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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
LITHUANIA
FROM 22 TO 30 OCTOBER 2019
IN ORDER TO
EVALUATE OFFICIAL CONTROLS ON FEED ADDITIVES, THEIR INGREDIENTS AND TRACEABILITY

Executive Summary

This report describes the outcome of an audit carried out in Lithuania from 22 to 30 October 2019 as part of the European Commission's Directorate-General for Health and Food Safety 2019 work programme. The audit is part of a series of audits aimed at verifying that official controls in the area of feed additives and ingredients for their production are carried out in accordance with Regulation (EC) No 882/2004 of the European Parliament and of the Council and other relevant EU legislation, in particular Commission Regulation (EC) No 1831/2003 and Commission Regulation (EC) No 183/2005.

In Lithuania, there is a risk-based system in place for planning of official controls (inspections and sampling) on feed and it is supported by well-developed procedures on registration and approval of feed business operators. The implementation of relevant EU requirements is supported by adequate national legislation, guidance and checklists.

The inspections are performed with planned frequencies and adequately verify operators' fulfilment of relevant requirements concerning hygiene, facilities, equipment maintenance and traceability. Where non-compliances were detected, these were adequately followed up.

Notwithstanding these positive aspects, the effectiveness of the control system is weakened by three main factors: (a) insufficient official assessment of feed business operators' Hazard Analysis Critical Control Points systems, due to a lack of knowledge of the feed inspectors, (b) insufficient official controls on labelling, as evidenced by the inaccuracies in certain labelling identified by the audit team but missed by the official inspections and (c) inadequate official sampling. The latter, whilst (properly) risk-based was undermined by incorrect implementation of EU and national sampling requirements, thus weakening the reliability of results and the effectiveness of the whole official sampling programme.

The report makes a number of recommendations to the Lithuanian competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementation of the official controls in the area of feed additives and ingredients for their production.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
BIP	Border Inspection Post
FeBO	Feed Business Operator
GMO	Genetically Modified Organism
HACCP	Hazard Analysis and Critical Control Points
RASFF	Rapid Alert System for Food and Feed
SFVS	State Food and Veterinary Service
VMFD	Veterinary Medicines and Feed Department

1 INTRODUCTION

The audit took place in Lithuania from 22 to 30 October 2019 as part of the European Commission's Directorate-General for Health and Food Safety 2019 work programme. The mission team comprised two auditors from the Commission, and was accompanied by a representative from the central competent authority (Veterinary Medicines and Feed Department (VMFD) of the State Food and Veterinary Service (SFVS)) throughout the audit.

An opening meeting with the competent authority was held on 22 October 2019 during which the objectives, itinerary and the reporting procedures for the audit were confirmed.

2 OBJECTIVES AND SCOPE

The main objective of the audit was to verify that official controls carried out pursuant to Regulation (EC) No 882/2004 of the European Parliament and of the Council are suitable to verify compliance by operators with applicable rules in the area of feed additives, their ingredients and traceability, and in particular those for (1) feed additives laid down in Regulation (EC) No 1831/2003 of the European Parliament and the Council, (2) feed hygiene laid down in Regulation (EC) No 183/2005 of the European Parliament and of the Council, and (3) undesirable substances in animal feed laid down in Directive 2002/32/EC of the European Parliament and of the Council. Council Directive 90/167/EEC on medicated feedingstuffs was not within the scope of the audit.

The audit focussed on the competent authority performance of official controls on feed additives and ingredients for their production. In pursuit of the objective, the following sites were visited:

Visit/meetings	No	Comments
Competent authority	2	Opening and closing meetings
Producers of feed additives	1	
Producers of premixtures	1	
Importers and traders[1] of feed additives and/or premixtures	4	
Compound feed producers using feed additives and/or premixtures	3	

3 LEGAL BASIS

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

[1] Provided they meet the definition of "feed business" and "feed business operator" laid down by Article 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council

4 BACKGROUND

Feed additives and their mixtures (premixtures) are the essential ingredients in modern compound feed manufacture and their use is steadily increasing[2]. A substantial quantity of feed additives and ingredients for their production is sourced from third countries and it is important to be able to demonstrate that such imports do not contain undesirable substances. From 2010 to the end of 2017, there were 79 notifications issued for feed additives under the Rapid Alert System for Food and Feed (RASFF) for the presence of non-authorised genetically modified organisms (GMOs) (26), dioxins (21), heavy metals (17), veterinary medicinal products (5), microbiological contaminants (3) and other non-specified hazards (7). Most of these were for imported feed additives and ingredients for their production. Thus proper traceability of those substances/products is a vital prerequisite for effective control.

