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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

BELGIUM

FROM 18 TO 27 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 Belgium, from 18 to 27 November 2013.

The overall objective of the audit was to evaluate whether the system for official controls was effective in verifying that business operators along the feed chain identified hazards and properly managed associated risks. The audit also assessed the effectiveness of the corrective actions undertaken in response to previous recommendations concerning feed safety. 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 the new requirements of Annex II to Regulation (EC) No 1831/2003. 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 there is a solid and advanced system of official controls which is largely effective in verifying that business operators along the feed chain identify hazards and manage properly the associated risks. The organisation and the delivery of official controls are risk based, strengthened by useful software tools and underpinned by a comprehensive set of check-lists, technical sheets and verification measures. Moreover, it is worth highlighting that the competent authorities make use of the results of structured and largely comprehensive own-checks programmes run by a number of professional organizations of feed business operators during the planning of the sampling programme for undesirable substances. However, official controls in food establishments supplying food by-products to the feed chain are still at an early stage of development and those concerning the measures put in place by feed business operators to limit the risk of carry-over of coccidiostats in non-target feed do not focus sufficiently on the verification of the effectiveness of such preventive measures. Moreover, although steps have been taken to identify the risks associated with the direct drying of feed materials using various fuels, official controls in this area are not yet well developed.

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

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
BEMEFA	Belgian Compound Feed Industry Association
BOOD	Belgian database of food/feed business operators
Cross-contamination	Presence, due to production, of additives, medicines or ingredients in feed which should not contain them
FASFC	Federal Agency for the Safety of the Food Chain
FVO	Food and Veterinary Office
GMP	Good Manufacturing Practice
HACCP	Hazard analysis and critical control point
OVOCOM	Belgian platform for companies active in the animal feed chain
PAHs	Polycyclic aromatic hydrocarbons
PCB	Polychlorinated biphenyls
PCUs	Provincial Control Units
Report 2010-8469	Report of an audit carried out in Belgium from 13 to 23 April 2010 concerning feed safety
SYNAGRA	Association of Traders in Grains and other Agricultural products

1 INTRODUCTION

The audit took place in Belgium from 18 to 27 November 2013.

The audit team, which comprised two auditors from the Food and Veterinary Office (FVO), was accompanied throughout the audit by representatives from the Federal Agency for the Safety of the Food Chain (*Agence fédérale pour la Sécurité de la Chaîne alimentaire* – FASFC).

An opening meeting was held on 18 November 2013 with representatives of the of the FASFC and the Federal Public Service for Health, Safety of the Food Chain and the Environment (FPS HSFCE), 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 business 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 a few 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	3
	Local	2
Feed mills	2	Both GMP certified and using coccidiostats
Fat blender	1	Not yet in operation as fat blender but where other feed activities take place
Biodiesel plant	1	
Importer	1	Acting also as intermediary
Chemical plants	2	Placing on the market mineral feed materials.
Food establishment	1	Supplying the feed chain with food by-products

Oil processor		1	Where crushing of linseed and refining of linseed oil takes place
Feed dryer		1	Using direct drying system

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 business 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, Commission 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 was started in 2012, focusing on some requirements of the legislation which concern the identification of hazards and the management of the associated risks.

4.2 PREVIOUS FVO AUDITS

Report DG(SANCO) 2010-8469 – MR Final (hereafter: report 2010-8469) describes the results of a previous audit concerning feed safety carried out in Belgium from 13 to 23 April 2010, and contains background information relevant to the current audit. This report made a number of recommendations to the competent authorities, which subsequently informed the Commission services of actions that had been or would be taken aimed at addressing the recommendations made. Where appropriate, both the relevant recommendations and the afore-mentioned actions are outlined in section 5. The report is accessible at the following address.

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

4.3 INFORMATION ON THE FEED SECTOR

Report 2010-8469 provides an overview of the feed sector in Belgium. In addition, the following information was provided by the FASFC about business operators delivering products or co-products to the feed chain (the information presented is limited to establishments relevant for the scope of this audit and which have not been covered by previous audits):

- Establishments supplying food co-products and surplus food to the feed chain: not exactly defined (¹)
- Driers of feed: not exactly defined (¹)
- Establishments covered by Regulation (EU) No 225/2012:
 - processors of crude vegetable oil: one establishment
 - oleochemical manufacturers of fatty acids: no establishments
 - biodiesel plants: two establishments
 - fat blenders: one establishment
- Establishments (other than those covered by the above types) placing on the market at the same time feed grade and technical (non-feed) grade products: not exactly defined (²).

5 FINDINGS AND CONCLUSIONS

5.1 OFFICIAL CONTROL SYSTEMS

5.1.1 *Competent authorities*

Legal requirements

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

Findings

The designated competent authority in charge of official controls on feed business operators included in the scope of the audit is FASFC. Within the FASFC there are three directorates-general directly involved in the checks. The Directorate-General Control Policy is responsible for policy and legislation on control measures and programmes along the food, feed and plant health chain. It is in charge of the preparation of multi-annual controls, inspections and sampling plans on a risk-based approach. The Directorate-General Control is involved in the co-ordination and integration of the control activities carried out by the 11 Provincial Control Units (PCU). The Directorate-General Laboratories co-ordinates all activities on analyses carried out by internal laboratories (federal laboratories of the FASFC) and external laboratories. At local level the 11 PCUs carry out official controls and are divided, from an operational point of view, into three sectors: a) primary production, b) processing (which includes also traders and transporters) and c) distribution. Under the competence of DG Control, one director in the Flemish Region and another in the Walloon Region have been designated with the purpose to act as co-ordinators between PCUs and central

1 Despite these business operators being registered, there are no means to distinguish them from those belonging to the same generic category, i.e. “producers of raw materials”.

