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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2014-7037 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ITALY

FROM 18 TO 27 FEBRUARY 2014

IN ORDER TO EVALUATE THE IMPLEMENTATION OF THE SPECIFIC REQUIREMENTS FOR PRODUCTION, STORAGE, TRANSPORT AND DIOXIN TESTING OF 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 Italy from 18 to 27 February 2014.

The overall objective of the audit was to evaluate the implementation of the specific requirements concerning the production, storage, transport and dioxin testing of oils, fats and products derived thereof for use in animal feeding introduced in Regulation (EC) No 183/2005 through its amendment, Regulation (EU) No 225/2012.

Overall the report concludes that the system of official controls is largely effective in verifying that operators along the feed chain comply with the requirements concerning production, storage, transport and dioxin testing of oils, fats and products derived thereof. However, it is at an early stage of development and, although some good practices were noted, it is not applied in a consistent way throughout the country. The main reason for this situation is linked with a general delay in the process of development and adoption of comprehensive check-lists that would facilitate a structured and systematic verification of relevant requirements, in particular during the approval of establishments. Moreover, although some measures to reduce the turnaround time for analyses of dioxins have been taken, these are still not sufficient to ensure that corrective actions are taken in a timely fashion.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
APAG	European Oleochemicals & Allied Products Group
ASL	Local Health Units
FNCP	Feed National Control Plan
FVO	Food and Veterinary Office
PCB	Polychlorinated biphenyls
Report 2012-6492	Report of an audit carried out in Italy from 20 to 30 November 2012 on measures in place for the identification of hazards and management of risks along the feed chain

1 INTRODUCTION

The audit took place in Italy from 18 to 27 February 2014.

The audit team, which comprised two auditors from the Food and Veterinary Office (FVO), was accompanied throughout the audit by representatives from the Ministry of Health (*Ministero della Salute*).

An opening meeting was held on 18 February 2014 with representatives of the veterinary service from the central and regional levels, 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 is effective in verifying the implementation of the requirements concerning oils, fats and products derived thereof for use in animal feeding.

The above was assessed against the following audit criteria:

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

The audit took account of a previous FVO audit concerning the identification of hazards and management of the associated risk along the feed chain (audit DG(SANCO) 2012-6492) but it did not assess the effectiveness of the corrective actions undertaken in response to the recommendations made in its relevant report (hereafter, report 2012-6492).

In terms of scope, the audit focused on the official control of the requirements of Regulation (EC) No 183/2005 introduced by Commission Regulation (EU) No 225/2012 ([1]) namely the requirements for establishments placing on the market, for feed use, products derived from vegetable oils and blended fats, including those concerning dioxin testing (see section 4.1).

For the sake of clarity and for easier reading, whenever a reference is made to all new requirements introduced by Regulation (EU) No 225/2012, the report will hereafter quote "Regulation (EU) No 225/2012" instead of "requirements introduced by last amendment of Regulation (EC) No 183/2005".

1 Commission Regulation (EU) No 225/2012 of 15 March 2012 amending Annex II to Regulation (EC) No 183/2005 of the European Parliament and of the Council as regards the approval of establishments placing on the market, for feed use, products derived from vegetable oils and blended fats and as regards the specific requirements for production, storage, transport and dioxin testing of oils, fats and products derived thereof (OJ No. L 77, 16.03.2012, 1).

The itinerary for the audit included the following visits:

Visits/meetings		No	Comments
Competent authority	Central	2	Opening and final meeting
	Regional	3	
	Local	3	
Compound feed manufacturers		3	Using oils and fats, two of them also importers
Fat blenders		2	Both compound feed manufactures. One of them not in operations yet as fat blender
Oil processor		1	Where refining activities take place and placing on the market crude and vegetable oils and fatty acids
Olechemical plants		2	Both placing on the market distilled fatty acids
Biodiesel plant		1	Placing on the market glycerine

3 Legal Basis

The audit was carried out under the general provisions of 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

4.1 Rationale of the audit series

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, Regulation (EU) No 225/2012 amending 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. A series of audits have been carried out by the FVO in Member States since 2013 with the purpose to assess the level of implementation of, among others, those new requirements, which are expected to be reviewed in 2014.