In Lithuania, there is one approved feed additive manufacturer and 3 approved premixture manufacturers. There are 48 approved importers and 182 traders trading feed additives and/or premixtures. The total number of the compound feed producers is 59 (out of which 19 are approved, 40 registered).

This is the first time that official controls on feed additives and ingredients for their production in the EU have been specifically audited by the Commission in Lithuania.

5 FINDINGS AND CONCLUSIONS

Legal acts quoted in this report are provided in Annex I and refer, where applicable, to the last amended version. Relevant articles or sections of the legislation cited in Annex I are referred to in the individual findings in this section of the report. In addition, Annex II to this report summarises the main legal requirements related to the specific provisions and measures laid down in the body of EU legislation pertaining to the control of feed additives.

5.1 STRUCTURE OF THE SYSTEM FOR OFFICIAL CONTROLS ON FEED ADDITIVES AND INGREDIENTS FOR THEIR PRODUCTION

5.1.1 Competent authorities involved

1. The organisation of official controls on feed business operators (FeBOs) is described in the Commission services' country profile for Lithuania.[3]

2. At the central level, since September 2019 a new department (VMFD) of the SFVS is responsible for the planning of official controls including routine and targeted inspections and sampling. The VMFD is also responsible for training of local inspectors, communication with stakeholders, managing/communicating feed-related RASFF notifications and representing Lithuania in the relevant European Commission

[2] In the EU in 2016, the annual consumption of minerals, feed additives and vitamins was approximately 5.4 million tonnes (compared to 4.6 million tonnes in 2014 and 4.7 million tonnes in 2015).

[3] Available at: http://ec.europa.eu/food/audits-analysis/country_profiles/index.cfm?co_id=LT

Committee. The Lithuanian Ministry of Agriculture is responsible for legislation and policy making in the feed sector.

3. The implementation of official controls is the task of the local inspectors in the 52 territorial SFVS units. As of December 2019, a new structure of territorial SFVS is planned: 10 territorial departments will be created, with the task to coordinate the responsibilities of several different territorial units.

4. The National Food and Veterinary Risk Assessment Institute is the national reference laboratory for feed analyses. This institute is also responsible for the drafting of feed monitoring sampling plan and performance and evaluation of results of laboratory analyses. The institute also publishes scientific advice and/or recommendations mainly based on European Food Safety Authority opinions.

5. In 2019, the SFVS organised training courses for local inspectors in three different administrative parts of Lithuania. During these courses local inspectors received information/presentations on labelling requirements, and in particular those relevant to feed additives, cross-contamination and carry-over of coccidiostats, differentiation between premixtures and complementary feeds, implementation of Hazard Analyses Critical Control Points (HACCP) audits (comprehensive assessment). The audit team assessed these training materials and concluded that these adequately addressed the relevant requirements of Regulation (EC) No 1831/2003, Regulation (EC) No 183/2005, Regulation (EC) No 767/2009 and Regulation (EC) No 882/2004.

6. In the previous years, several central and local inspectors participated in Better Training for Safer Food trainings on different topics (feed law/animal nutrition, HACCP/feed HACCP, RASFF). The information provided in these training courses was disseminated to other feed inspectors. The training materials are available to the local inspectors.

7. To raise awareness of the operators of the requirements in the feed sector, in 2019 the SFVS gave a presentation at a feed workshop organised by the main feed operators` association in Lithuania. The presentation highlighted different risks of various feed ingredients, the labelling requirements applicable to feeds including feed additives and the main weak points in performance of FeBOs identified during previous official controls.

5.1.2 Registration/approval of feed business operators

8. There is a procedure in place for the registration/approval of FeBOs which is described in the country profile of Lithuania (see finding 1). The procedure is supported by a guidance document and checklists (national order number 3D-606 and 3D-607) for the harmonised implementation of the approval/registration procedure. There is a clear instruction on documentary and on-the-spot checks to be carried out before the approval, in accordance with the requirements of Article 13 of Regulation (EC) No 183/2005. The two national orders give the power to the competent authority to suspend/withdraw the approval and/or registration of a FeBO in case of serious infringements, recurrent

deficiencies and if a FeBO does not operate for more than a year (except the case of reconstruction or repair), which is in line with the requirements of Article 14 of Regulation (EC) No 183/2005.

