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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ESTONIA

FROM 04 TO 08 MARCH 2013

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

## ***Executive Summary***

*This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Estonia, from 4 to 8 March 2012.*

*The overall objective of the audit was to evaluate the implementation of requirements aiming at ensuring the identification of hazards and management of risks along the feed chain, taking account of the relevant requirements on feed laid down by Regulation (EC) No 1831/2003 and other related legislation and on official controls on the afore-mentioned legislation. In terms of scope, the audit focused on activities which, in the light of experience and past feed crises, are known to be more of a risk than others. The audit also assessed the measures taken in response to the recommendations made following a previous FVO audit concerning feed safety.*

*Overall, the report concludes that the competent authorities have in place a largely satisfactory system for official controls, which is underpinned by a good knowledge of most of the establishments and operators carrying out activities along the feed chain, including those falling under the scope of this audit. However, there are some deficiencies concerning the prioritisation of official controls at the level of establishments carrying out direct drying of feed and processing crude vegetable oil.*

*Official controls along the feed chain largely ensure compliance with the requirements concerning sourcing and labelling, equipment, and traceability. However, there are weaknesses in official controls on measures put in place by operators to minimise cross-contamination and to monitor dioxins, as well as on requirements concerning the identification of certain hazards in the manufacturing of feed.*

*The report makes a number of recommendations addressed to the Estonian 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**

<b>Abbreviation</b>	<b>Explanation</b>
Cross-contamination	Presence, due to production, of additives, medicines or ingredients in feedingstuffs which should not contain them
FVO	Food and Veterinary Office
HACCP	Hazard analysis and critical control points
Report 2007-7233	Report of an audit carried out in Estonia from 3 to 7 September 2007 concerning feed safety
PCBs	Polychlorinated biphenyls
VFB	Veterinary and Food Board ( <i>Veterinarinaa ja Toiduamet</i> )

## 1 INTRODUCTION

This audit took place in Estonia from 4 to 8 March 2013.

The audit team, which comprised two auditors from the Food and Veterinary Office (FVO), was accompanied throughout the audit by a representative from the central competent authority, the Veterinary and Food Board (*Veterinaar ja Toiduamet* -VFB).

An opening meeting was held on 4 March 2013 with the central competent authority, during which the audit objectives, itinerary, and the standard reporting and follow-up procedures were confirmed, and additional information required for the satisfactory completion of the audit was requested.

## 2 OBJECTIVES

The overall objective of the audit was to evaluate the implementation of the requirements concerning the identification of hazards and management of risks along the feed chain. To that extent, the audit took account of the relevant requirements on:

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

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

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

The itinerary for the audit included the following visits:

Visits/meetings		No	Comments
Competent authority	Central	2	Opening and closing (de-briefing) meetings
	Regional	√	Discussion held in one County and in the visits to premises
Feed mills		2	One approved using a veterinary medicine and one registered manufacturing compound feed
Processor of crude vegetable oil		1	Placing on the market feed products derived from vegetable oil (rapeseed cake and acid oil)
Drier of feed		1	Drying cereal grains and rape seeds
Manufacturer of feed and technical (non-feed grade) products		1	Quarry producing calcium carbonate
Food establishment		1	Placing on the market co-products as feed

### 3 LEGAL BASIS

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

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

### 4 BACKGROUND

Report DG(SANCO) 2007-7233 – MR Final (hereafter: 2007-7233) describes the results of a previous audit concerning feed safety carried out in Estonia from 3 to 7 September 2007, and contains background information relevant to the current audit. This report made a number of recommendations to the competent authorities, which subsequently informed the Commission services of actions that had been or would be taken aimed at addressing the recommendations made; where appropriate, both the relevant recommendations and the afore-mentioned actions are outlined in section 5. The report is accessible at the following address:

[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_id=1858](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=1858)

FVO audits on feed safety in Member States have shown important deficiencies across the board on the implementation and official controls on procedures based on the hazard analysis and critical control points (HACCP) principles. In parallel, a number of past feed safety crises (e.g. dioxins in fatty acids or in dried food co-products) were linked to poor hazard identification and risk management measures by the feed operators concerned. These crises have also shown that some activities can be considered more of a risk than others and, in some cases, this has resulted in the legislation being amended (e.g. approval of establishments operating in the oil and fat chain). For these reasons, a new series of audits is being rolled out as of 2012, focusing on some requirements of the legislation concerning key areas where hazards have been identified and, therefore the consequent risks have to be managed.