2 Despite these business operators being registered, there are no means to distinguish them from those belonging to the same generic category, i.e. “producers of raw materials” or “producers of critical products”, depending on the type of product placed on the market.

level. Moreover, a co-ordination unit (National Implementation and Co-ordination Unit) has been designated in order to co-ordinate controls, implement instructions and harmonise their application in the PCUs. This unit evaluates the PCU's activities and regularly reports the outcome of such evaluations to the central level.

- The DG Control Policy is certified according to ISO 9001:2008 "Quality management systems - Requirements" and the DG Control is accredited according to ISO 17020:2012 "Requirements for the operation of various types of bodies performing inspection". The audit team noted that the accreditation scope includes activities carried out at central and PCU level.
- At central level and in the PCUs visited the audit team noted that the responsibilities were clearly defined and all members of staff met were aware of their tasks and duties in relation to feed controls. At PCU level, a head of sector had been appointed and a number of inspectors and control officers (the latter mainly involved in sampling) had been allocated.
- According to information provided by the central competent authority, all feed establishments relevant to the scope of this audit, are considered as establishments included in the sector "b" (processing) which also contains food establishments and establishments dealing with animal by-products (ABP) and derived products. In the PCUs visited the audit team confirmed that this classification is actually in place.
- During visits to establishments and meetings with PCUs, the audit team noted that the level of experience and the knowledge of staff were largely adequate for their tasks.
- Concerning co-ordination between central and local level, on a monthly basis a meeting between the head of the DG Control, the two regional directors and the head of each PCU is organised in order to ensure the harmonisation of policy for official controls. The audit team saw some examples of minutes of such meetings. In addition to that, the audit team saw examples of actions organised by the above-mentioned national implementation and co-ordination unit. One of these concerned the risk of cross-contamination of antibiotics in non-medicated feed (the project, which took place in 2011, involved 16 feed business operators and most of the PCUs with their local inspectors). Another has been launched in 2013 in order to harmonise the approach when carrying out inspections in establishments of food of non-animal origin supplying the feed chain.

Conclusions

The competent authority responsible for carrying out official controls in feed establishments has been designated, and arrangements for co-operation and co-ordination are satisfactory. Therefore, these pre-requisites for the functioning of a system of official controls are in place.

5.1.2 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 1831/2003, Directive 2002/32/EC, Regulation (EC) No 1831/2003 and Regulation (EC) No 767/2009.

Findings

The organisation of official controls on feed remains largely as described in report 2010-8469 and in the Country Profile (valid as of February 2013).

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

In summary, the core process of the official control plan is described in the Multi-Annual National Control Programme (correlated with the FASFC's Business Programme) valid for the period 2012-2014. It consists of the following three steps: a) a control programme is drafted by the FASFC on a risk basis; the control programme has two parts: one for inspections and the other for sampling, where a number of analyses are assigned via the plan sent to each PCU; b) each PCU adapts the plan to its geographic area of competence and c) each PCU delivers inspections and sampling in the geographic area of competence .

The base-frequency of inspections is decided taking into account the resources available and a general knowledge of the risks that can be reasonably attributed to the different types of activities carried out by the feed business operators. In the feed sector, this base-frequency can be reduced by 50% if the establishment has had its own-control system certified by an accredited certification body (see section 5.2.6) and can provide evidence of satisfactory checks during the previous two years. If necessary, 10% of those establishments where non-compliances had been found, are re-inspected the year after in order to ensure that the corrective measures taken are effective.

The sampling programme is designed on a risk-basis and by using a solid statistical approach. A database is used as a source of information. Such data and information include, among others: results of official samples, results of sampling programmes run by various associations of feed business operators (see section 5.2.4 on undesirable substances), RASFF notifications and scientific literature.

Relevant recommendations made in report 2010-8469 concerned the planning of official controls. In particular, these referred to the past records of compliance as one of the criterion for the planning and to the risk-based planning of inspections in food establishments supplying food by-products to the feed chain). Moreover, another recommendation concerned the prior announcement of official controls. In response to these recommendations the competent authority undertook to take various actions.

- In the PCUs and the establishments visited, the audit team saw that a comprehensive software (PLANITRA) is used for the planning of inspections and that these had taken place largely according to established frequencies (thus, the relevant recommendation in Report 2010-8469 has been satisfactorily addressed). PLANITRA is interconnected with a database of food/feed business operators (BOOD), where all feed business operators are listed (see section 5.1.3), and this allows a smooth and reliable allocation of inspections. Moreover, this software permits an easy verification of the state of play of the inspection programme during the course of the year. According to representatives from the FASFC, all other PCUs avail of the same IT tools. In the establishments visited the audit team could obtain evidence that inspections are always unannounced. Thus, the relevant recommendation in report 2010-8469 has been satisfactorily addressed.