9. Concerning registration, the territorial SFVS considers the application submitted and, if no concerns are raised, assigns a registration number to the entity in accordance with the procedure laid down in the national order No 3D-606 (see finding 8). Whenever required, the territorial SFVS performs an on-the-spot inspection and issues an inspection report. The decision on registration is taken by the head of the territorial SFVS and the newly registered FeBO is added to the publicly available registered feed operators list (see finding 12).

10. When approval is necessary, the territorial SFVS examines whether the documents presented are in compliance with the relevant requirements laid down by Regulation (EC) No 183/2005. Then, normally an on-the-spot inspection is carried out and an inspection report is issued. An on-the-spot inspection is not compulsory when the FeBO does not produce and/or store feed at its premises, but only places it on the market (so called paper traders). The head of the territorial SFVS evaluates the inspection report and documents submitted, makes a decision on the approval of the FeBO and adds it to the register of approved FeBOs.

11. The audit team assessed the implementation of the approval procedure in one recently approved FeBO. The territorial SFVS granted a conditional approval for three months. During this period, the operator produced a very small amount of product and did not place it on the market. Two and a half months after the end of the conditional approval period the FeBO started commercial activity and the local inspector carried out another on-the-spot inspection (on HACCP, delivery and storage of the final product). Based on the outcome of the second on-the-spot inspection, the FeBOs got full approval. The audit team noted that the competent authority did not prolong the conditional approval (which lapsed at the end of three month period) and did not carry out the required inspection within this time. This led to a few months' gap in the approval status of the operator (between the date of expiry of the conditional approval and the date of granting the full approval following the second on-site inspection).

12. All establishments visited were registered and, when necessary, approved as required by Articles 9, 10 and 13 of Regulation (EC) No 183/2005, and the associated documentation was available. The list of approved or registered FeBOs is regularly updated and published on the Ministry of Agriculture website, in accordance with Article 9(3) and Article 19 of Regulation (EC) No 183/2005.

Conclusion on the structure of the system for official controls on feed additives and ingredients for their production

13. The organisational arrangements in place including the designation of competent authorities, distribution of relevant tasks and responsibilities, provision of comprehensive guidance documents and checklists and staff training arrangements

underpin the planning and implementation of official controls and support feed inspectors in carrying out their duties competently and in a consistent manner.

14. There system for registration and approval of feed business operators is well-developed and complies with relevant EU legislation in this respect.

5.2 PLANNING AND IMPLEMENTATION OF OFFICIAL FEED CONTROLS

5.2.1 Inspections

5.2.1.1 PLANNING OF INSPECTIONS

15. The planning of feed inspections takes into account the risks associated with the business activity, outcome of the previous official controls, any complaints and RASFF notifications in relation to the FeBO and the reliability of the FeBO`s own-controls system based on HACCP principles. Based on these four risk factors, each territorial SFVS has to carry out an annual individual risk assessment of all relevant FeBOs. The central SFVS prepared a comprehensive guidance document to harmonise the individual risk assessments by different territorial SFVS. This approach to planning of inspections is in line with the requirements of Article 3 of Regulation (EC) No 882/2004. The audit team noted that participation in private certification schemes does not influence the risk assessment or frequency of official controls on certified FeBOs.

16. Based on the individual risk assessment of the FeBO, the minimum routine inspection frequency relating to very low risk operators (e.g. feed operators involved in retail trade of pet food) is every six years. The highest routine inspection frequency relates to high risk operators (e.g. approved compound feed manufacturers, premix manufacturers, etc.) and is once every year. In addition to the planned routine inspections, there are also targeted (non-routine) inspections. These non-routine inspections relate to consumer complaints, recalls, RASFF notifications or other *ad hoc* identified risks.

17. The SFVS has developed a comprehensive set of guidance documents including checklists to ensure the uniformity of the official inspections of all types of FeBOs. The audit team reviewed the guidance document and those checklists which were updated on 18 June 2019. These documents covered matters of relevance for the premises (e.g. hygiene, cleanliness of buildings and equipment), the adequacy of the FeBO's HACCP systems, review of the FeBO's approval/registration including registration/approval of the suppliers, review of traceability and FeBO's own-sampling programme. The documents also contain information and questions on the official inspection of labelling requirements including labelling of feed additives and premixtures. The documents reviewed by the audit team were adequate to support the inspectors in verifying compliance with the relevant requirements of Regulation (EC) No 1831/2003, Regulation (EC) No 183/2005, Regulation (EC) No 767/2009 and Regulation (EC) No 178/2002.