### 5 FINDINGS AND CONCLUSIONS

#### 5.1 INFORMATION ON THE FEED SECTOR

Report 2007-7233 provides an overview about the feed sector in Estonia. In addition, the following information was provided by VFB about establishments delivering their 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):

Type of establishment supplying the feed chain	Number
Processors of crude vegetable oil	1
Driers of feed (direct)	5
Manufacturers of feed and technical (non-feed) grade products	3

## 5.2 OFFICIAL CONTROL SYSTEMS

### 5.2.1 Competent authorities

#### Legal requirements

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

#### Findings

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

[http://ec.europa.eu/food/fvo/follow\\_up\\_en.cfm?co\\_id=EE](http://ec.europa.eu/food/fvo/follow_up_en.cfm?co_id=EE)

In summary, within the VFB, the feedingstuffs office is responsible for the control system for feedingstuffs, risk assessment and preparation of the supervision plan, developing and updating inspection guidelines and manuals and assessing the effectiveness of internal supervision. The fifteen County Veterinary Centres are responsible for the practical implementation of the official control plans. The competent authorities in charge of feed are organised at regional level; each of these regions covers the area of three or four County Veterinary Centres. There are four feed inspectors, one per region.

For improving co-operation between the competent authorities, a number of co-operation agreements have been signed and there are agreements laying down general principles for the authorities carrying out the monitoring activities. Based on such co-operation agreements, the supervisory authorities can use, if necessary, another supervisory authority databases, to conduct joint surveillance operations and trainings.

The VFB central office has responsibility for co-ordination of the inspection activity under the responsibility of that organisation. Meetings between VFB management and heads of the 15 CVC are held at least once per quarter. There are also meetings, at least once a year, between specialists from the central office and inspectors from the 15 counties to discuss general and specific issues of feed safety.

- The audit team noted that the competent authorities in charge of official controls have been designated. All officials met had a clear understanding of their tasks and activities and of the system in place for official controls on feed.
- The audit team saw records of regular meetings between VFB and County Veterinary Centres where issues regarding feed had been discussed. Records of meetings between the official in charge of feed at VFB (Chief specialist) and regional feed inspectors were also available.

#### Conclusions

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

## 5.2.2 Organisation and delivery of official controls

### Legal requirements

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

### Findings

According to the information provided by VFB, inspection and sampling activities are designed following a risk-based approach and their frequency for each establishment is calculated on the basis of a risk rate. The so-called inspections include two types of control visits: regular inspections and audits. The latter are designed to perform a thorough check of the establishments and its documentation whereas the former are designed to monitor only some of the activities or documents of the relevant establishment. Sampling usually takes place in the course of these regular inspections.

The frequency of inspections and audits for approved establishments is fixed at central level by VFB in two visits (one audit and one inspection) per year. For the rest of establishments, the said frequency depends on the risk rate allocated by regional feed inspectors. They take account of several factors for this rating, amongst others, type of feed manufactured, imported, stored, transported or used; whether it contains veterinary medicines, coccidiostats or animal protein; type of packaging; quality of the own-control system of the relevant establishment and its history of non-compliances.

As regards sampling, each year VFB decides the total number of samples to take for each of the substances to be analysed. This number is worked out combining the risk rate mentioned above with other types of information such as risks related to certain types of materials (be it derived from its origin, likelihood of contamination, past records of incidents related to it, etc.) and the relevant legal requirements. Feed inspectors decide where to take the samples from (type of establishment and matrix) following guidelines issued by VFB.