- According to representatives from FASFC, the large majority of feed business operators listed in BOOT are subject to planned inspections by using PLANITRA. The only exceptions are food establishments supplying food by-products and transporters of feed ⁽³⁾.
- Concerning food establishments supplying food by-products to the feed chain, the FASFC's position foresees that, by default, these are also feed business operators (this concept is known as “implicit activity”). Thus, such business operators are included in the official list of registered feed business operators. Nevertheless, official controls on feed legislation in these business operators have started only recently. Since January 2013, food inspectors have been instructed to focus also on activities implying the placing on the market of any feed material. If the food business operator delivers any feed material directly to farms this activity has to be identified in BOOD and the business operator is subject to routine feed inspections according to the planned frequency (once every three years). On the other hand, if the food business operator delivers any feed material to business operators other than farmers (e.g. feed mill, food surplus collectors, etc.) this activity is not identified in BOOD. As a consequence, the business operator is not subject to feed inspections but during routine food inspections some feed requirements are verified. The audit team noted the following: a) according to representatives from FASFC, those food establishments supplying feed material directly to farms are still unknown and, b) for those food establishments supplying feed material to feed business operators other than farmers, the verification of requirements on feed legislation is limited to a single generic question contained in the inspection check-list about whether or not the feed delivered to third parties is safe. The above-mentioned evidence indicates that requirements laid down by Article 3 of Regulation (EC) No 882/2004 are not fully met for official controls on these particular feed operators. Thus, the relevant recommendation in report 2010-8469 has not been satisfactorily addressed.
- Concerning transporters of feed, despite the fact that these are not included in the inspections programme they are, nonetheless, subject to a number of inspections carried out under the co-ordination of the national investigation unit of the DG Control on the basis of suspicion and it covers all the food and feed chain. According to information provided by representatives from FASFC, a total of 705 inspections were carried out in 2012 and 2500 had been planned for 2013.
- In the PCUs and establishments visited, official samples on undesirable substances had been largely carried out according to established frequencies and, in some cases, additional samples had been taken after the detection of positive results (i.e., in order to follow-up non-compliances). Moreover, technical sheets have been issued to explain practical arrangements during the official sampling and, according to representatives from FASFC, one of them is going to be amended in order to clarify the requirements laid down by Regulation (EC) No 152/2009. In addition, the audit team noted an example of good practice; according to information provided by FASFC, official sampling programmes take into account the types and the results of analyses carried out by the professional association (in particular by the Belgian Compound Feed Industry Association - BEMEFA) and in 2012 it resulted in a reduction in the number of official samples as follows: mycotoxins (-15%), heavy metals (-15%) and pesticide residues (-14%) in the raw materials delivered to food manufacturers.
- Concerning the presence of dioxins in feed, and according to information provided by FASFC, 49 samples were taken for dioxins and 57 for dioxins-like PCB in dried feed materials in 2012. In two cases (one for each category) the maximum limits set up by

3 In their response to the draft report the competent authorities noted that the food establishments supplying food by-products and transporters of feed are inspected during control visits applicable to the food sector and during concerted action with the police.

Directive 2002/32/EC was exceeded (see also section 5.2.3 on dioxins monitoring). However, the audit team noted that: a) none of these samples had been taken directly from feed dryers where direct drying takes place; b) all these samples had been taken at feed mill level but no information on their origin had been recorded in the official control system (i.e. they could have been purchased from other Member States); and c) no or very limited information is available in Belgium on the presence of dioxins in dried feed materials, since feed operator's sampling plans usually do not include analyses for these substances in feed materials (see section 5.2.4 on undesirable substances). This is not fully in line with Article 3 of Regulation (EC) No 882/2004.

- According to representatives from FASFC the turnaround time for the analysis of samples for dioxins and dioxin-like polychlorinated biphenyls (dioxin-like PCBs) is a few days for the "CALUX" screening method and a maximum of one week for the high-resolution gas chromatography - high resolution mass spectrometry (HRGC-HRMS). This was confirmed by the audit team in the establishments visited.

Conclusions

The large majority of feed operators included in the scope of the audit are subject to inspections which are carried out regularly, on a risk basis, with appropriate frequency and without prior warning. However, there are still a number of food establishments supplying food by-products to the feed chain which are not subject to planned and regular official controls because these have not yet been properly identified. Therefore, with the exception of the recommendation referred to on official controls in food establishments supplying food by-products to the feed chain, all other recommendations in report 2010-8469 can be considered satisfactorily addressed.

A comprehensive and risk-based sampling programme to detect undesirable substances in feed has been devised and largely implemented on a risk basis. Moreover, this programme takes into account the types of analysis and the results of own-checks carried out by a number of professional associations of feed business operators. However, although steps have been taken to identify the risks associated with the direct drying of feed materials, due to a limited knowledge of the fuels used and the lack of results of dioxins tests for these materials, the risk of presence of dioxins has not been satisfactorily addressed by the competent authorities during official controls.

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

Relevant recommendations made in report 2010-8469 concerned records of official controls on food establishments supplying food by-products into the feed chain and transporters. In response to this recommendation the competent authority undertook to introduce the concept of "implicit activity" (see section 5.1.2) in order to ensure regular and documented official controls on these feed operators.

- A comprehensive set of technical sheets on various topics and specific check-lists for different types of activities carried out by feed business operators, have been developed to facilitate the delivery of official controls of all feed business operators included in the scope of the audit. These documents are an integral part of the FASFC's certified quality management system and are available on-line by inspectors. Overall, these documents provide useful support for the performance of official controls, although a specific check-list for food establishments supplying food-by products has not been developed yet (see section 5.1.2) and the technical sheet concerning official sampling does not contain clear instructions on how to take samples in order to verify compliance with Directive 2002/32/EC (see section 5.1.2). This is largely in line with Article 8(1) of Regulation (EC) No 882/2004.
- In all PCUs and establishments visited, official controls (i.e. inspections and sampling) had been recorded using the relevant check-list and a copy was always left with the business operator. This is largely valid, although with some limitations (see section 5.1.2), also for official controls carried out in food establishments supplying food by-products into the feed chain and transporters; thus, the relevant recommendation has largely been satisfactorily addressed.
- In all PCUs and establishments visited, the audit team noted that officials always make use of a laptop through which they can access to their central database (FOODNET). This allows them to trace-back and download inspection and sampling reports in order to follow-up any previous non-compliance.
- According to information provided by FASFC, the result of audits on HACCP carried out by the certification bodies during their controls (see section 5.2.6) are also available on-line from a central data base.