18. Before 2018, official audits of FeBO`s HACCP system were planned centrally and were not part of the routine inspections. Since 2018, the system has been changed and the HACCP audits have become a part of the routine inspections. Since 2018 audits have not been carried out in the feed sector.

5.2.1.2 IMPLEMENTATION OF INSPECTIONS

19. The average number of inspections carried out annually on feed additive and premixture manufacturers was around ten in each of the last three years, which was always higher than the number of planned inspections (three to four). In general, the routine inspection frequency of traders and importers of feed additives and premixtures is once every two to four years. The number of implemented official inspections has varied in the last three years (between 50 to 100 inspections per year). Planned official inspections of traders and importers were achieved in the last three years. Routine inspections are unannounced.

20. All establishments visited had been inspected with the planned frequency (see finding 16). Local inspectors met always used the centrally prepared guidance/checklists; the previous years' inspection reports were available. For one establishment affected by a RASFF notification, the territorial SFVS took this notification into account in the individual risk assessment and increased the inspection frequency for the following year (see findings 15 and 16).

21. Local inspectors met could demonstrate sufficient knowledge on official controls related to hygiene and maintenance of facilities and equipment, which is in line with the requirements of Annex II "FACILITIES AND EQUIPMENT" of Regulation (EC) No 183/2005.

22. All of the FeBOs visited had implemented HACCP-based systems. Detailed assessment criteria for HACCP-based procedures are described in the guidance/checklists (see finding 17). However, the local inspectors met could not demonstrate sufficient knowledge to assess the adequacy of the HACCP-based procedures, in particular hazard analysis of feed additives. This is not in line with the requirements of Article 6 and 7 of Regulation (EC) No 183/2005.

23. All of the FeBOs visited, where tests on homogeneity of mixing and on carry-over of coccidiostats were relevant, included relevant tests their HACCP plans and carried out such tests regularly. The audit team noted that these tests, as described in the FeBOs' procedures, were not fit for purpose in a number of operators visited. However the local inspectors met were not able to adequately evaluate the methods and the results of testing and assess compliance with the requirements laid down in Point 3 of Annex II section "PRODUCTION" of Regulation (EC) No 183/2005.

24. The audit team saw evidence that local inspectors had adequately checked the calibration of measuring devices (scales) during inspections, which is in line with the

requirements of Point 3(a) of Annex II "FACILITIES AND EQUIPMENT" of Regulation (EC) No 183/2005.

25. In 2018, the central competent authority established a Joint Inspection Group programme to harmonise the performance of official feed controls. This inspection group comprises one inspector from the central level and two-three inspectors from different territorial SFVS. In total, 34 inspections were carried out under this programme, mainly at feed manufacturers. Based on this programme, the central competent authority had already identified weaknesses relating to official controls and/or to the knowledge of the local inspectors (labelling control, evaluation of FeBOs sampling plan and carry-over testing, use of feed additives). The 2019 training programme (see finding 5) mainly focused on these weak points.

26. FeBOs are required to ensure that the feed, including feed additives and premixtures, they import satisfies the safety requirements of the relevant EU requirements in accordance with Article 23(1)(d) of Regulation (EC) No 183/2005. The audit team reviewed the available documents at the importers visited and noted that FeBOs had put the necessary arrangements in place to ensure that the imported feed additives/premixtures fulfilled relevant safety requirements. Local inspectors regularly checked these documents during routine inspections.

5.2.1.3 TRACEABILITY

27. Verification of the FeBO's traceability systems is part of the routine inspections. There is a guidance document (see finding 17) which contains a procedure for verification of product traceability in different types of establishments. During the audit, local inspectors met could demonstrate sufficient knowledge and understanding of the requirements relating to the evaluation of FeBOs' traceability systems. In the establishments visited, the local inspectors could sufficiently carry out an assessment on the effectiveness of FeBOs' traceability system. This is in compliance with the requirements laid down in Article 18 of Regulation (EC) No 178/2002 and Annex II to Regulation (EC) No 183/2005.