- In the establishments visited, the audit team noted that official controls were, most of the time, announced only on the same day of the visit. Establishments were controlled in accordance with the scheduled frequency.
- The audit team noted that all of the establishments visited had been risk-rated and in most cases this rate takes account of the relevant risks linked to activities and operations. However, in the files concerning direct driers examined and in the processor of crude oil visited, the audit team noted that these establishments had been allocated the lowest possible risk value (which entailed an inspection visit every seven years) despite the fact that some of the operations they carry out (namely, direct drying fuelled by diesel and placing on the market of deodistillates by the oil processor) are known to pose a risk in terms of the presence of dioxins and dioxin-like PCBs.
- The audit team noted that two transport companies registered both as feed and animal by-products operators were targeted by feed inspectors, as they had been given a higher risk score due to this dual registration.
- According to the information provided by VFB, official controls (in particular audits) include an assessment of the operators' procedures based on HACCP principles; a number of



non-compliances in that regard were identified during official controls in 2011 (21) and 2012 (28). However, the audit team noted that such controls are not always able to identify when these procedures are not fit for purpose. As a consequence, they overlook that some establishments have devised HACCP-based procedures that do not address all relevant risks (see section 5.3.5).

- According to the documentation examined by the audit team, the distribution of official sampling covers additives, premixtures, feed materials and compound feed throughout the feed chain. Targeting of official sampling for undesirable substances generally takes account of risks linked to the ingredients and the manufacturing process. The audit team noted the following:
  - Samples taken for assessing cross-contamination with veterinary medicinal products were not taken from the first fraction of the clean feed placed on the market after the one containing the veterinary medicines. (See section 5.3.3).
  - The presence of coccidiostats in feed for non-target species found in 2012 triggered an increase in the frequency of sampling of these substances for the programme of 2013.
  - Guidelines issued by VFB indicate what types of feed should be prioritised when sampling for detecting the presence of dioxins and dioxin-like PCBs. From 2011 to 2012, samples for measuring these substances were taken on the following materials: rapeseed oil, rye, a compound feed containing a mixture of cereals, mineral feed, mono-calcium phosphate and limestone. However, the processor of crude oil visited has never been sampled for dioxins and dioxin-like PCBs. In addition, only one (out of five) direct driers of feed was sampled for these substances (in 2008, with results compliant with the legal limits), while the one using diesel as fuel has never been sampled. On the document reflecting the priorities for the feed control programme for 2014, the audit team saw that inspection and sampling of direct driers was included therein.

## Conclusions

Official controls are regularly carried out and the frequency of inspections, which follows some of the criteria referred to in Article 3 of Regulation (EC) No 882/2004, is largely appropriate. However, the risk-rate allocated to some feed establishments (namely those carrying out direct drying of feed and processing crude vegetable oil) does not fully take account of their activities and operations, which has a negative impact in the frequency with which these establishments are inspected. In addition, official controls overlook a number of shortcomings regarding HACCP-based procedures. This impairs the ability of the competent authority to assess operators' own control systems, which is essential for an adequate risk-rating of establishments.

Concerning official sampling, while the risk-based approach followed is largely satisfactory in most cases, it is poorly targeted in the area of feed with potential cross-contamination with veterinary medicines. In addition, official sampling does not fully take account of the risks posed by the possible presence of dioxins and dioxin-like PCBs in certain types of feed (namely, cereal grains dried in a direct drier fuelled by diesel, acid oil and rapeseed cake). Consequently, the relevant requirements of Article 3(1) of Regulation (EC) No 882/2004 are not fully met.

### 5.2.3 *Records of official controls*

#### **Legal requirements**

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

#### **Findings**

- Documents covering sampling, inspection, audit and risk-rating of feed establishments and are available to feed inspectors. All the officials met were aware of their existence and were making use of them.
- The audit team noted that check-lists were used by feed inspectors when performing audits. In the case of inspections, an inspection report was completed containing detailed information about what was covered, a list of findings and corrective actions when non-compliances were detected. Comprehensive check-lists for inspections will be used from this year on. Feed operators met had received copies of infringements and non-compliances identified during official controls.

#### **Conclusions**

The requirements laid down by Articles 8(1) and 9 of Regulation (EC) No 882/2004 concerning documented procedures and reports on official controls are satisfactorily met.

### 5.2.4 *Verifications of official controls*

#### **Legal requirements**

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

#### **Findings**

According to the information provided by VFB, a number of systems combine to meet the requirements concerning verifications of official controls, amongst others, a) assessments of the work performed by county inspectors on the basis of a three-year (rolling) plan and an annual sectoral instruction. This supervision always involves on-the-spot assessment. Each inspector must be supervised in this way once in three years. Individual reports are prepared and any necessary follow-up is verified, b) The job descriptions of the Chief specialists in VFB require them to review/supervise reports from counties and c) audit systems; following public tender, the contract with a large audit firm had been renewed for the period 2012-2014 and an audit on the feed control system was scheduled for 2012.

