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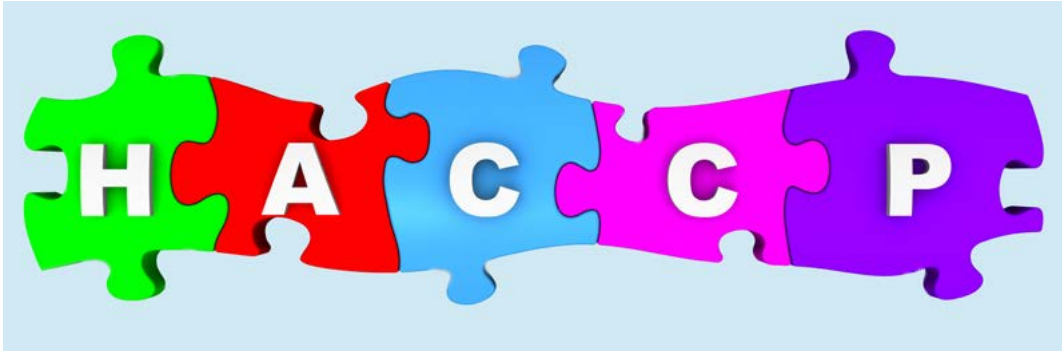

DG Health and Food Safety

OVERVIEW REPORT

Official controls on feed additives, their ingredients and traceability

Health and Food Safety

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OVERVIEW REPORT OF AUDITS CARRIED OUT IN CERTAIN MEMBER STATES IN 2018-2019 IN ORDER TO EVALUATE OFFICIAL CONTROLS ON FEED ADDITIVES, THEIR INGREDIENTS AND TRACEABILITY

Executive Summary

This report presents the key results of 10 audits carried out by the European Commission's Directorate for Health and Food Audits and Analysis in 2018-2019 that focused on how Member States were implementing official controls on feed additives and their mixtures (so called 'premixtures').

Feed additives and their premixtures are the essential ingredients in modern compound feed manufacture and their use is steadily increasing. The expanding group of feed additives and their premixtures includes substances which, by a variety of mechanisms, help maintain the health of the animals, increase their production and performance, improve the animals' uptake of feed and improve the characteristics of animal products they produce. The EU has established a comprehensive set of rules on placing on the market, labelling and use of feed additives. This series of audits examined how competent authorities have set up their official control systems and implemented those to ensure that feed business operators are complying with the relevant legal requirements.

Overall, the audits found that there were robust and risk-based systems in place for the planning of official inspections and sampling in the feed additives/premixtures sector. Inspectors generally adhered to this planning and were able to adequately verify operators' fulfilment of the main requirements concerning hygiene, facilities, equipment, maintenance and traceability. Training programmes and guidance documents supported inspectors in carrying out their duties.

Nevertheless, despite the satisfactory planning, some weaknesses in the way official controls were being implemented were noted in key areas, such as the assessment of feed business operators' hazard analysis and critical control points' systems, the assessment of operators' tests on homogeneity and measures to minimise unavoidable carry-over of certain feed additives, the follow-up of non-compliances, official controls on retained samples, controls on labelling and official sampling and interpretation of results.

In relation to controls on imported feed additives and premixtures, Member States competent authorities' generally satisfied existing EU requirements although the practical approaches on carrying out these controls varied.

Further to these audits the Commission made a number of recommendations to the respective Member States to improve their control systems, and is actively following up on the corrective actions provided in response to these recommendations. A series of audits in the area of general feed hygiene commenced in 2020 and a planned workshop with Member States' officials should provide further opportunities to share good practice and facilitate the implementation of more effective official controls.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
BTSF	Better Training for Safer Food
EU	European Union
Feed additive	As defined in Article 2(2)(a) of Regulation (EC) No 1831/2003 of the European Parliaments and of the Council ([1]), 'feed additive' means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions: (a) favourably affect the characteristics of feed, (b) favourably affect the characteristics of animal products, (c) favourably affect the colour of ornamental fish and birds, (d) satisfy the nutritional needs of animals, (e) favourably affect the environmental consequences of animal production, (f) favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs, or (g) have a coccidiostatic or histomonostatic effect.
HACCP	Hazard Analysis and Critical Control Points, as further defined in Article 6(2) of Regulation (EC) No 183/2005.
Premixture	As defined in Article 2(2)(a) of Regulation (EC) No 1831/2003, 'premixture' means mixtures of feed additives or mixture of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals.

([1]) OJ L 1268, 18.10.2003, p. 29.

1 INTRODUCTION

1.1 WHAT ARE FEED ADDITIVES AND WHY ARE THEY USED?

Feed additives and their mixtures (so called premixtures) are essential ingredients in modern compound feed manufacture and their use is steadily increasing. The expanding group of feed additives and their premixtures includes substances which, by a variety of mechanisms, help maintain the health of the animals, increasing their production, improving the animals' absorption and utilisation of feed and improving the characteristics of animal products they produce. For example, additives such as amino acids, vitamins and microelements can improve the amount of nutrients animals get from their feed; coccidiostats can prevent the parasitic infestation of the digestive tract; probiotics can enhance the favourable bacterial microflora; enzyme preparations can improve the digestibility of nutrients; flavourings can increase palatability of feed; antioxidants can ensure stability of some feed materials.