28. Documents related to the FeBOs' traceability systems (e.g. product specifications, recipes, production sheets, labels, results of laboratory analysis, delivery documents) were available on-the-spot, allowing for comprehensive traceability of feed additives and premixtures. This is in line with the requirements of point (2)(b)(i) and (iii) of Annex II "RECORD-KEEPING" to Regulation (EC) No 183/2005. The local inspectors met were aware of how to use the relevant documents to control the FeBOs' traceability systems.

29. The audit team randomly checked retained samples stored in the different feed manufacturers visited. All of these samples had been appropriately taken, labelled, sealed and kept under control in dedicated storage places. Retained samples from feed additives and premixtures used as ingredients were kept at least for three to six months after the end of their use. Retained samples from produced feed additives and

premixtures were kept until the end of the shelf-life of these products. Retained samples of compound feeds were kept at least for three months or until the end of the shelf-life of the produced products. This is in line with the requirements of point 4 of Annex II "QUALITY CONTROL" to Regulation (EC) No 183/2005. The local inspectors met were aware of these requirements and had checked compliance of the FeBOs on this aspect during the routine inspections.

5.2.1.4 LABELLING

30. Verification of whether labels of feed additives and premixtures comply with relevant legislative requirements is part of the routine inspections. This is in line with Article 10(2)(b)(vi) of Regulation (EC) No 882/2004. The centrally prepared guidance (see finding 17) gives detailed instructions on the labelling checks and includes relevant requirements laid down by Regulation (EC) No 1831/2003 and Regulation (EC) No 767/2009.

31. The audit team checked the documentation/labelling of imported feed additives and noted that generally these products fulfilled the relevant authorisation requirements laid down in Article 3 of Regulation (EC) No 1831/2003. Some shortcomings were identified relating to amino acids (no safety information on the label or on the bag, inadequate identification number was put on the label). The competent authority had overlooked these non-compliances during previous official inspections.

32. At the remaining (non-importer) FeBOs visited, official inspections included the labelling control of feed additives and premixtures during preceding inspections. There were instances of inadequate labels which were spotted and reported; the FeBOs remedied the issues. At the time of the audit, in the majority of the establishments visited the audit team identified some shortcomings relating to labelling of feed additives/premixtures used as ingredients for production and to the labelling of premixtures and complementary feeds. Examples of non-compliances included:

- Safety recommendations regarding the use and/or specific requirements mentioned in the authorisation of the feed additive were not labelled on the product, contrary to Article 16(1)(e) of Regulation (EC) No 1831/2003.
- Identification numbers of feed additives were missing on the labels of premixtures, contrary to the legal requirement in Article 16(1)(7) of Regulation (EC) No 1831/2003.
- The use of certain complementary feed containing vitamin A in accordance with the label instruction would lead to the established maximum levels of vitamin A in complete feed for fattening pigs and dairy cattle being exceeded, which is contrary to the requirements laid down in Commission Implementing Regulation (EU) No 2015/724.
- Labelling of complementary feed containing feed additives with maximum levels did not contain adequate instructions for proper use required by point 4 Annex II Regulation (EC) 767/2009.

- Complete feed contained a higher concentration of an antioxidant than the established maximum limit, contrary to the requirements of Commission Regulation (EC) No 2316/98.
- Complementary feed was labelled as compound feed which is not in line with the requirements of Article 15(a) of Regulation (EC) No 767/2009.
- Instructions on the labelling of feed additives allowed using this feed additive in combination with another feed additive for which the authorisation was suspended. This is not in line with the requirements of point 1 Article 3 of Regulation (EC) No 1831/2003.

The competent authority had overlooked these non-compliances during previous official inspections.

Conclusion on the planning and implementation of inspections

33. Planning of inspections is based on appropriate risk-related factors and ensures that the official controls are carried out regularly, on a risk-basis and with an appropriate frequency. With regard to implementation, whilst the verification of hygiene and maintenance of facilities and equipment, and FeBO`s traceability systems, were carried out adequately, the effectiveness of the inspections was weakened by several factors, most notably inadequate assessment of FeBOs HACCP systems including tests on homogeneity of mixing and carry-over of coccidiostats, and shortcomings in officials' verification of the correctness of feed labelling.