- In the regional meeting held, the audit team noted that the feed inspector performance had been evaluated by the feed Chief specialist from VFB through checks on inspection reports and a joint visit to a feed establishment. A report with the findings and recommendations was subsequently drafted.
- The audit team saw the report drafted by the external auditor on the feed control system, which included a list of findings and recommendations.

## **Conclusions**

The requirements laid down by Article 8(3)(a) of Regulation (EC) No 882/2004 concerning verification of official controls are satisfactorily complied with.

### *5.2.5 Registration and approval*

## **Legal requirements**

Articles 9 and 10 of Regulation (EC) No 183/2005 lay down, respectively, requirements for the registration and approval of feed establishments by the competent authorities; Article 19 lays down requirements for the list of these establishments.

## **Findings**

VFB maintains a list of approved and registered feed establishments published on its web page. A system of numbers and letters allow to combine types of products (feed materials, additives, premixtures, compound feed, medicated feed, co-products from the food industry and processed animal protein) with certain activities (import, production, processing, placing on the market, packaging, storing, transport and use) for each establishment.

- The audit team noted that all the establishments visited were approved or registered as applicable, as well as all the suppliers, customers and all transporters (with one exception) checked.
- The audit team noted that, with the exception of the feed drier, the codes on the publicly available lists reflected accurately the activities performed in the establishments visited. In addition, the audit team saw evidence of the said lists being updated regularly.
- The audit team noted that VFB had identified five direct driers of which they also knew the type of fuel used. However, VFB could not provide the audit team with a list of the total number and location of driers operating in the country. In addition, there is no specific code on the lists of registered or approved establishments for designating this activity (drying of feed).
- The co-existence of feed grade and technical grade activities is not part of the information which is routinely collected during the registration or approval process of feed establishments, and only if this activity is reflected on the HACCP plan which the establishment submit to the competent authority, the latter becomes aware of it during the said approval/registration process. Nevertheless, the audit team saw that the inspection and audit check-lists include a specific question in this regard. In addition, VFB was able to provide a list of these establishments to the audit team.
- According to the information provided by VFB, there are no food surplus recyclers in the country, and only some individual food establishments place on the market their co-products as feed.

## **Conclusions**

There is a good knowledge of the establishments and operators active in the feed chain, including those specifically covered in this audit and lists of approved/registered establishments reflecting their activities are kept at central level. However, the competent authorities have information concerning only a limited number of driers of feed, which could negatively affect the registration and listing of these establishments, as well as official controls at this level.

### 5.2.6 *Actions in case of non-compliance*

#### **Legal requirements**

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

#### **Findings**

- In the establishments visited and in the meetings held with feed inspectors, the audit team saw numerous examples of non-compliances detected and listed, deadlines given for taking corrective action and follow-up of the former carried out in a timely manner.

#### **Conclusions**

The requirements laid down in Article 54 of Regulation (EC) No 882/2004 concerning actions in case of non-compliance are satisfactorily met.

## **5.3 OFFICIAL CONTROLS ALONG THE FEED CHAIN**

### 5.3.1 *Sourcing and labelling*

#### **Legal requirements**

Article 5(6) of Regulation (EC) No 1831/2003 requires feed business operators to source and use feed only from registered and/or approved establishments. The labelling of feed materials and compound feed placed on the market must identify them as such, as laid down by Article 15 of Regulation (EC) No 767/2009; for feed additives and premixtures, the same principle is laid down by Article 16 of Regulation (EC) No 1831/2003.

#### **Findings**

- Official controls include a verification on whether the suppliers of feed materials, premixtures and additives of the feed establishments inspected are registered or approved as required. The audit team noted that in all the establishments visited, those suppliers checked were approved or registered, as applicable. According to the inspection reports seen, feed inspectors perform these type of checks systematically.
- Verification that ingredients used for the production of feed are labelled as such are included in the scope of official controls. The audit team noted that in the establishments visited, all the ingredients but one checked were correctly labelled as feed. According to the inspection reports seen, feed inspectors carry out these type of checks systematically.