Conclusions

A number of detailed and comprehensive guidance documents and check-lists for the performance of the official controls have been issued and these contribute to the delivery of effective and harmonised official controls, with the only exception of official controls on food establishments supplying food by-products to the feed chain (see section 5.1.2). The level of information included in inspection reports and their easy accessibility through the central database acts as valuable source of information for follow-up controls. The relevant recommendations in report 2010-8465 can be considered largely satisfactorily addressed.

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

Verification of official controls is carried out as described in report 2010-8469. Further verifications are carried out by the accreditation body in the context of its supervision on ISO 17020 accreditation and by the certification body as part of its supervision on ISO 9001 certification (see below).

The relevant recommendation made in report 2010-8469 concerned the internal supervision. In response to this recommendation the competent authority undertook to develop a software tool and organise training sessions.

The DG Control has been accredited in 2012 according to ISO 17020:2012 “Requirements for the operation of various types of bodies performing inspection”. The accreditation scope includes activities carried out at central and PCU level. In addition to that, DG Control Policy has been certified according to ISO 9001:08 in 2011.

- In the PCUs visited the audit team noted that the software PLANITRA is widely used to verify the state of play of inspections and sampling programmes (see section 5.1.2). The head of sector reviews two inspection reports for each inspector under his/her responsibility (one with remarks and one without remarks). In addition to that, twice per year, the head of sector carries out joint inspections with each inspector. Comprehensive procedures describe this task and several details are provided on how to assess inspectors' performance. The audit team saw some examples of records of joint inspections in a PCU visited and saw records of training provided to the head of sectors concerning the assessment of inspector's performances. Thus, the relevant recommendation in report 2010-8469 has been satisfactorily addressed.
- According to information provided by FASFC all accredited certification bodies, are subject to supervision by the Belgian accreditation body (BELAC) This supervision consists of office and witness audits on the spot, with a frequency varying from 12 to 18 months. In addition, those certification bodies involved in GMP certifications (which includes controls on HACCP on behalf of FASFC, see section 5.2.6), are subject to supervision by FASFC. Every year a number of certification bodies are selected and audited by FASFC on the basis of alerts or in case of anomalies noted during routine official inspections.

Conclusions

A satisfactory system to verify the effectiveness of official controls has been devised and implemented. The relevant recommendation in report 2010-8469 can be considered satisfactorily addressed.

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 listing of these establishments.

Findings

Concerning registration and approval of establishments, the system in place is largely described in report 2010-8469. In summary, a database of business operators (BOOD) has been created and it lists, among others, all feed business operators included in the scope of the audit. Moreover, FASFC has made use of the provisions of Article 10(2) of Regulation (EC) No 183/2005. As a consequence, feed business operators subject to registration according to the said Regulation but falling under its Annex II and placing on the market some feed considered as critical, are subject to authorisation.

The relevant recommendation made in report 2010-8469 concerned the information on activities carried out by feed business operators. In response to this recommendation the competent authority undertook to highlight the need to verify the consistency between the activities actually carried out by feed business operators and those indicated in BOOD, during forthcoming meetings.

- All establishments visited and their suppliers were approved or registered as required. Feed business operators requiring approval according to Regulation (EU) No 225/2012 visited by the audit team had been approved on the basis of the positive result of an inspection carried out by PCU's inspectors. This is in line with Articles 9 and 10 of Regulation (EC) No 183/2005.

Concerning lists of registered and approved feed establishments:

- BOOD is synchronised with another central database called “banque carrefour des entreprises” where all business operators have to make an application prior to starting a business. Among others, information concerning activities and relevant activity-codes are to be included when an application is made.
- According to representatives of FASFC, the verification of activities actually carried out by the feed business operator and the consistency with those indicated in BOOD always takes place during routine inspections. In the PCUs and the establishments visited the audit team could see evidence that this is done. Thus, the relevant recommendation in report 2010-8469 has been satisfactorily addressed.
- From FASFC website it is possible to access the lists of authorised and approved feed establishments and to know whether a feed business operator is registered or not and for which activities. These lists are regularly updated. The audit team noted that all types of feed business operators included in the scope of the audit are included in these lists, although information concerning the placing on the market of food by-products by some food business operators is only partly known by the competent authority (see section 5.1.2). This evidence indicates that requirements concerning the list of feed establishments, laid down by Article 19 of Regulation (EC) No 183/2005 are largely met.

Conclusions

The process of registration and approval of feed establishments is largely effective and, as a consequence, the large majority of feed establishments are known by the competent authorities and are included in publicly available lists. Moreover, with the only exception of some food establishments (see section 5.1.2) the information contained in such lists fulfil relevant requirements. The relevant recommendations in report 2010-8469 can be considered satisfactorily addressed.

5.1.6 Actions in case of non-compliances

Legal requirements

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

Findings

The system in place to assess non-compliances and to determine subsequent measures and sanctions remains as described in report 2010-8469. In summary, for each item of the check-lists used during inspections, a weight is attributed on the basis of the severity of the relevant non-compliance.

Depending on the total score of the check-list and the number of major non-compliances, an inspection can be considered: favourable, favourable with remarks or non-favourable. In the latter case, different actions have to be taken by the PCU. These actions include warning letters, and official reports where fines are imposed.

The relevant recommendation made in report 2010-8469 concerned the need to ensure that appropriate actions are always taken when non-compliances are identified. In response to this recommendation the competent authority undertook to modify their operating procedures accordingly.

- Amended procedures are in place to ensure an adequate follow-up of non-compliances. The software FOODNET allows inspectors to easily access to previous inspection reports and samples results. Several examples of non-compliances found during official controls were seen by the audit team in the PCUs visited. These were adequately recorded and followed up satisfactorily. Thus, the relevant recommendation in report 2010-8469 has been satisfactorily addressed.