5.2.2 Sampling

5.2.2.1 PLANNING OF OFFICIAL SAMPLING

34. The National Food and Veterinary Risk Assessment Institute is responsible for the drafting of the annual official feed sampling plan. This plan is risk-based and takes into consideration the results of the feed sampling from previous years, RASFF notifications, European Food Safety Authority opinions on undesirable substances, feed additives, other feed contaminants, legal requirements and also laboratory capacities. In the draft plan the VMFD allocates the exact number of samples to each territorial SFVS. During the allocation the VMFD pays attention to the types and amounts of feed produced, type of FeBOs and animals kept, use of feed of animal origin and coccidiostats in the territorial SFVS. The draft plan is consulted with the central and the territorial SFVSs and finally approved by the director of the SFVS.

35. The final plan contains an instruction to the territorial SFVS for each type of analysis: the matrix, the place and the number to be sampled. Generally it is approximately 600 samples relating to analyses of feed annually including sampling of imports at the Lithuanian Border Inspection Posts (BIPs). The average number of samples from feed

additive/premixture manufacturers is around 100 and from feed additive/premixture traders around 50 annually.

36. The sampling of imported feed additives and premixtures is carried out by the inspectors of the BIPs. There is a pre-established sampling frequency: at least one sample per ten consignments of the same feed additive or premixtures from the same country of origin, if it is transported by train or truck and one sample per each consignment if it transported by ship.

37. The plan contains samples for the control of contamination/presence of heavy metals, mycotoxins, dioxins/polychlorinated biphenyls (PCBs), pesticides, feed of animal origin (feed ban), maximum limits of trace elements, and genetically modified organisms (GMOs). The audit team noted that the parameters established by Directive 32/2002/EC, were included. The plan also includes sampling for microbiological criteria (Salmonella, Enterobacteriaceae), carry-over of coccidiostats/antibiotics and quality parameters for feed ingredients.

38. Official feed samples are analysed by the national reference laboratory (see finding 4), or, in case it has no accreditation for a specific analytical method, the sample is forwarded to another accredited laboratory. This is in line with the requirement of Article 12 of Regulation (EC) No 882/2004. There is an instruction for the turnaround times of the laboratory analyses (generally up to ten working days). The laboratory sends back the results and its assessment to the territorial SFVS. The assessment clearly concludes that the result is in line or not with the relevant legal requirements. The audit team randomly checked some results and the assessment of these results were correct. In most of the cases the turnaround time was respected.

5.2.2.2 IMPLEMENTATION OF OFFICIAL SAMPLING

39. There is no specific guidance on sampling of feed but in general local inspectors have to follow the requirements of Regulation (EC) No 152/2009; the said Regulation is used for official microbiological sampling as well.

40. In 2017 and 2018, all of the planned official samples were taken. In 2017 and 2018, six and four positive results, respectively, were found in feed at traders and/or manufacturers; and one and three respectively at the BIPs.

41. Local inspectors have to collect one aggregate official sample which is divided in four final samples. One sample is sent to the national reference laboratory for analysis, two samples are kept by the inspector and one is kept by the FeBO (defence sample). All of these samples are sealed. FeBOs have the right to request the analysis of their defence sample when it is relevant. This is in line with the requirements of Article 11 of Regulation (EC) No 882/2004.

42. Several local inspectors met were not knowledgeable on, and subsequently could not follow, the official sampling requirements laid down by Regulation (EC) No 152/2009,

including the concept of 'sampled portion' and calculation the number of incremental samples.

43. Local inspectors use a common sampling protocol for official sampling of feed and food. This protocol contains information on, *inter alia*, the type of product, total quantity of the product, type of the laboratory analysis, quantity of the sample and the address of the laboratory. In the protocol, there is no requirement to note the size of the sampled portion. The audit team reviewed some sampling protocols and could conclude that the protocols did not contain the information required by point 10 of Annex 1 to Regulation (EC) No 152/2009.

Conclusion on the planning and implementation of sampling

44. Planning of official sampling is effective and risk-based. Notwithstanding strong laboratory performance, several factors (such as flawed sampling protocols, and a lack of understanding of sampling requirements) weaken the implementation of sampling and thus the effectiveness of the whole official sampling system.

5.2.3 Actions taken on non-compliances

45. There are procedures in place for the implementation of different actions to be taken in the event of non-compliances being detected (warning, restriction to supply of products to the market, suspension/withdrawal of approval/registration, fines, etc.). FeBOs always receive a report on the identified non-compliance which is in line with the requirements of Article 9 of Regulation (EC) No 882/2004.