#### **Conclusions**

Official controls are able to ensure that establishments comply with the requirements of Article 5(6) of Regulation (EC) No 1831/2003 concerning sourcing of feed from registered and/or approved establishments. Similarly, official controls are in a position to ensure compliance with the requirements of Article 15 of Regulation (EC) No 767/2009 and Article 16 of Regulation (EC) No 1831/2003.

### 5.3.2 *Facilities and equipment*

#### **Legal requirements**

Article 5(2) of Regulation (EC) No 183/2005 indicates that the requirements set out in its Annex II shall be met for operations other than those regarding primary production; amongst others, these requirements concern separation arrangements for establishments producing feed and technical (non-feed) grade products.

#### **Findings**

- In the establishments visited, the audit team noted that feed inspectors pay attention during official controls to the applicable requirements of Annex II to Regulation (EC) 183/2005.
- Facilities and equipment of the establishments visited were largely in line with the said requirements.

#### **Conclusions**

Official controls are able to ensure that establishments comply with the requirements on facilities and equipment referred to in Article 5(2) of Regulation (EC) 183/2005.

### 5.3.3 *Cross-contamination, homogeneity and undesirable substances*

#### **Legal requirements**

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

#### **Findings**

As regards cross-contamination:

- According to the information provided by VFB, feed inspectors have received specific training for targeting correctly feed samples with a view to assess cross-contamination with coccidiostats or veterinary medicines. The audit team noted that cross-contamination is investigated during official controls.
- According to the operator of the approved feed mill visited, zinc oxide is used as veterinary medicine in feed destined for pigs. The said operator stated that he had performed a carry-over test in the past using zinc as a tracer. The results thereof indicated a high level of carry-over so, on the basis of these results, he decided to start flushing the line with at least one tonne of wheat bran after the production of any medicated feed. In addition, a sequencing programme was established whereby medicated feed for pigs can only be followed by feed also destined for pigs. The audit team noted that: a) in the records of the manufacturing history checked the sequencing programme had always been followed, and b) the operator did not carry out a test to assess the efficiency of the flushing in keeping the levels of cross-contamination within the legal limits.
- In the approved feed mill mentioned above, official services took a sample for assessing carry-over. This sampling was taken after detecting in a farm (in a compound feed produced in this feed mill) levels of zinc above those permitted by the relevant legislation. For the said

assessment of carry-over, the feed inspector used a company sample (kept by the establishment for traceability purposes) from the first batch manufactured after the one containing the flushing material. The results were considered compliant by the competent authority. However, the audit team noted that the sample used was an aggregate one which contained several runs of the line after the use of the flushing material. Therefore, the level of cross-contamination present on the first fraction of the first clean feed manufactured and placed on the market could not be accurately determined.

As regards homogeneity:

- According to the information provided by VFB, feed inspectors are instructed to check whether feed operators ensure that their mixers achieve a homogeneous mixture. The audit team noted that this requirement is checked during official controls.
- According to the operator of the registered feed mill visited, a number of homogeneity tests have been carried out so far. To this end, the operator used a trace element contained in a premixture (whose quantity was stated on the label) and took three samples (at the beginning, in the middle and at the end) of the mixing cycle. The result of these tests were considered satisfactory by the operator. The audit team noted that: a) the operator did not know the exact content of the trace element used as a tracer since he used for his calculations the quantity stated in the label, which is allowed to contain a certain level of variation. Therefore, the value obtained after the sampling might not reflect the real degree of homogeneity in the mixture, and b) in 2009, official sampling for measuring the accuracy of the contents declared in the label of compound feed produced in the establishment detected bigger variations than those allowed by Regulation (EC) No 767/2009. The operator declared that after the competent authority made him aware of these results, he changed the order at which the different materials were incorporated in the mixer in order to achieve a more homogeneous mixture. The deficiencies mentioned above were not detected by the official services.
- According to the operator of the approved feed mill visited, the results of the homogeneity tests showed values around 10 % (coefficient of variation). These figures were considered by the said operator to show a high degree of dispersion in the mix. Based on this result, he declared that he was going to replace the mixer for trying to achieve values around 4 %. The audit team noted, after examining the audit reports, that during the last two audits (in 2010 and 2011), the feed inspector did not check the documentation concerning tests performed by the operator to assess the ability of the mixer to produce homogeneous mixes. Therefore, he was not aware of the high value obtained in the test performed by the operator mentioned above.

