registration or approval numbers, an activity code, a company name and address, notes related to the activity and remarks. The audit team noted that the fields concerning activity notes and remark remained empty in many cases, therefore they do not allow to know what an establishment does in reality and what kind of product it deals with. In particular, the activity of establishments is noted by codes (used for classifying operators in different categories during preparation of annual control programmes) which are not explained, therefore the activity remains unclear. An NFCSO representative stated that national feed legislation contains explanations of the activity codes but acknowledged that there is no reference to this legislation in the lists.

Conclusions

The requirement concerning approval of feed establishments has been satisfactorily complied with. However, the competent authorities are not in a position to ensure that all operators along the feed chain, notably transporters and establishments supplying part of their production to the feed chain but whose main activity is not in the feed area, are registered and listed; therefore, the relevant requirements laid down by Articles 9 and 19 of Regulation (EC) No 183/2005 are not met, and the relevant recommendation of the previous report has only been partially addressed. Moreover, although lists of registered and/or approved establishments are available to the public, contrary to the requirements laid down by Article 19 of this Regulation, the lists do not reflect the activities for which the establishments have been registered or approved.

5.2.6 Actions in case of non-compliance

Legal requirements

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

Findings

According to NFCSO national legislation on administrative actions provides with legal basis for action in case of non-compliance and the range of measures which could be undertaken by officials.

Observations:

- The audit team noted that apart from the administrative measures, national legislation provides financial penalties which are dissuasive. In addition there is an instruction explaining how the relevant legislation for action in case of non-compliance should be used; officials met were familiar with this instruction.
- The officials met stated that they judged severity of non-compliances on the basis of their opinion and experience of their cooperation with the operator concerned. The audit team noted that there is no guide instructing officials how to rank of different non-compliances depending on their seriousness.
- Due to deficiencies in records of official controls (see section 5.2.3), the audit team could not ascertain if the competent authorities have verified whether previous non-compliances had been timely rectified or not.
- The audit team noted that county officials met efficiently investigated shortcomings

identified by the audit team during this audit and all investigation results were presented before the end of the audit together with actions and deadlines for improvements.

Conclusions

The competent authorities have undertaken action in order to rectify the deficiencies detected during this audit, but deficiencies in records concerning the results of official controls (see section 5.2.3) do not allow ascertaining whether this is always the case or not.

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 1831/2003 requires feed business operators to source and use feed only from registered and/or approved establishments. 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 1831/2003.

Findings

According to NFCSO checks on sourcing and labelling are part of the regular control programme. Controls carried out in 2011 and 2012 revealed two non-compliant cases where labels were missing identification of the establishment supplying feedingstuffs.

Observations:

- With the exception of the feed mill receiving fat of animal origin (see section 5.2.5), the pig farm receiving former foodstuffs, and a dairy plant dispatching cheese whey for feeding purposes, for which there were no proper commercial documents indicating that those products are feed-grade, in all other establishments visited both feed materials used for production and finished products were clearly labelled as feedingstuffs.
- At all establishments visited, the audit team noted that ingredients and finished products were properly labelled.
- Although a few operators met stated that they verify the registration/approval status of their suppliers on a regular basis, some operators stated that they had never (or only occasionally) carried out checks in this respect. One operator met stated that since his suppliers are ISO and/or GMP certified this could be considered as a sufficient safety guaranty.
- The officials met stated that they do verification of suppliers or customers of feedingstuffs on a random basis during traceability checks, but this verification was seldom documented in inspection reports.

Conclusions

The requirements for labelling laid down by Articles 16 and 17 of Regulation (EC) No 767/2009 and by Article 16 of Regulation (EC) No 1831/2003 are largely complied with. However, official controls are not able to ensure that establishments confirm their sourcing of feed from only

approved and/or registered establishments; therefore, the requirement laid down by Article 5(6) of Regulation (EC) No 183/2005 is not fully met.

5.3.2 Facilities and equipment

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, facilities and equipment.