4.2 Information on the sector

According to the information provided by the representatives from the Ministry of Health prior to the audit, those establishments requiring approval according to Regulation (EU) No 225/2012 are the following:

- processors of crude vegetable oil: two establishments
- oleochemical manufacturers of fatty acids: four establishments
- biodiesel plants: two establishments
- fat blenders: six establishments

5 Findings And Conclusions

5.1 Official control system

5.1.1 Competent authorities

Legal requirements

Article 4 of Regulation (EC) No 882/2004 lays down, among others, requirements for the designation of the responsible competent authorities and for their co-ordination and co-operation. Article 6 of Regulation (EC) No 882/2004 requires the competent authorities to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

Findings

The organisation of the official control system is provided in the country profile, which is available at the following link:

http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=IT

In summary, within the Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection, which is one of three Departments in the Ministry of Health, the Directorate-General for Animal Health and Veterinary Medicine (in particular, Office VII) is responsible for drafting the multi-annual control plan for the feed chain and collating the results of its implementation. At regional level, Regional Veterinary Services develop regional plans based on the national plan and guidance, taking into account regional and local information on risk. At local level, Local Health Units (ASL) are responsible for carrying out official inspections and sampling.

- The competent authorities in charge of official controls on requirements concerning feed legislation, are also responsible for those requirements laid down by Regulation (EU) No 225/2012. The audit team noted that officials met had a clear understanding of their tasks and activities.
- A number of mechanisms are in place to ensure co-ordination and co-operation between different competent authorities involved in official controls. The audit team noted that these tools are mainly circular letters, meeting minutes and exchange of e-mails.
- A number of seminars and meetings, in which stakeholders were also involved, had been organised by the competent authorities on dioxins and the requirements of Regulation (EU) No 225/2012. The audit team noted that feed inspectors met had, overall, a sufficient knowledge of provisions of Regulation (EU) No 225/2012, and in a number of cases this was very good.

Conclusions

The designated competent authorities responsible for carrying out official controls in feed establishments are also in charge of official controls on the new requirements laid down by Regulation (EU) No 225/2012; on this matter, arrangements for co-operation and co-ordination between central and regional and local competent authorities are satisfactory and the knowledge showed by competent authorities was adequate. 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 183/2005, Directive 2002/32/EC, Regulation (EC), No 1831/2003 and Regulation (EC) No 767/2009.

Findings

The organisation of official controls remains as described in Report 2012-6492. In summary, the Feed National Control Plan (FNCP) 2012-2014 represents the framework for official controls on the feed chain. It contains three main sections: a general descriptive one, a technical section related to various sampling plans for different types of substances and a third section with check-lists, templates and practical information on how to carry out official controls. Regions have to develop and implement their own multi-annual control plan, in line with the FNCP and have to submit periodic reports to the central competent authority. The FNCP may be amended during the course of its period of validity and in such case an Addendum is issued.

As regards the frequency of inspections, the third section of the FNCP contains criteria and explanations for evaluating establishments according to their risk. In principle, all feed establishments should be rated as being either: “low”, “medium” or “high” risk. For each risk-class a corresponding frequency of inspections has to be assigned by the relevant ASLs taking into account the minimum frequency of inspections established in the the FNCP. These minimum frequencies are, one inspection per year for establishments requiring approval (it includes also those establishments whose approval has been introduced by Regulation (EU) No 225/2012) and one inspection every two years for traders and retailers of feed.

As regards sampling, there are two categories of plans. The first is called “Monitoraggio” and refers to samples to be taken in order to evaluate any evolution of the presence of contaminants throughout the feed chain. The second is called “Sorveglianza” and includes samples to be taken to detect the presence of contaminants on a risk basis. The second section of the FNCP allocates a number of samples for all the Regions and for both categories of sampling plans. A specific chapter (or plan) of this section is dedicated to dioxins, dioxin-like polychlorinated biphenyls (PCB) and non-dioxin like PCB.