Conclusions

Non-compliances detected during official controls are largely followed up. This allows competent authorities to ensure that largely suitable corrective actions are taken. The relevant recommendation in report 2010-8469 can be considered satisfactorily addressed.

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; among 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 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

- In all establishments visited the audit team noted that inspectors pay attention to the requirements concerning the sourcing and the labelling of feed and relevant check-lists include various questions concerning this topic.
- In all establishments visited, the audit team noted that business operators had procedures in place to qualify all their suppliers. In addition, those located in Belgium have to be GMP certified. According to such standard, which is a private-sector standard, the registration in accordance with Article 9 of Regulation (EC) No 183/2005 is a pre-condition to obtain a certification.
- In the feed mills, in the dryer and in the food establishment supplying food by-products the audit team noted that feed placed on the market was labelled and always accompanied by

delivery notes/invoices indicating the nature of the products, as required by the feed legislation.

- In the oil processor, importer, chemical plants, quarry and in the feed mills using fats and oils the audit team noted that feed placed on the market was labelled as feed material and always accompanied by delivery notes/invoices indicating the wording “feed material” followed by further detailed information, as required. In the same establishments, other similar products not destined for use in the feed chain, were generally accompanied by delivery notes/invoices specifying other purposes than feed, as required by the feed legislation.

Conclusions

The system of official controls is largely effective in verifying that requirements concerning the safe sourcing of feed and the labelling of feed are fulfilled by feed business operators.

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

- In the establishments visited the audit team noted that feed inspectors paid attention to the infrastructural and organisational requirements of Annex II to Regulation (EC) 183/2005, and that facilities and equipment, with the exception of one establishment, were largely in line with these requirements. In the establishment concerned (compound feed manufacturer not yet in operation as fat blender), the audit team noted some problems on general hygiene and infrastructure; however, these deficiencies had been already identified by the feed inspector during the last inspection carried out shortly before the audit.
- In the chemical plants dealing with feed and technical grade products and in the oil processor visited, the audit team noted a clear physical separation between the two different types of products. Inspectors, by making use of relevant check-lists, paid attention to the risk of contamination due to infrastructures or equipments, as required by Annex II of Regulation (EC) 183/2005.
- In the food establishment visited some food by-products were placed on the market as feed material but other food by-products, which are not feed-grade, according to their HACCP plan, were dispatched for biogas production. The audit team noted that a number of comprehensive procedures and technical arrangements had been put in place to prevent cross-contamination between these two types of food by-products.
- In all other establishments visited the audit team noted that products which are not feed-grade were always collected in bags/container/silos/tanks and were adequately labelled, as required by Annex II of Regulation (EC) 183/2005.

Conclusions

The system of official controls is largely effective in verifying that infrastructure and organisational requirements, notably those aimed at preventing feed coming into contact with non-feed products, are satisfactorily implemented by feed business operators.

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, among others, dioxin monitoring arrangement for fats, oils or products derived thereof.

Findings

In Belgium, an extensive monitoring of dioxins and dioxin-like PCBs in the feed sector has been in place for more than a decade. The most recent version of this programme can be found in the Royal Decree of 21/02/2006 which lays down the conditions as regards approval and authorisation of establishments in the feed sector and some requirements concerning the monitoring of feed considered as critical. Some Circulars have been issued by FASFC in order to clarify relevant requirements contained in the last amendment of Regulation (EC) No 183/2005. The last version was issued in October 2013.

FASFC provided the audit team with an extract of the results of inspections carried out in 190 establishments in 2013. As regards requirements on dioxin monitoring the following outcomes are highlighted: a) presence of proof attesting the application of European dioxin monitoring for all incoming consignments (among oleochemical and biodiesel plants, fat blenders and feed compounders): 29 conformities; 0 non-conformities and 161 not applicable; b) testing of incoming products according to dioxin monitoring: 43 conformities, 0 non-conformities and 147 not applicable; c) testing of outgoing products according to dioxin monitoring: 20 conformities, 3 non-conformities and 163 not applicable.

Further information provided by FASFC concerning 1850 official samples for dioxins in 2012 resulted in the following: 100% conformities in 25 samples of additives; 100% conformities in 102 samples of premix of additives; 99.8% conformities in 350 samples of feed materials (one non-conformity refers to a case of dioxins found in dried feed material supplied from a different Member State)

- According to the national legislation, sampling for dioxins, which is one of the obligations for feed business operators, has to be carried out by accredited bodies. The audit team noted that this provision is more stringent than those laid down by Annex II of Regulation (EC) No 183/2005 ⁽⁴⁾. Moreover, all applicable requirements concerning dioxin monitoring are regularly verified during official controls.
- With the exception of the oil processor, in all establishments visited by the audit team the dioxin monitoring system was in line with the requirements of Annex II of Regulation (EC) No 183/2005. In the oil processor, where the crushing of linseed and the refining of linseed oil takes place, some 60,000 tonnes of linseed expeller are placed on the market annually as feed material. Used bleaching earth is added to this expeller up to 1%. The bleaching earth is used for the physical refining of the crushed oil, which is subsequently placed on the market for cosmetic, food and other technical applications. The audit team noted the following:

4 In their response to the draft report the competent authorities noted that this provision, nonetheless, complies with the principle of subsidiarity.

- According to the business operator's sampling plan, dioxins are tested twice per year on the raw material (linseed) and three times per year on the refined oil. No positive cases have been found, so far.
- Bleaching earth is purchased five or six times per year from a single supplier. These consignments are accompanied by a certificate of analysis indicating the absence of dioxin. The audit team saw examples of such certificates of analysis.
- According to the business operator's sampling plan, samples for dioxins are neither carried out for the expeller nor for the used bleaching earth. Although this is not in line with the last amendment of Annex II of Regulation (EC) No 183/2005, which requires a monitoring regime for such types of products, the business operator explained that the decision not to sample was taken on a risk-basis deduction which took into account a recent position of the Federation of the European Vegetable Oil and Protein-meal Industry (FEDIOL) on this matter. This shortcoming had been identified by the inspector during official controls.