Findings

Observations:

- In the establishment manufacturing mineral additives, the audit team noted that, from the production site to the storage of the final products, all sections dealing with technical and feed grade materials were separated. The operator had procedures in place preventing cross-contamination between these products.
- In all establishments visited the audit team noted that the operators met followed the general rules for hygiene, cleanness and separation, calibration of measuring devices, maintenance of equipment and pest controls.

Conclusions

The requirements laid down by Article 5(2) of Regulation (EC) No 183/2005 concerning facilities and equipment are satisfactorily complied with.

5.3.3 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 and the monitoring of undesirable substances; in particular, Directive 2002/32/EC sets out maximum permitted levels for undesirable substances in feed.

Findings

Assessment of homogeneity, the level of cross-contamination and establishing of cross-contamination preventive measures are elements of the approval process. Maximum levels of cross-contamination in various types of feedingstuffs are laid down in national legislation which, in case of undesirable substances, follows the maximum permitted levels set out in Directive 2002/32/EC.

Observations:

- In all feed mills visited officials responsible for approval carried out checks on homogeneity and trials on cross-contamination levels. Records of these activities together with approval files were presented to the audit team. The audit team noted that officials together with operators had established flushing as a measure to prevent cross-contamination. In all feed mills visited the flushing procedures were rigorously followed.

- In all feed mills visited operators carried out homogeneity tests regularly, the results of those checks were checked by officials. The audit team noted that in the feed mills the results were always below the limits set in the national legislation.
- In one of the feed mills visited, the audit team noted that the last three samples for cross-contamination tests for oxytetracycline were taken neither from a flushing batch nor from the first batch following production of feed with antibiotics. The official inspector met stated that he had checked that samples for cross-contamination were taken always from the first batch after flushing batches; however, the audit team noted that, in the above-mentioned situation, the operator collected these samples from batches produced a few days after the last batch with antibiotics.
- All feed producers visited had in place procedures to verify the previous loads which had been transported prior to the delivery of feed to their establishments and records of this verification. According to the operators most of transporters contracted by them were ISO or GMP certified, and their contracts contained conditions on the nature of materials that could be transported before the transport of feedingstuffs.
- Monitoring of undesirable substances was carried out in the feed establishments visited. The audit team noted that this monitoring was not always based on a hazard analysis and a risk assessment of the ingredients used for the production of feed as these were not always in place (see section 5.3.5). However, in most of the establishments visited, the monitoring of undesirable substances carried out by the operators, on request of the officials, reflected potential risks.

Conclusions

The requirements laid down by Article 5(2) of Regulation (EC) No 183/2005 concerning cross-contamination, homogeneity and monitoring of undesirable substances are largely complied with.

5.3.4 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

Observations:

- The audit team noted that all operators visited had systems in place to trace back the materials used for production of finished products and products sold to customers. Most of the operators met verified the system on a regular basis as part of their internal control procedures. Records concerning incoming and outgoing consignments were in place; operators kept archive samples and documentation concerning laboratory analyses carried out as part of their own-check procedures.
- In some of the establishments visited the audit team challenged the system for traceability, which in all cases proved to be effective.

- With one exception of use on the label, instead an individual, four different identification numbers of a feed establishment (see section 2.3 of Annex 2), no particular issues concerning traceability were identified by the audit team during this audit.

Conclusions

The requirements laid down by Article 5(2) of Regulation (EC) No 1831/2003 concerning records for traceability and the keeping of samples are largely complied with.

5.3.5 HACCP-based procedures

Legal requirements

Articles 6 and 7 of Regulation (EC) No 1831/2003 lay down requirements for feed business operators concerning procedures based on the HACCP principles.

Findings

The relevant recommendation of report 2008/7720 concerned HACCP-based procedures. In response to this recommendation, the central competent authority undertook to provide series of training for officials involved in checks on HACCP.

The competent authority declared that HACCP-based procedures are required by all operators placing their products in the feed chain; officials carry out an assessment of these procedures during approval of establishments. According to NFCSO most officials received a “cascade” training on HACCP.