- In the ASLs and establishments visited, feed business operators had been inspected regularly, according to the planned frequencies (in most cases those were the minimum frequencies set out by the FNCP) or, in a number of cases, with a higher frequency, when non-compliances were found, and all of them had been classified in terms of risk. The audit team saw a number of records of inspections where requirements laid down by Regulation (EU) No 225/2012 had been taken into account in 2013 and even in 2012. Although the use

of check-lists containing these requirements has not started yet in a consistent way in all Regions (see section 5.1.3).

- As regards official sampling for the detection of dioxins and dioxin-like PCB in feed, in 2012 a total of 398 samples had been planned and 462 were actually taken. The same amount of samples has been planned for 2013 and 2014. Since 2012, the maximum level for dioxins set down in Directive 2002/32/EC, was exceeded only once in a sample of hydrogenated fatty acid of palm oil (see section 5.1.6). The audit team noted that, some 25% of these samples refers to feed materials as oils and fats. In the establishments visited and during the meetings with representatives from the the ASLs the audit team noted that samples to detect dioxins and dioxin-like PCB had been taken from establishments according to risk criteria.

Conclusions

Feed operators included in the scope of the audit are subject to inspections which are carried out regularly. Sampling programmes to detect the presence of dioxins in feed and to determine its evolution in the feed chain have been devised and largely implemented on a risk basis. The way inspection and sampling activities are planned and implemented largely enables the competent authorities to assess the level of compliance of feed establishments.

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

- An Addendum of the FNCP (Addendum 1/2013) was issued in May 2013 by the Ministry of Health. It contains, among others, clarifications concerning the requirements introduced by Regulation (EU) No 225/2012 and an updated check-list to be used for inspections, where all relevant requirements introduced by Regulation (EU) No 225/2012 have been included. A Circular Note with further detailed explanations concerning these new requirements was prepared by the Ministry of Health in December 2013 and distributed to all Regions. Although no major flaws or inconsistencies in official controls have been identified by the audit team, only one Region, out of the three visited, has recently adopted a check-list in line with the afore-mentioned one issued by the Ministry of Health. In the other two Regions the check-lists used during inspections do not contain yet the new above-mentioned requirements. This is not fully in line with article 8(1) of Regulation (EC) No 882/2004.
- In all ASLs and establishments visited, official controls (i.e. inspections, audits and sampling) had been recorded and a copy was always left with the business operator. With the exception of a few cases, which mainly refer to pre-approval on-the-spot visits (see section 5.1.5) records of inspections seen by the audit team were largely in line with Article 9 of Regulation (EC) No 882/2004. In a number of cases the audit team noted good practices where inspection reports were comprehensive, and included detailed findings and references to documents reviewed, allowing the reader to easily understand the reason why relevant requirements were fulfilled or not.

Conclusions

A number of measures have been devised by the central competent authority to facilitate appropriate and consistent official controls on the new requirements introduced by Regulation (EU) No 225/2012. These include a national check-list which, however, has not been fully adopted in all the Regions. Records of official controls usually contain adequate information, with the exception of a limited number of cases related to the process of approval (see section 5.1.5).

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

The system of verification of official controls remains as described in Report 2012-6492 and it also includes official controls carried out on Regulation (EU) No 225/2012. In summary, every six months, ASLs must send the results of official controls to the Regional Veterinary Services which, in turn, must submit these data to the Ministry of Health. This information is then evaluated both at regional and central level. Regional Veterinary Services can carry out internal audits on the ASLs under their remit to assess their performance as regards official controls on the feed chain. In addition, Office VII of the Directorate-General for Animal Health and Veterinary Medicine carries out audits (usually one Region per year) to evaluate the implementation of relevant requirements of the feed legislation.