Conclusions

In Belgium, an extensive monitoring of dioxins and dioxin-like PCBs in the feed sector has been in place for more than one decade and it has created a solid basis for the development of the current system of official controls which is effective in verifying that the EU dioxin monitoring requirements are satisfactorily implemented by feed business operators. Feed establishments largely fulfil requirements on dioxin monitoring.

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, among others, cross-contamination, homogeneity as well as undesirable substances. In particular, Directive 2002/32/EC sets out maximum permitted levels for undesirable substances in feed.

Findings

A guide for the self-control in the feed sector (Guide Autocontrôle Alimentation animale) has been developed by the Belgian platform for companies active in the animal feed chain (OVOCOM) and has been approved by FASFC. It contains provisions on how to develop and maintain procedures based on HACCP principles in various sectors of the feed chain and how to manage certain hazards, including dioxin and the cross-contamination of coccidiostats/antibiotics in non-target feed. According to representatives from FASFC, compliance with requirements laid down in this guide is a prerequisite to obtain a GMP certification.

Cross-contamination

The relevant recommendation made in report 2010-8469 concerned the carry-over of coccidiostats. In response to this recommendation the competent authority undertook to modify a check-list used during inspections and to remind the associations of feed business operators about this issue.

- The audit team noted that official controls in feed establishments include the verification of the issue concerning cross-contamination. The relevant check-list contains questions on this topic and further clarifications are included in specific technical sheets. A Circular has been

issued by FASFC in 2011 with clarifications for business operators on how to manage the risk of cross-contamination of coccidiostats and other antibiotics.

- In one feed mill visited, the risk posed by the carry-over of coccidiostats into non-target feed is mitigated by flushing the production line with wheat immediately after the production of feed containing coccidiostats and by sequencing production. The carry-over is tested every two years by applying a method in line with the one described in the OVOCOM guide. This method makes use of micro-tracers and foresees a number of samples to be taken, without flushing, both after the mixer (mixer-run samples) and after the pelleting stage (before the loading). The last test was performed in 2011 and the carry-over resulted 4,3%. Depending on the type of coccidiostat used, the flushing consists of two charges of 400 or 250 Kg of wheat added to the mixer which has 5 tonnes capacity. The business operator explained that the number of charges has resulted by applying a method which takes into account the type of coccidiostat used and the actual carry-over measured. This method has been validated by FASFC and it is contained in the BEMEFA guidelines. The business operator explained the size of the flushing batches had been determined on the basis of experience. However, the audit team noted that the effectiveness of the flushing, notably, the specific size of the flushing charges, had never been proved as adequate by the business operator. This is not fully in line with the requirements laid down by Annex II of Regulation (EC) No 183/2005. Official controls overlooked this shortcoming.
- In the other feed mill visited, where a mixer of six tonnes capacity is used, the batch size of the final product is, on average, 17 tonnes. According to the business operator a mixer run usually varies from two to five tonnes, therefore, a batch of final product can contain from three to eight mixer runs. The carry-over is tested annually by applying a method in line with the one described in the OVOCOM guide (see section 5.2.6). The last test results indicate a carry-over varying from 3 to 5%. According to the business operator, the preventive measure to mitigate carry-over consists of the sequencing production, i.e. the manufacturing of feed destined to less sensitive non-target species after the manufacturing of feed containing coccidiostats. However, the audit team noted that the preventive measure actually consists of a dilution of any carry-over contained in the first mixer-run after the production of feed containing coccidiostats into a bigger batch of final product made by gathering more than three mixer-runs. Moreover, the business operator was not in a position to demonstrate that this preventive measure was effective, since the three tests available, had been taken not from the first mixer-run after the use of coccidiostats but randomly (in one case from the eighth mixer run). Moreover, these samples are taken by BEMEFA in the context of their sampling programme which is not aimed at proving the effectiveness of preventive measures adopted by each single establishment, but only with the purpose of collecting data from all establishments which are part of their monitoring programme. Thus, this is not fully in line with the requirements laid down by Annex II of Regulation (EC) No 183/2005 because the business operator was not in a position to demonstrate the effectiveness of its preventive measure. Official controls overlooked this shortcoming. However, a number of official samples had been taken from both feed mills, and none of them showed any carry-over of coccidiostats in non-target feed exceeding the permitted level laid down by Directive 2002/32/EC.

Homogeneity

- The audit team noted that official controls in feed establishments include the verification of homogeneity. The relevant check-list contains questions concerning this topic and further clarifications are included in specific technical sheets.

- In both feed mills visited the homogeneity of feed was regularly verified by the business operator by applying a method in line with the one described in the OVOCOM guide (see section 5.2.6). According to the information provided by both business operators, the mixing time is usually kept fixed and tests for homogeneity take place using the same settings. The audit team saw a number of reports from both the feed mills showing a coefficient of variation (CV) always below 10%.