The Hungarian feed industry translated into Hungarian a guide to good practice by European feed manufactures, and made it available on the internet at:

<http://www.gabonaszovetseg.hu/dokumentumok/GMP-takarmany.pdf>

Observations:

- All operators visited had HACCP-based procedures in place. However, the audit team noted that out of four operators visited which were also acting in areas outside feed production, only the chemical industry plant HACCP-based procedures covered systematically all products (including feed materials). In the remaining establishments procedures held by the operators focused mainly on their main products, excluding co-products dispatched to the feed chain from the scope of the HACCP-based procedures.

In particular, the audit noted that in the food establishment visited the procedures considered co-products as waste, therefore: a) criteria which should be met by such products to be dispatched as feed materials were not specified, b) hazards affecting products' safety were not identified, and c) critical limits, monitoring methods and actions in case of non-compliance were not established.

- With the exception of the chemical plant, in the other feed establishments visited, operators did not carry out an identification of hazards for all ingredients used for the production of feed. In one of those establishments the operator met explained that no risk was associated with the incoming materials since all suppliers were obliged to provide feed materials in accordance with standards set in their contracts; moreover all of them were subject to regular audits which were also considered as additional safety guarantees for the products. In the remaining establishments no similar practices had taken place.

- With the exception of two establishments visited the risk assessments mainly focussed on possible contaminations of feed by disinfectant or cleaning substances (chemical contamination), presence of rodents or birds faeces (biological contamination) and presence of unwanted seeds (botanical contamination). The risk assessments only occasionally reflected some hazards arising from different operation steps caused by chemical, heating or mechanical operations. As a consequence, critical control points were incorrectly established, not defined or did not fit for measuring and monitoring; e.g.:
 - In one of the feed mills visited the presence of undesirable substances (antibiotics and coccidiostats) was considered as a critical control point; however, these substances were monitored as part of carry-over own-checks with a monitoring frequency ranging from once to twice a year.
 - In one of the approved feed mills visited, critical control points established at various steps of operation, referred to botanical impurities and harmful particles (in a non-specific way); however, no critical limits were established.
 - In the feed drying establishment visited, the first critical control point concerned drying due to possible microbiological (in a non-specific way) hazards, and the drying time and the temperature were considered as the critical parameters. However, only the maximum time and the maximum temperature for drying were established as the critical limits. In addition, the time limit reflected the entire time for passage through several production steps, and not the real time for drying. The second critical control point was established at storage of finished product and referred to the presence of rodents and insects; there were no critical limits and monitoring requirements for this critical control point.
 - In the establishment manufacturing mineral feed visited, critical control points identified at various steps of operation referred to the presence of biological, chemical and physical contaminants but no critical limits, monitoring and recording requirements were established. Presence of dioxins of naturally occurring dioxins was not taken into account as possible hazard therefore was not included in a risk assessment.
 - In one of the approved feed mills visited, a number of critical control points was established, while the rules for periodical checks, reflected in the own-checks plan, suggested that these should be considered rather as preventive measures or control points.
- The audit team noted that during their inspections officials checked if the operators had the procedures in place, rather than assessing these procedures as to whether they were correct and fit for the type of activity (see section 5.2.2).

Conclusions

It is ensured that operators have put in place HACCP-based procedures; however, official controls are not in a position to detect and correct a number of shortcomings in these procedures. In particular, this concerns the following: a) in many cases there are deficiencies in the definition of critical control points and also in their monitoring, and b) at establishments whose main activity is not in the feed area but supply part of their production to the feed chain, the scope of HACCP-based procedures does not include feed products. Therefore the requirements laid down by Articles 6 and 7 of Regulation (EC) No 1831/2003 are still not complied with and the relevant recommendation of the previous report has not been addressed.