- During the meetings held with representatives from ASLs and the Regional Veterinary Services, the audit team noted that periodic reports with number of inspections carried out and samples taken had been submitted by ASLs and reviewed by Regions largely as planned. Moreover, the audit team saw examples of periodic reports submitted by Regions to the Ministry of Health, as planned.
- In 2013, one of the two audits carried out by representatives from the Minister of Health focussed, among other topics, on the implementation of requirements laid down by Regulation (EU) No 225/2012. The outcome of the audit revealed some shortcomings in relation with the above-mentioned Regulation. The audit team noted that coherent recommendations have been made, although no satisfactory replies have been provided yet by the relevant Regional Veterinary Service.
- In a number of ASLs the audit team noted that advanced intranet databases were in place. Through specific applications, not only inspections and sampling programmes, but also records of inspections and samplings can be easily downloaded. These software contribute to a better verification of official controls and are considered good practice by the audit team.

Conclusions

The system of verification of official controls remains as described in Report 2012-6492. It is largely appropriate and implemented satisfactorily.

5.1.5 Approval of establishments

Legal requirements

Articles 10 and 13 of Regulation (EC) No 183/2005 lay down, respectively, requirements and procedures for the approval of feed establishments. Article 19 of this Regulation lays down requirements for the listing of these establishments.

Findings

Concerning the approval of feed establishments;

- All five establishments visited by the audit team requiring approval according to the new provisions introduced by Regulation (EU) No 225/2012 had been approved. The process of approval had always included a pre-approval on-site visit to verify the fulfilment of relevant requirements. However, although the audit team did not note any significant shortcomings in the establishments concerned, the verification of applicable requirements during the pre-approval on-site visit showed some weaknesses, thus this was not always in line with Article 13 of Regulation (EC) No 183/2005, as follows:
    - In a producer of animal fat visited, the audit team noted that an approval was granted as a fat blender, although no blending operations were taking place. At the time of the audit the establishment was a producer of animal fat but the business operator explained that an approval as a fat blender had been requested in order to allow the blending of different fats of animal origin if customers would have requested different products. The audit team noted that although the dioxin monitoring plan implemented by the feed business operator was in line with relevant requirements applicable for a producer of animal fat, this was not the case with those requirements applying to a fat blender. In this regard, the business operator stated that its sampling plan reflected the *status quo,* therefore, no specific arrangements had been planned yet to fulfil those requirements which apply to a fat blender. This shortcoming had not been identified by the feed inspector during the on-site visit prior to the approval and no check-list containing the applicable requirements had been used by the inspector.
    - In other cases the approval had been granted on the basis of the outcome of inspection reports which did not contain sufficient information to conclude which requirements had been verified and whether these were fulfilled or not. For example, in an oleochemical plant visited, the records of the on-the-spot visits prior to the approval consisted, *de facto,* of a generic sentence of compliance with relevant requirements of Regulation (EC) No 183/2005 and the date of the visit was missing. In another establishment located in a Region not visited by the audit team, according to information provided by the relevant competent authorities, an on-site visit took place in order to obtain the approval according to Regulation (EU) No 225/2012. However, the audit team noted that the inspection report did not contain any information concerning the assessment of relevant requirements.

Concerning lists of registered and approved feed establishments;

- In Italy each Region maintains a list of approved and registered establishments and the Ministry of Health maintains the list of approved manufacturers of additives. These lists are publicly available on the website of the Ministry of Health. Regional Veterinary Services must submit to the Ministry of Health an update of the lists every three months. For approved establishments the activities reflected on the regional lists follow the descriptions contained in Regulation (EC) No 183/2005, including the relevant Article.

- The Addendum No 1/2013 of the FNCP contains provisions on how relevant activities referred to in Regulation 225/2012 have to be included in the list of approved establishments.
- Most of the establishments requiring approval visited are included in the relevant list and their activities are indicated as requested. However, the audit team noted that in one case the establishment producing animal fat which was approved as a fat blender does not appear in the relevant list (see previous paragraph on approval of feed establishments). In another establishment visited, which was manufacturing compound feed and blending/placing on the market oils and fats, the activities indicated in the list do not include the blending of oils and fats. Moreover, the audit team reviewed all lists of approved establishments available on-line from the website of the Ministry of Health and noted that in one Region this list does not contain information on the activities carried out and in two other Regions the link does not work or not exist, respectively. Thus, the above evidence indicates that the requirements laid down by Article 19 of Regulation (EC) No 183/2005 are not fully met.