46. Approximately 50% of the inspections in the past three years (see finding 19) identified non-compliances but the vast majority of these non-compliances were minor and did not have an impact on the inspection frequencies. Most of these non-compliances related to incorrect labelling, incomplete HACCP procedures and incomplete traceability systems.

47. The audit team reviewed some cases where non-compliances had been detected and noted that action plans with deadlines had been requested from the FeBOs and adequate measures had been taken to ensure that the operator(s) remedied the situation. This is in line with the requirements of Article 54 of Regulation (EC) No 882/2004.

Conclusion on actions taken on non-compliances

48. Notwithstanding conclusions 33 and 44, for those non-compliances which are detected, these are adequately followed up and documented.

6 OVERALL CONCLUSION

In Lithuania, there is a risk-based system in place for planning of official controls (inspections and sampling) on feed and it is supported by well-developed procedures on registration and approval of feed business operators. The implementation of relevant EU requirements is supported by adequate national legislation, guidance and checklists.

The inspections are performed with planned frequencies and adequately verify operators' fulfilment of relevant requirements concerning hygiene, facilities, equipment maintenance and traceability. Where non-compliances were detected, these were adequately followed up.

Notwithstanding these positive aspects, the effectiveness of the control system is weakened by three main factors: (a) insufficient official assessment of feed business operators' Hazard Analysis Critical Control Points systems, due to a lack of knowledge of the feed inspectors, (b) insufficient official controls on labelling, as evidenced by the inaccuracies in certain labelling identified by the audit team but missed by the official inspections and (c) inadequate official sampling. The latter, whilst (properly) risk-based, was undermined by incorrect implementation of EU and national sampling requirements, thus weakening the reliability of results and the effectiveness of the whole official sampling programme.

7 CLOSING MEETING

A closing meeting was held on 30 October 2019 with the representatives of the Veterinary Medicines and Feed Department. The main findings and preliminary conclusions of the audit were presented by the audit team. The authority present did not indicate any major disagreement with these.

8 RECOMMENDATIONS

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within 25 working days of receipt of this audit report.

No	Recommendation
1	Ensure that official controls are implemented consistently in order to allow for the verification that feed business operators` HACCP systems meet the requirements of Articles 6 and 7 of Regulation (EC) No 183/2005 as required by Article 10 of Regulation (EC) No 882/2004. *Recommendation based on conclusion: 33* *Associated findings: 22, 23*
2	Ensure that official controls are capable of verifying that feed business operators' labelling satisfies the requirements laid down in Article 16 of Regulation (EC) No 1831/2003 and Articles 15 and 17 of Regulation (EC) No 767/2009. *Recommendation based on conclusion: 33* *Associated findings: 31, 32*
3	Ensure that official staff carrying out official sampling follow the sampling requirements laid down in Annex I to Regulation (EC) No 152/2009. *Recommendation based on conclusion: 44* *Associated findings: 42, 43*

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

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2019-6631

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
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. 1831/2003	OJ L 268, 18.10.2003, p. 29-43	Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition
Reg. 767/2009	OJ L 229, 1.9.2009, p. 1-28	Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 152/2009	OJ L 54, 26.2.2009, p. 1-130	Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed

Annex II MAIN LEGAL REQUIREMENTS RELATED TO SPECIFIC PROVISIONS AND MEASURES

Chapter	**Regulation (EC) No**						**Directive (EC) No**
	178/2002	**1831/2003**	**882/2004**	**183/2005**	**152/2009**	**767/2009**	**2002/32**
5.1 Competent authorities involved			Articles 4-6				
5.1.2 Registration/approval of feed business operators			Article 31 (2(e,f))	Articles 9.10, 11(b), 13, and 19			
5.2.1.1 Planning of inspections			Articles 3, 8(1)	Article 6 and 7, Annex II			
5.2.1.2 Implementation of inspections			Article 3	Articles 6,7 and Annex II			
5.2.1.3 Traceability	Article 18		Article 10 (2)	Article 5 and Annex II. "Record-keeping" (4) and "Quality control" in Annex II			
5.2.1.4 Labelling		Article 16 and Annex III				Article 4, 11, 12, 14-17 and 19	
5.2.2.1 Planning of official sampling			Article 12				Article 3 and Annex I
5.2.2.2 Implementation of official sampling			Article 11(1)		Article 1 and Annex I		
5.2.3 Action taken on non-compliances			Article 54				