As regards undesirable substances:

- According to the information provided by VFB, feed inspectors are instructed to check whether feed operators have implemented a procedure for verifying the presence of undesirable substances. The audit team noted that this requirement is checked during official controls.
- In the drier of feed visited, the audit team noted that the operator regularly takes samples for detecting the presence of one type of mycotoxin-producing mould (*Fusarium* spp) in cereal grains. However, tests for measuring the levels of mycotoxins, in particular aflatoxins, were not carried out.
- In the files of direct driers examined, the audit team noted that in two of the three, cereal grains had been sampled for the presence of aflatoxins in the past (in 2010 and 2011 respectively); the results thereof were compliant with the relevant legal limits.

- In the quarry visited, the audit team noted that the operator had designed and followed a comprehensive sampling programme which included tests for measuring the levels of heavy metals and dioxins and dioxin-like PCBs.
- According to the information provided by the operator of the processor of vegetable oil visited, crude rapeseed oil was processed using chemical refining and acid oil and rapeseed cake were placed in the market as feed. Distillates derived from the deodorisation stage of the refining process (also known as deodistillates) were incorporated into the material from which the acid oil was obtained. In addition, used bleaching earth was usually incorporated into the rapeseed cake. The operator stated that neither the acid oil nor the rapeseed cake had ever been sampled for measuring the levels of dioxins and dioxin-like PCBs, since there was no addition of a compound containing chlorine during the process of refining. According to the said operator, this would render the risk of dioxin formation negligible. In addition, he added that refined oil for human consumption had been tested for dioxins and dioxin-like PCBs several times and had always come back negative. However, the audit team noted the following:
  - According to technical documentation issued by the federation of producers of vegetable oils and protein meals, a 300 times concentration in the level of dioxins and dioxin-like PCBs can take place during the deodorisation stage of the chemical refining process and those concentrated products end up in the deodistillates. Therefore, testing the refined oil for the presence of such contaminants does not indicate the level of contamination of the above-mentioned deodistillates.
  - The operator did not have any documentation or laboratory results allowing to rule out the risk of the presence of dioxins and dioxin-like PCBs derived from the kaolinitic clays contained in the bleaching earth.

The above mentioned deficiencies were not detected by the official services.

- In the registered feed mill visited, the audit team noted that the operator had not taken samples for measuring the levels of undesirable substances in incoming materials or finished products. Moreover, the said operator stated that the quality of this year's cereals was poor due to the high amount of rain which occurred in the country. He added that this triggered in his customers a high demand for the inclusion of mycotoxin binders in the compound feed destined for pigs. The audit team noted that this did not prompt the operator to take samples in the cereal grains received or to request a certificate of analysis from his supplier for monitoring the presence of mycotoxins. The above deficiencies were overlooked by official services.
- According to the information provided by the operator of the approved feed mill visited, incoming feed material and finished products were sampled for the presence of undesirable substances on an ad hoc basis, rather than following a pre-determined frequency. The said operator held that he had agreed with his suppliers on the maximum level of contaminants that the feed materials supplied could contain. In this respect, the audit team noted that: a) the agreements with the suppliers seen referred only to materials of vegetable origin; the values reflected on them complied with the relevant legal requirements, b) except one analysis for dioxins in rapeseed oil, the rest of the samples focused on the detection of mycotoxins (with results always below the legal limit), c) heavy metals were not included in this monitoring, as the company relied on the official samples results for this parameter and d) since 2010, four samples had been taken by officials to measure heavy metals (one for arsenic, two for mercury and one for lead) always in the final product; the results thereof were always compliant with the legal requirements.

- In the approved feed mill above, the audit team noted that neither the acid oil nor the mycotoxin binder (which contained kaolinitic clays) received were tested for the presence of dioxins and dioxin-like PCBs. After examining the technical documentation available for both substances, the audit team noted that: a) in the documentation related to the acid oil there was no information allowing to rule out the risk of dioxins and dioxin-like PCBs (this was not detected by the official services), and b) the information concerning the mycotoxin binders indicated that the producer is a member of a well known feed safety scheme.