Conclusions

Although no significant shortcomings have been identified by the audit team in the establishments concerned, the process of approval of feed establishments falling into the scope of Regulation (EU) No 225/2012 is not always effective in assuring that these establishments fulfil all applicable requirements. This is mainly due to the fact that relevant requirements and the results of their assessment are not always adequately described in relevant reports of official controls.

Lists of feed establishments are publicly available and updated at central level on the basis of information provided by the Regions. However, the information included in these lists does not always contain appropriate information about activities carried out, possibly undermining the ability of competent authorities to plan controls effectively and for operators to ensure feed materials come from appropriate sources.

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 a non-compliance is identified.

Findings

The system of measures and actions to be taken following the detections of non-compliances remains as described in Report 2012-6492. In summary, the FNCP contains instructions for feed inspectors on how to proceed when non-compliances are found during official controls. National legislation allows sanctions to be imposed where non-compliances are found in the framework of Regulation (EC) No 183/2005.

- In the establishments visited and in the meetings held with representatives from the ASLs, the audit team saw examples of non-compliances detected, deadlines given for taking corrective actions and follow-up carried out in a timely manner. A few of these non-compliances were linked to the new requirements introduced by Regulation (EU) No 225/2012). This is in line with requirements laid down by Article 54 of Regulation (EC) No 882/2004.

- The Addendum No 1/2013 of the FNCP has introduced a limit of 30 days for the turnaround time of official analysis for dioxins and dioxins-like PCBs but the audit team noted that this limit was not respected in most cases seen and in a number of cases the turnaround time exceeded 70 days. The positive case mentioned in section 5.1.2 refers to a sample of hydrogenated fatty acids of palm oil taken in 2012 where the concentration of dioxins exceeded the maximum level set down in Directive 2002/32/EC. The audit team noted that it took 54 days for the sample to be analysed and although follow-up investigations were initiated promptly once the result was known, most of the contaminated batch (19.15 out of 20 Tonnes) had already been distributed through the feed chain. As a consequence, a wide traceability action to withdraw from the market the compound feed containing these hydrogenated fatty acids was necessary and, eventually, only part of these compound feed could be withdrawn. This is not fully in line with the provisions laid down by Article 54 of Regulation (EC) No 882/2004 .

Conclusions

Non-compliances detected during official controls are largely followed up and suitable corrective actions are taken. However, although some measures to reduce the turnaround time for analyses of dioxins have been taken, these are still not sufficient to ensure that when official analyses show non-compliances in this respect, adequate corrective actions are taken in a timely fashion.

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.

The labelling of feed materials and compound feed placed on the market must identify them as such, as laid down by Article 15 of Regulation (EC) No 767/2009. Moreover, Annex II of Regulation (EC) No 183/2005, amended by Regulation (EU) No 225/2012, requires that the labelling of the product shall clearly indicate whether they are intended for feed of other purposes and that if a batch/product is declared as not intended for feed/food use, this declaration shall not be subsequently altered at a later stage of the chain.

Findings

The Addendum No 1/2013 of the FNCP and the Circular Note issued by the Ministry of Health contain various explanations on the new requirements concerning sourcing and labelling introduced by Regulation (EU) No 225/2012.

- In all establishments visited the audit team reviewed lists of suppliers and a number of incoming consignments and confirmed that all suppliers were approved or registered as required by Article 5(6) of Regulation (EC) No 183/2005. Moreover, the audit team noted that these requirements are largely verified during routine inspections, although relevant lists are not always accurate (see section 5.1.5).
- In the majority of establishments visited (seven out of nine), requirements concerning sourcing and labelling had been verified during routine official controls. In a couple of cases

the audit team noted that inspection reports did not include the necessary information to conclude whether these requirements had been verified or not.