6 OVERALL CONCLUSIONS

There is a control system in place focusing mainly on feed mills and intermediaries. However, although the system also covers some establishments supplying part of their production to the feed chain but whose main activity is not in the feed area, the competent authority is not yet in the position to ensure that all of these establishments are identified, registered and subject to official controls focusing on feed related matters. Moreover, there are some deficiencies in the reports on the official controls carried out. Finally, although many requirements along the chain are satisfactorily complied with, there are still some deficiencies in this respect, notably concerning HACCP-based procedures. Most recommendations of the previous report, relevant for the scope of this audit, remain not addressed.

7 CLOSING MEETING

A closing meeting was held on 24 May 2012 with the representatives of the central competent authorities. At this meeting, main findings and preliminary conclusions of the audit were presented by the audit team. The central competent authorities 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. In addition the competent authority presented preliminary proposals to an action plan in order to address shortcomings identified during this audit.

8 RECOMMENDATIONS

The competent authorities of Hungary 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 that establishments supplying part of their production to the feed chain, but whose main activity is not in the feed area, are subject to official controls on feed issues, as laid down by Article 3 of Regulation (EC) No 882/2004.
2.	To ensure that reports on official controls required by Article 9 of Regulation (EC) No 882/2004 include information on the result of the official controls and, where necessary, the actions that the concerned operator is to take.
3.	To record the implementation of procedures for the verification of the effectiveness of official controls required by Article 8(3)(a) of Regulation (EC) No 882/2004.
4.	To register and list, as required by Articles 9 and 19 of Regulation (EC) No 183/2005 respectively, transporters and establishments supplying part of their production to the feed chain but whose main activity is not in the feed area.
5.	To ensure that the lists laid down by Article 19 of Regulation (EC) No 183/2005 reflect

N°.	Recommendation
	the activities for which establishments have been registered and/or approved.
6.	To ensure that feed business operators are in a position to confirm that they only source feed from registered and/or approved establishments, as laid down by Article 5(6) of Regulation (EC) No 183/2005.
7.	To ensure that the requirements for HACCP-based procedures laid down by Articles 6 and 7 of Regulation (EC) No 183/2005 are complied with, notably as regards the definition and monitoring of critical control points and the scope of these procedures at establishments whose main activity is not in the feed area but supply part of their production to the feed chain.

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=2012-6481

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 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. 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
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

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

According to NFSCO verification of labelling requirements has always been an element of the official controls carried out by feed inspectors. These checks were focusing on the way the labels were drafted and on verifications if the declared content of ingredients meets the reality. Once Regulation (EC) No 767/2009 entered into force, the competent authority initiated some actions to familiarise both officials and the feed industry with the requirements of the new legislation.

The Ministry of Rural Development produced a guide introducing some aspects of this Regulation, e.g. the catalogue of feed materials and register of feed materials and high-concentrate products. The guide is available at:

<http://www.fvm.hu/main.php?folderID=1425&articleID=16597&ctag=articlelist&iid=1>

The competent authority has considered training as more effective than instructions, and repeatedly organized training sessions concerning requirements laid down in Regulation (EC) No 767/2009, among others, the labelling and claims; in particular, one feed expert from each county participated in training, being afterwards responsible for training other inspectors at each county. In addition, the competent authority organised meetings with the feed industry during which the objectives and requirements of Regulation (EC) No 767/2009 were presented and discussed.

Official controls organised in 2011 and in 2012 revealed, in total, ten non-compliances as regards labelling issues; these dealt with the absence of establishment registration numbers, instructions for the user, classification of feed, a constituent content and/or the best-before date.

2.1 DECLARATION OF ADDITIVES

Legal requirements

Article 15(f) of Regulation (EC) No 767/2009 lays down general mandatory labelling requirements on how to label feed additives in feed materials or in compound feed; these requirements are further specified in Chapter I of Annex VI and VII to this Regulation.

Findings

According to NSCSO representatives met, the requirements laid down by Article 15(f) of Regulation 767/2009/EC were accepted by the feed industry which has started with their implementation. However, there are some requirements for which the industry disputes the value of the provisions, namely the requirement requesting to indicate the amount of the chemical compound containing a trace element rather than the content of the trace element itself.