## **Conclusions**

Official controls cannot ensure that feed mills implement adequate measures to ensure that the level of cross-contamination derived from the use of veterinary medicines is minimised. The lack of correct targeting of official sampling in this regard prevents the competent authorities from clearly establishing the extent of this problem (see section 5.2.2). In addition, official controls overlook some gaps in the ability of operators to achieve homogeneous mixes and in the methodology used to determine the effectiveness of mixers.

Finally, official controls overlook some important deficiencies concerning the monitoring of undesirable substances carried out by feed establishments, notably as regards dioxin and dioxin-like PCBs and aflatoxins.

Therefore, it cannot be ensured that the relevant requirements of Article 5(2) of Regulation (EC) No 183/2005 are satisfactorily complied with.

### *5.3.4 Traceability*

## **Legal requirements**

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

## **Findings**

- According to the information provided by VFB, check-lists used by feed inspectors cover the verification of traceability arrangements put in place by feed operators, including the manufacturing history, keeping of incoming and outgoing documentation and the taking of samples of ingredients and final products. The audit team noted that these requirements were checked during official controls.
- In most of the establishments visited, the audit team noted, through practical exercises, that the traceability arrangements in place were largely effective.
- In all but one establishment visited, the audit team noted that not all the required traceability samples were kept; this concerned, depending on the establishment, incoming materials, final products, feed materials, additives, premixtures and products both in bulk or sacked. These shortcomings were overlooked by the official services.

## **Conclusions**

Official controls are able to ensure that establishments comply with those traceability requirements related to keeping records showing the link between ingredients and final products. However, they



cannot ensure that establishment keep all the necessary samples of ingredients used and final products placed on the market.

### 5.3.5 HACCP-based procedures

#### **Legal requirements**

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

#### **Findings**

- According to the information provided by VFB, feed inspectors have designed and implemented a written procedure based on HACCP principles. The audit team noted that this requirement was checked during official controls.
- In the meetings held with feed inspectors, the audit team saw an example of a poorly designed HACCP plan detected during official controls. The relevant feed inspector was in the process of discussing with the operator involved the changes needed as regards hazard analysis and preventative measures contained in the said plan.
- In the establishment manufacturing feed and technical (non-feed) grade quarried mineral products visited, the audit team noted that all relevant risks related to materials, operations and activities were included in the HACCP plan. In addition, the sampling programme implemented was designed on the basis on the identified risks mentioned above.
- In the processor of crude oil visited, the audit team noted that: a) the operator had developed a specific HACCP plan for the rapeseed cake, but the risk derived from the dioxins and dioxin-like PCBs potentially present in the used bleaching earth added to the cake was not considered, and b) the HACCP plan for the acid oil was only at a very early stage of design and consequently, there was no hazard analysis for this product. Therefore, the risk posed by the potential concentration of dioxins and dioxin-like PCBs during the deodorisation step of the chemical refining was not taken into account. Official services overlooked the said deficiencies.
- In the registered feed mill visited, the audit team noted that the operator had designed a very detailed HACCP plan. However, there was no clear identification of the different hazards derived from the different incoming materials, and the reflection of those risks in the sampling plan was also missing. For instance, the risk of the presence of dioxins in the dried grains of cereals was not contemplated in the HACCP plan and there were no samples foreseen for searching those contaminants in the sampling plan. This shortcoming was not identified by the official services.
- In the approved feed mill visited, the audit team noted that the hazard analysis designed by the operator took account of most risks linked to the different ingredients received. It was noted that this establishment receives acid oil from the processor of crude vegetable oil mentioned above. However, the risk derived from the potential presence of dioxins and dioxin-like PCBs in such products was not taken into account, despite not having any information from the supplier allowing to rule it out. This deficiency was overlooked by the official services.

## Conclusions

Official controls cannot always ensure that establishments comply with the requirements on procedures based on the HACCP principles laid down by Articles 6 and 7 of Regulation (EC) No 1831/2003, since there are deficiencies in their design and implementation, in particular as regards the identification of hazards linked to incoming materials or processes followed during production of feed.

### 6 OVERALL CONCLUSIONS

The competent authority have in place a largely satisfactory system for official controls, which is underpinned by a good knowledge of most of the establishments and operators carrying out activities along the feed chain, including those falling under the scope of this audit. However, there are some deficiencies concerning the prioritisation of official controls at the level of establishments carrying out direct drying of feed and processing crude vegetable oil.