1.2 WHAT PARTS OF THE FEED ADDITIVES INDUSTRY NEED TO BE CHECKED BY REGULATORS?

Section 2 of this report outlines the legal framework applicable to official controls ([2]) on feed additives and premixtures in the European Union (EU). In short, each feed business operator is ultimately responsible for ensuring the safety of the product they put on the market, and competent authorities ([3]) verify that this is the case. This requires in the first instance that Member States' competent authorities approve or register such feed establishments so that they know who is operating on their territory and this is an important prerequisite for the authorities to plan and implement risk-based official controls.

Competent authority officials – inspectors – must be adequately trained so that they can identify non-compliance with the rules and take appropriate action to mitigate or eliminate any adverse consequences arising as a result of the non-compliance. They must be capable of taking appropriate samples for laboratory testing and must be able to adequately evaluate each operator's permanent written procedures based on the hazard analysis and critical control points principles (HACCP system) and the results of their own-checks ([4]). They must be able in particular to verify that the operator is producing a homogeneous end product (i.e. that the additives are uniformly distributed throughout the mixture) and that the operator has put in place procedures to mitigate the carry-over of certain feed additives (e.g. coccidiostats) to non-target feed. Finally, inspectors must be able to assess whether the labelling of such products accurately reflects their contents and that the operator can ensure proper traceability of the product should a problem be identified along the feed chain.

([2]) An official control in the scope of this report refers mainly to inspecting feed business establishments and goods, including sampling and testing products when necessary.

([3]) A competent authority in the scope of this report is the central authority of a Member State whose legal responsibility it is to carry out official controls or any other authority to which that responsibility has been conferred.

([4]) Testing carried out by the operator.

1.3 WHAT IS THE FOCUS OF THIS REPORT?

This report presents the key results of 10 audits carried out by the European Commission's Directorate for Health and Food Audits and Analysis in EU Member States in 2018-2019. The audits focused on how Member States were implementing official controls on feed additives and premixtures during their manufacture, distribution, placing on the market and use. The Annex to this overview report lists the Member States audited.

This report briefly describes the EU legal framework governing official controls on feed additives and premixtures and details the planning of official controls, registration/approval of establishments, the training of official staff, and the implementation of official controls including actions to taken where non-compliances are identified. There is a separate section dealing with official controls on the importation and export of feed additives. The final part of the report gives an overall assessment of Member States' performance and describes the follow-up action taken by the Commission in light of the findings made in this series of audits.

2 WHAT ARE THE EU LEGAL REQUIREMENTS GOVERNING OFFICIAL CONTROLS ON FEED ADDITIVES AND PREMIXTURES?

Regulation (EC) No 1831/2003 of the European Parliament and of the Council ([5]) establishes a common procedure for authorising feed additives and lays down rules for their placing on the market, labelling and use. General rules on feed hygiene are laid down in Regulation (EC) No 183/2005 of the European Parliament and of the Council ([6]). Specific requirements on undesirable substances in animal feed are laid down in Directive 2002/32/EC of the European Parliament and of the Council ([7]). Requirements on methods of sampling and analysis for official controls on feed are laid down in Commission Regulation (EC) No 152/2009 ([8]), and on the placing on the market and use of feed in Regulation (EC) No 767/2009 of the European Parliament and of the Council ([9]). Regulation (EC) No 882/2004 of the European Parliament and of the Council ([10]) on official controls performed, *inter alia*, to ensure the verification of compliance with feed law, was in force at the time of all the audits. This Regulation was repealed and replaced by Regulation (EU) 2017/625 of the European

([5]) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition, OJ L 1268, 18.10.2003, p. 29.

([6]) Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene, OJ L 35, 8.2.2005, p. 1.

([7]) Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed, OJ L 140, 30.5.2002, p.10.

([8]) Commission Regulation (EC) No 152/2009 of 27 January 2009, laying down methods of sampling and analysis for the official control of feed, OJ L 54, 24.2.2009, p.1.

([9]) 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, OJ L 229, 1.9.2009, p. 1.

([10]) 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, OJ L 165, 30.4.2004, p. 1–141.

Parliament and of the Council ([11]) on official controls and other official activities performed, *inter alia*, to ensure the application of feed law, with effect from 14 December 2019.

All feed additives used/placed on the EU market have to be authorised ([12]). A register of feed additives which are authorised to be used/placed on the EU market is published on the website of the European Commission ([13]).

Non-EU authorised feed additives and premixtures may also be exported to third countries under certain conditions ([14]).

3 PLANNING OF OFFICIAL CONTROLS

3.1 REGISTRATION/APPROVAL OF FEED BUSINESS OPERATORS

All establishments visited in the audited Member States were registered (mandatory for all feed business operators, mainly administrative procedure) or approved (mandatory for specific categories of feed business establishments, requires on-site visit by the competent authority prior to start-up of any activity). The competent authorities had adequate procedures in place for the registration/approval of feed business operators in accordance with the requirements of EU legislation. The lists of the registered/approved operators were publicly available and were updated regularly by the competent authorities. The up-to-date lists provided a good basis for the competent authorities to plan their official controls, including inspections and sampling, on a risk-basis taking into account the operators' activities and their past record of compliance with EU rules.