Undesirable substances

- The audit team noted that official controls in feed establishments include the verification of how the feed business operators manage the risk of undesirable substances. The relevant check-list contains some questions concerning this topic and further clarifications are included in specific technical sheets.
- Professional associations like BEMEFA and the professional Association of Traders in Grains and other Agricultural products (SYNAGRA) have developed sampling programmes to ensure the safety of the feed chain among their affiliates. These sampling programmes are devised taking into account the potential hazards linked with different types of feed materials and compound feed. The number of samples and their allocation among feed business operators are defined taking into account the volume of production of each establishment. The audit team noted that these sampling programmes included most of undesirable substances which might affect the safety of feed, i.e. heavy metals, mycotoxins and dioxins in the relevant sector.
- In both feed mills visited, the sampling plan for undesirable substances consisted, in practice, of a number of analysis taken in the context of the BEMEFA sampling programme. The audit team noted that these sampling plans were largely adequate to the specific risks in each of those establishments, although only in one of them the sampling plans actually reflected the outcome of the hazard analysis for raw materials and ingredients (see section 5.2.6).
- In the feed dryer visited, two drying installations were using diesel and one natural gas as fuel. In all cases the drying system was direct (i.e. direct contact of the combustion gases with the feed). The risk due to the direct contact of fumes with the feed was taken into account in the HACCP plan and regular tests for the presence of polycyclic aromatic hydrocarbons (PAHs), were planned and were actually taken since 2005 in the framework of the SYNAGRA sampling programme and in accordance with national legislation. However, the audit team noted that, at least since since 2005, no samples for dioxins and heavy metals have ever been taken (see the following bullet point).
- During 2012-2013, FASFC, in collaboration with SINAGRA, carried out a survey among a number of feed dryers with the purpose of identifying the type of fuel and the type of drying systems (direct or indirect) used. The outcome of this survey indicated that the vast majority of fuel used was diesel and gas and that both direct and indirect systems are used. On the basis of the assumption that diesel and gas do not usually contain substances which may pose significant risks when burned, and in order to extend the sampling of dried products to include foreign products, FASFC took the decision not to take samples for dioxins from feed dryers but to target samples only at feed manufacturer level. However, the audit team noted the following: a) the survey did not provide detailed information about the specific composition of the fuels, e.g. the level of impurities for the different types of gas and diesel used; b) according to representatives from FASFC, during routine inspections of feed dryers the specific analytical composition of fuels (e.g. level of impurities) is not verified; and c) according to scientific literature, despite the likelihood of presence of dioxins and heavy metals in feed which had been in contact with fumes during a direct drying process being

low if diesel is used, this cannot be considered as negligible, in particular when the specific analytical composition of the fuel is not known. The above evidence indicate that requirements laid down by Article 3 of Regulation (EC) No 882/2004 are not fully met in this specific case (see section 5.1.2).

- Concerning the presence of packaging material in food by-products placed on the market as feed materials, the competent authority considers the detection of any packaging residues to constitute a non-compliance. A technical sheet clarifies how to deal with this issue during inspections and in case of detection of non-compliance following sampling. According to information provided by FASFC, 44 samples had been taken in 2012, 10 from farms, 15 from feed establishments (including traders) and other 10 from food establishments. The audit team could see evidence of such sampling plans. Thus, the relevant recommendation in report 2010-8469 has been satisfactorily addressed.

Conclusions

The system of official controls and the measures put in place by feed business operators ensure that relevant requirements concerning homogeneity are fulfilled but there are weaknesses mainly related to the way feed business operators ensure the effectiveness of their control measures to prevent carry-over of coccidiostats in non-target feed and the way this is verified by the competent authorities. The relevant recommendation in report 2010-8469 has not been satisfactorily addressed.

Concerning undesirable substances, an advanced and risk-based official control system is largely effective in verifying that the risk posed by these substances is satisfactorily controlled by feed business operators. However, the specific risk posed by dioxins in dried feed materials should be reconsidered in order to address a more targeted measures (see section 5.1.2).

5.2.5 Traceability

Legal requirements

Article 5(2) of Regulation (EC) No 1831/2003 indicates that the requirements set out in its Annex II shall be met for operations other than those regarding primary production; these requirements concern, among others, records for traceability and the keeping of samples.

Findings

- The audit team noted that official controls in feed establishments include verification of traceability. The relevant check-list contains questions concerning this topic.
- In all places visited, backward and forward traceability was possible as regards the origin of almost all products used in a formulation and the destination of the finished product.
- In all places visited the business operators kept samples of feed materials, liquid materials and finished products for at least six months.

Conclusions

It can be concluded that there is a system in place that largely ensures compliance with requirements related to traceability

5.2.6 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

According to representatives from FASFC, official controls on HACCP-based procedures are carried out both by official feed inspectors and by auditors of accredited certification bodies. In case of feed business operators with a certified own-control system, official controls are based on three “key questions”, which are changed annually, with the purpose of obtaining an overview of the own-control systems. In case one or more negative answers are given, a further detailed assessment has to be carried out. This limited control is justified by the fact that these business operators are subject to annual audits by their certification bodies and, as part of such audits, a detailed verification of the HACCP system always takes place. On the other hand, if a feed business operator does not have a certified own-control system (i.e. is not subject to audit by a certification body) the official inspection programme includes more detailed checks of the HACCP-based procedures, according to established frequencies and by using comprehensive check-lists.

- In the PCU and in the establishments visited the audit team saw a number of audit reports carried out by certification bodies and inspection reports by the competent authorities confirming that the HACCP-based procedures are verified regularly and in a comprehensive way. However, the audit team noted some minor shortcomings, as follows: a) in one feed mill the risk for of all purchased dried food by-products was considered negligible irrespective of the type of fuel, the type of drying system used (direct or indirect) and the origin of the supplier; b) in a feed mill the risk of carry-over of coccidiostats into feed in the mixing step was considered as a critical control point (CCP) but the effectiveness of the relevant control measure (i.e., the flushing) had never been validated (see section 5.2.4); and c) in a food establishment visited, largely comprehensive procedures based on HACCP principles had been devised and adequately implemented. However, some food by-products containing packaging materials were not included in the flow diagram despite the fact that they were dispatched to an integrated recycler plant whose main activity is to recycle them into the feed chain. These shortcomings had not been identified during official controls.