Official controls along the feed chain largely ensure compliance with the requirements concerning sourcing and labelling, equipment, and traceability. However, there are weakness in official controls on measures put in place by operators to minimise cross-contamination and to monitor dioxins, as well as on requirements concerning the identification of certain hazards in the manufacturing of feed.

### 7 CLOSING MEETING

A closing meeting was held on 8 March 2013 with the representatives of the central competent authority. At this meeting, main findings and preliminary conclusions of the audit were presented by the audit team. The central competent authority did not indicate any major disagreement with these. During the meeting, additional information as requested by the audit team was provided by the central competent authorities.

### 8 RECOMMENDATIONS

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

N°.	Recommendation
1.	To ensure compliance with the requirements of Article 3 of Regulation (EC) No 882/2004, in particular as regards: a) identifying all the relevant risks linked to activities and operations when risk-rating feed establishments, b) ensuring that official controls always take account of the reliability of feed operators' own-checks and c) ensuring that official sampling takes better account of the relevant risk criteria, notably as regards dioxins and the possible presence of residues of veterinary medicines in feed for non-target species.

N°.	Recommendation
2.	To register establishments carrying out drying of feed and list them accordingly, as laid down, respectively, by Articles 9 and 19 of Regulation (EC) No 183/2005.
3.	To ensure the effectiveness of measures required concerning the minimisation of cross-contamination with veterinary medicines, as laid down by Article 5(2) of Regulation (EC) No 183/2005.
4.	To ensure that feed operators achieve homogeneous mixes, and that the methodology used allows determining the effectiveness of mixers, as laid down by Article 5(2) of Regulation (EC) No 183/2005.
5.	To ensure that the requirements concerning the monitoring of undesirable substances, notably dioxin and dioxin-like PCBs and aflatoxins, are complied with, as laid down by Article 5(2) of Regulation (EC) No 183/2005.
6.	To ensure that the requirements concerning the keeping of samples of ingredients used and final products placed on the market are complied with, as laid down by Article 5(2) of Regulation (EC) No 183/2005.
7.	To ensure that feed operators comply with the requirements concerning procedures based on the HACCP principles, as laid down by Articles 6 and 7 of Regulation (EC) No 183/2005, in particular as regards the identification of hazards linked to incoming materials or processes followed during the handling of feed.

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

[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_inspection\\_ref=2013-6740](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6740)

## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 767/2009	OJ L 229, 1.9.2009, p. 1-28	Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC
Reg. 1831/2003	OJ L 268, 18.10.2003, p. 29-43	Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition
Dir. 2002/32/EC	OJ L 140, 30.5.2002, p. 10-22	Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement
Reg. 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

## **ANNEX 2 - REQUIREMENTS CONCERNING THE MARKETING OF FEED**

### **1. BACKGROUND**

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

### **2. FINDINGS**

Verification of compliance with feed marketing rules forms part of feed control. Feed inspectors use specific check-lists for controlling these requirements on-the-spot.

#### **2.1 DECLARATION OF ADDITIVES**

##### **Legal requirements**

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

##### **Findings**

- According to the information provided by VFB, the provisions contained in Regulation (EC) No 767/2009 as regards the declaration of the quantity of trace elements, are neither followed by feed operators nor enforced by the competent authority. In this respect, it is the quantity of the element and not that of the compound which is included on the labels of feed produced in the country. The audit team noted that this was the case in all the labels examined.

#### **2.2 CLAIMS**

##### **Legal requirements**

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

##### **Findings**

- According to the information provided by VFB, feed inspectors are instructed to look for claims on the labels of the feed checked during official controls. At central levels, checks on the information circulating on the internet is also checked. VFB stated that most of the claims found so far relate to pet food, while only one case was found concerning farm animals.
- VFB stated that checking on the information submitted by feed operators to substantiate their claims is also done at central level. The Chief Specialist on feed at VFB declared that they have consulted with external specialists to assess the information concerning substantiation of claims.
- The audit team did not find any claims on the labels of feed produced in the country.

## **2.3 TRUTHFULNESS OF LABELLING**

### **Legal requirements**

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

### **Findings**

- According to VFB, truthfulness of labelling is considered to fall within the broader category of checks on claims.