- Among others, the above-mentioned Circular Note includes clarifications on the requirements concerning labelling. The audit team noted that, although it is comprehensive and detailed, it includes an interpretation of the requirement for the labelling of products not destined for the feed chain which is partly in contrast with the relevant provision laid down in Annex II "Production", point 8 of Regulation (EU) No 225/2012. The latter requires that the labelling of the products shall clearly indicate whether they are intended for feed or other purposes. The Circular Note specifies there is no obligation to label those products not destined for feed purposes. According to representatives from the Ministry of Health the logic behind this interpretation is that only feed grade products are allowed to be used in the feed chain and they are consequently subject to feed legislation on labelling. Thus, only products labelled as feed are allowed to be used in the feed chain.
- In all establishments visited, oils, fats and products derived thereof destined to the feed chain, were labelled as feed materials as laid down by Annex II "Production", point 8 of Regulation (EU) No 225/2012. However, in the biodiesel, oil processing and oleochemical plants visited the audit team saw examples of delivery notes of consignments and labelling of derived products (namely distilled fatty acids) destined for combustion, disposal or other technical use, where no indication of the intended use was indicated. This is not in line with Annex II "Production", point 8 of Regulation (EU) No 225/2012 and had not been identified during official controls, according to the national provisions.

Conclusions

The safe sourcing of feed is largely verified during official controls.

The labelling of oils, fats and products derived thereof destined to the feed chain, is satisfactorily verified during official controls. However, those products not destined to the feed chain are not labelled according to relevant requirements and this may negatively affect the overall system aimed at making a clear distinction between feed and non-feed products.

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, amended by Regulation (EU) No 225/2012, shall be met for operations other than those regarding primary production; among others, these concern some of the requirements at the level of facilities and equipment, production, storage and transport.

Findings

The Addendum No 1/2013 of the FNCP and the Circular Note issued by the Ministry of Health contain various explanations on the new relevant requirements introduced by Regulation (EU) No 225/2012.

- The audit team noted that in the oleochemical and biodiesel plants and in the oil processor visited, feed grade products and products destined for combustion or disposal (e.g. used bleaching earth, catalysts and derived products from distillation of fatty acids) were always kept separate as required by Annex II of Regulation (EC) 183/2005.

- In the majority of establishments visited (four out of six) infrastructure and organisational requirements had been verified during routine official controls. In a couple of cases the audit team noted that inspection reports did not include the necessary information to conclude whether these requirements had been verified or not.

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 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, amended by Regulation (EU) No 225/2012, shall be met for operations other than those regarding primary production; these requirements concern, among others, arrangement for monitoring dioxins in fats, oils or products derived thereof.

Findings

Concerning the dioxins and dioxin-like PCBs monitoring requirements for producers of animal fat, the Circular Note of the Ministry of Health contain some indications on how to take a representative sample in case of batches lower than 2,000 tonnes. The practical implications of such indications entails that if the batch of the final product is less than 2,000 tonnes the producer is not obliged to accompany every consignment with a certificate of analysis; nonetheless it should take an incremental sample from each delivery. When the size of the production batch reaches the amount of 2,000 tonnes, all incremental samples collected from each delivery should be gathered in an aggregate sample and then analysed. The producer has, consequently, the obligation to send to every customer (feed business operators) the analytical report referred to 2,000 tonnes of fat with the identification of every batch to which that analytical report is referred to. During the period before receiving such an analytical report, feed business operators have to ensure (e.g. by asking for a written declaration) that the producers of animal fats fulfil the relevant requirements of Regulation (EU) No 225/2012.

- In the majority of establishments visited (six out of nine) requirements concerning the dioxin monitoring regime had been verified largely in an appropriate manner and in all of them these were implemented by feed business operators largely in line with requirements laid down by Article 5(2) of Regulation (EC) No 183/2005. In a couple of cases the audit team noted that inspection reports did not include the necessary information to conclude whether these requirements had been verified or not and in another case (a producer of animal fat approved as fat blender, see section 5.1.5) this verification showed some weaknesses.
- In all the compound feed manufacturers visited the audit team noted that animal fats consignments were accompanied by periodic analytical reports for dioxins and dioxin-like PCBs. The audit team checked a number of consignments in every establishment and noted that most of them were linked with an appropriate certificate of analysis of an aggregate sample which always listed the identification-code of every consignment to which the analysis belonged. Only in a couple of cases the analytical certificates seen by the audit team

contained some minor flaws: in one case the content of dioxin-like PCBs was not stated and, in another case, the sum of dioxins and dioxin-like PCBs was not correct.