Conclusions

The system of official controls largely pay attention to business operators' HACCP-based procedures, which allows them to detect non-compliances in this regard and ensure these are rectified in a suitable way.

6 OVERALL CONCLUSIONS

There is a solid and advanced system of official controls which is largely effective in verifying that business operators along the feed chain identify hazards and manage properly the associated risks. The organisation and the delivery of official controls are risk based, strengthened by useful software tools and underpinned by a comprehensive set of check-lists, technical sheets and verification measures. Moreover, it is worth highlighting that the competent authorities make use of the results of structured and largely comprehensive own-checks programmes run by a number of professional organizations of feed business operators during the planning of the sampling programme for

undesirable substances. However, official controls in food establishments supplying food by-products to the feed chain are still at an early stage of development and those concerning the measures put in place by feed business operators to limit the risk of carry-over of coccidiostats in non-target feed do not focus sufficiently on the verification of the effectiveness of such preventive measures. Moreover, although steps have been taken to identify the risks associated with the direct drying of feed materials using various fuels, official controls in this area are not yet well developed.

7 CLOSING MEETING

A closing meeting was held on 27 November 2013 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.

8 RECOMMENDATIONS

The competent authorities of Belgium 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 make further progress in ensuring that food establishments supplying food by-products to the feed chain are subject to official controls as laid down by Article 3 of Regulation (EC) No 882/2004.
2.	To further develop official controls on feed dryers in order to better address the risk of presence of dioxins in feed materials which had been in contact with fumes during direct drying processes, as laid down by Article 3 of Regulation (EC) No 882/2004.
3.	To ensure that feed business operators have in place measures to verify the effectiveness of preventive measures to control the risk of carry-over of coccidiostats in non-target feed as laid down in Annex II to Regulation (EC) No 183/2005, in order to guarantee that the maximum permitted levels in non-target feed laid down in Directive 2002/32/EC are not exceeded.

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=2013-6748

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
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. 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. 152/2009	OJ L 54, 26.2.2009, p. 1-130	Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed
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

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.

Findings

The Federal Public Service for Health, Safety of the Food Chain and Environment (FPS–HSFCE) is the authority under the Minister of Health is responsible for the preparation of policy and relevant legislation, among others in the marketing and labelling of feed. A number of Memorandums have been published on this topic and Moreover, a web-site is publicly available with detailed information on feed legislation and feed marketing is also included.

<http://www.health.belgium.be/eportal/AnimalsandPlants/animalhealth/animalnutrition/index.htm>

- Quarterly meetings are organised by the Federal Public Service and FASFC with all the professional representatives of the animal feed sector. At these meetings, the Federal Public Service presents proposed amendments to the European legislation and explains any new rules. Discussions on provisions relating to Regulation (EC) No 767/2009 have taken place, and the audit team saw agendas and presentations given during these meetings.
- A number of training sessions organised by the Federal Public Service took place in 2010, and 2013 for inspectors involved in feed inspections. The audit team saw agendas and participants at these trainings.
- Verification of compliance with feed marketing rules forms part of feed control carried out by FASFC. A specific check-list on feed labelling have been devised. Feed inspectors are instructed to pay attention to these requirements during routine inspection to feed establishments. The audit team saw a number of such check-list filled in by inspectors.

2 FINDINGS

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

- The position of the Federal Public Service and FASFC concerning the declaration of the quantity of trace elements, is that the amount of micro-nutrients should be expressed in terms of the amount of the element added rather than the quantity of the additive (E.g. 'Copper sulphate – copper 15 mg/kg' (where 15 mg/kg represents the added amount of copper, not of copper sulphate). This position has been expressed in a letter sent to DG SANCO in March 2012 and was shared by all relevant associations of feed business operators.

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

- The Federal Public Service, in collaboration with the Federal Agency for Medicines and Health Products (AFMPS), has published an indicative list of claims considered not to be describing curative or preventive properties. The list applies to feed but also to other products such as 'cosmetics' for animals, biocides and other care-products for external use. It is accessible to the general public on the above-mentioned web-site.
- The Federal Public Service takes an active part in the mixed commission chaired by the Federal Agency for Medicines and Health Products which is active since 2009. This commission meets eight times per year and the members of the various authorities give an opinion on the legislation applicable to the products which they monitor. Since 2009 about 450 dossiers have been evaluated and, according to FASFC, more than 50% of them concerned feed. Where products are not considered to be covered by the legislation on medicines but related to Articles 11 and 13 of Regulation (EC) No 767/2009, and irregularities are identified, these are communicated to the AFSCA, which is a member of the mixed commission, and can take the appropriate measures.
- Claims are regularly verified during feed inspections by using the check-list on labelling where some questions are specifically dedicated to this issue. Annually a small number of non-compliances are reported by FASFC (these amount to about 5-10% of the total number of checks on such issue, when this is applicable). In case of doubts, FASFC inspectors ask clarification to the Federal Public Service and this can be the case when claims refer to curative and preventive animal diseases properties. In 2012 three cases were submitted to the Federal Public Service by FASFC.
- According to information provided by FASFC, only one case of scientific substantiation dossier on a claim has been received by the Federal Public Service to date. It was assessed at the request of the AFSCA on the basis of documents provided by the business operator. The cause-and-effect relationship in one of the two claims submitted was considered to have not been sufficiently demonstrated. A standardised evaluation procedure is currently being drawn up, based on the demonstration of cause and effect. A draft procedure is also being drafted.

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 FASFC, this area is perceived to be related to claims and the focus within the latter relates to medical claims (see section 2.2).