Observations:

- In the feed mills visited, the audit team noted that in some cases the labels attached to compound feed containing additives missed the heading “Additives” and/or a sub-heading indicating a functional group of the additive used. In such situations the additives (e.g. vitamins or trace elements) were listed under the heading “Composition” or under the heading “Analytical constituents”. The audit team noted that when trace elements were listed as analytical constituents their added amount instead of the total content was mentioned.
- In all feed establishments visited, the audit team noted that labels attached to premixtures, concentrates and complementary feed, indicated trace elements mostly as additives. The labels indicated the name of the trace element, the name of the chemical compound, the number from the Community register of feed additives and the amount [e.g.: Zinc (zinc sulfate monohydrate)(E6) 800.24 mg]. The operators met stated that the content of the trace elements referred to is, in most cases, the content of the trace element and not the content of the chemical compound containing it; the operators stated that at this stage it is more difficult for them to establish the precise amount of the trace element in various chemical compounds than its total amount in feedingstuffs.
- The feed inspectors met stated that if all producers had started with declaration of the chemical compound only, they would have difficulties calculating the content of the trace element used and available through different feedingstuffs. On the basis of the discussion held with the feed inspectors met, the audit team noted that although inspectors carry out checks and identify some non-compliances as regards indicating the content of trace elements, they abstain from imposing administrative measures since they consider the current situation as a transitional period necessary for adjustment to the new rules.

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

Apart from the guide by the Ministry of Rural Development there is no other instruction for feed inspectors allowing them differentiate between statements which could be considered as reliable or unreliable claims. Whenever feed inspectors have doubts they can consult the situation with their superiors and with the central office; in addition they could use guides produced by associations of feed producers available on the internet.

According to NFCSO, the use of claims is only occasionally used by the producers of pet food. Moreover, some feed operators seek advice concerning labelling requirements, therefore NFCSO can react before wrongly labelled products are placed on the market.

Observations:

- According to NFCSO representatives met, in 2011 and 2012, checks on claims were carried out during regular annual controls on feed establishments. In addition verification of claims was part of a specific control campaign, targeted on the labelling of feedingstuffs, carried out in 2011.
- In the feed mills visited, the audit team noted that several feed operators used claims on their products stating that the products are free from hormones, growth promoters and antibiotics. Feed inspectors did not react on such claims and consider them as acceptable. The officials

met explained that this kind of statements were traditionally placed on the labels because clients expected that products did not contain these substances.

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 NFCSO representatives, for them there is no difference between untruthful labelling and use of unsubstantiated claims, therefore feed inspectors would treat them in an uniform way. NFCSO did not issue a specific guideline in this respect. Possible verifications of the truthfulness (or claims) would be made on the basis of complaints or if the issue emerged during inspection visits.

Observations:

- According to NFCSO checks on the truthfulness of labelling were also part of regular control programmes in 2011 and in 2012, and targeted control campaign in the field of feed labelling organised in 2011. With the exception of ten shortcomings on labelling no other issues concerning truthfulness were found. The NFCSO representative met stated that feed inspectors carrying out checks focussed mainly on claims present at bag labels rather than in other formats (e.g. media, internet and leaflets).
- In 2011 the competent authority received a notification about a product present on the market and labelled at the same time as feed and as a product with medicinal properties. The investigation revealed that it was a veterinary medicated product which was unduly labelled as feed. Following administrative actions, the operator responsible for the placing of the product on the market changed the label accordingly.
- The audit team noted that the competent authority has never requested scientific substantiation for feedingstuffs in order to verify the specific nutritional characteristic or process or to a specific function related to any of these.
- In one of the feed mills visited, the audit team noted that the label of bags of compound feed contained two approval and two registration numbers of the same feedingstuffs producer. The official met explained that according to national legislation each production line in the feed mill has its own registration and/or approval number; however, he acknowledged that for the sake of clarity the label should only indicate the number referring to the line on which the feed was produced.