- In the oleochemical plants visited the incoming material consisted of refined palm oils and crude animal fats and the final products placed on the market as feed materials were hydrogenated fatty acids of animal and vegetable origin. These derived products are the result of a distillation of the fatty acids which takes place after the hydrolysis of the incoming oils and fats. The audit team verified a number of incoming consignments of fats and noted that these were subject to dioxin checks as requested by Annex II of Regulation (EC) No 183/2005. Moreover, in both plants, on the basis of a risk assessment carried out in the context of their HACCP plan, it was planned to take a few samples per year to verify the presence of dioxins and dioxin-like PCBs in the the final products placed on the market as feed, although no (or only partial) results of these tests were available ([2]).
- In one of the two oleochemical plants the audit team saw a dossier issued by the European Oleochemicals & Allied Products Group (APAG) on the risk of dioxin contamination in the oleochemical products. Among other information, this dossier provides some explanations to support the thesis that after the hydrolysis and the distillation steps there is no increase of the dioxin contamination in the final products (fatty acids distillates). However, the audit team noted that studies from other organisations ([3]) indicate there might be an increase in dioxins and dioxin-like PCBs in oils and fats derived products under certain circumstances.

Conclusions

The system of official controls is largely able to ensure that dioxin monitoring requirements are satisfactorily implemented by feed operators.

6 Overall Conclusions

The system of official controls is largely effective in verifying that operators along the feed chain comply with the requirements concerning production, storage, transport and dioxin testing of oils, fats and products derived thereof. However, it is at an early stage of development and, although some good practices were noted, it is not applied in a consistent way throughout the country. The main reason for this situation is linked with a general delay in the process of development and adoption of comprehensive check-lists that would facilitate a structured and systematic verification of relevant requirements, in particular during the approval of establishments. Moreover, although some measures to reduce the turnaround time for analyses of dioxins have been taken, these are still not sufficient to ensure that corrective actions are taken in a timely fashion.

2 In one plant, although a few results were available, these did not refer to those fatty acids derived from animal fat which, according to the analytical results of the incoming batches, were expected to be more at risk.

3 According to the dossier of APAG the bleaching of oils entails a reduction of the content of dioxin in the oil, whereas, a recent survey presented by the Federation of the European Vegetable Oil and Protein meal Industry (FEDIOL) in September 2013, revealed that the bleaching process does not remove the dioxin in the oil because no concentration of dioxin has been observed in the used bleaching earth. Moreover, according to the dossier of APAG the hydrogenation of oils/fats causes a reduction of the dioxin toxicity whereas, a Dutch Institute for Safety (RIKILT) pilot experiment, demonstrated that partial hydrogenation of palm fatty acid distillate may increase the toxicity of dioxins.

7 Closing Meeting

A closing meeting was held on 27 February 2014 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 Italy 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 procedures to carry out official controls in feed operators requiring approval in accordance with the last amendment of Regulation (EC) No 183/2005, contain all necessary information and instructions, as laid down in Article 8(1) of Regulation (EC) No 882/2004.
2.	To ensure that the on-site visit prior to approval, for those establishments requiring approval in accordance with the last amendment of Regulation (EC) No 183/2005, demonstrates that all relevant requirements are met, as laid down in Article 13 of Regulation (EC) No 183/2005.
3.	To ensure that lists of feed establishments contain relevant information about activities carried out, as laid down in Article 19 of Regulation (EC) No 183/2005.
4.	To ensure that, whenever a non-compliance is detected during official sampling, the turnaround time for analyses of dioxins enables the carrying out of corrective actions in a timely fashion, as laid down in Article 54 of Regulation (EC) No 882/2004.
5.	To ensure that oils, fats, and products derived thereof not intended to be used in the feed chain are adequately labelled as required by Article 5(2) of Regulation (EC) No 183/2005.

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=2014-7037

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Reg. 183/2005	OJ L 35, 8.2.2005, p. 1-22	Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene
Reg. 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
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. 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