In the vast majority of Member States audited, a check of the registration/approval status is part of the routine official inspection and this is carried out regularly by inspectors. The audit teams noted minor shortcomings in some Member States' implementation of approval procedures (e.g. the lack of an on-the-spot inspection prior to approval and lengthy periods between the conduct of the on-the-spot inspection and the approval of the establishments) but these were isolated cases which did not affect the otherwise well-functioning registration/approval systems.

([11]) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), OJ L 95, 7.4.2017, p. 1–142.

([12]) See https://ec.europa.eu/food/safety/animal-feed/feed-additives/authorisation-types-withdrawal_en

([13]) See https://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register_en

([14]) Article 12 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24.

3.2 TRAINING OF OFFICIAL STAFF

In all of the Member States audited, training programmes were in place and training was provided to officials responsible for performing official controls in the feed sector. These programmes highlighted, *inter alia*, the requirements for official controls on feed additives and premixtures. In several cases, these training programmes used a combination of theoretical knowledge (e.g. legislative requirements, adequate use of guidance/checklists, etc.) and practical exercises (e.g. case studies, simulation exercises on-the-spot, etc.). In all of the Member States visited, inspectors had attended Better Training for Safer Food (BTSF) courses on different topics (e.g. feed law/animal nutrition, assessment of HACCP systems in feed establishments, etc.). Information and materials provided in these BTSF courses had been disseminated to other inspectors during national/regional/local training courses. In all of the Member States visited, these training programmes were comprehensive and sufficiently detailed to help inspectors plan and implement their official controls effectively. Training programmes paid particular attention to the assessment of operators' HACCP systems, and in most cases included the assessment of operators' tests on homogeneity of mixing and carry-over, assessment of operators' traceability systems, and controls on labelling, including special requirements for labels of feed additives and premixtures.

Notwithstanding the above, in several Member States visited, the inspectors met could not proficiently implement the information provided in these training programmes during their inspections (see point 4.1, 4.2, 4.3 and 4.4).

3.3 PLANNING OF OFFICIAL INSPECTIONS

In all of the Member States audited, there was a risk-based approach to planning of official inspections of feed business operators in the whole feed sector, i.e. the same principles were applied to the planning of inspections of all feed manufacturers/traders, including those dealing with feed additives and premixtures. There were some common criteria applied for the determination of the risk category and further setting of the inspection frequency. These included for example (i) the type of activities carried out by the operator, (ii) past records as regards compliance with feed law, and (iii) the reliability of the operators' own-checks.

In many Member States, there were additional criteria to establish the risk category of individual feed businesses, the most common being the volume of the feed manufactured/traded. Other criteria included the level of maintenance of the facilities/equipment, the origin of feed materials, the willingness of the feed business operators to address any shortcomings, the use of feed of animal origin, etc. The number of risk classes resulting from the application of these various risk categorisation models varied considerably between Member States.

Overall, the frequencies of official inspections in the Member States visited were linked to the relevant risk categorisation attributed to the various feed business operators by the competent authorities. This is as expected given the obligation for the competent authorities to carry out official controls on a risk-basis. As the models applied by the Member States

visited reflected the country-specific organisation of official control systems, and, to some extent, different socio-economic contexts, the inspection frequencies applied for similar types of operator did vary from one Member State to another. For example, operators deemed to pose the highest risk were subject to an inspection frequency ranging from a maximum of four times per year to a minimum of once per year. For operators categorised as posing a lower risk (usually retailers, traders and transporters), the frequency varied from once per year to once every 10 years. In general, feed additive and premixture producers are considered to belong to the high-risk category and retailers and traders belong to the medium/low risk category.

3.4 PLANNING OF OFFICIAL SAMPLING

In all of the Member States visited, the planning of official sampling was largely risk-based. The sampling plans covered all of the groups of relevant contaminants (e.g. undesirable substances, microbiological contamination, genetically modified organisms, etc.). There were no special plans for sampling of feed additives and/or premixtures, however the general feed sampling plans required the taking of samples from feed additives and premixtures.

Generally, Member States used one of two models for planning. In the first model, the central competent authority prepared a very detailed sampling plan describing the type of analyses, the type of establishment from where the sample must be taken and the type of feed that had to be sampled (e.g. three samples for cadmium from a premixture in a compound feed producing establishment).

The second model gave more flexibility to regional/local inspectors and here the central competent authority would allocate the number of analyses to the regional/local competent authorities and these authorities prepared their own plan describing the place and the type of feed that had to be sampled (e.g. central level requested five samples for heavy metals, the regional level requested local inspectors to take three samples of cadmium and two samples of lead from trace elements in a premixtures' producing establishment).

Regardless of the model followed, the central competent authorities prepared comprehensive guidance documents to support local inspectors in planning their sampling programmes effectively. Notwithstanding the model used by the central competent authorities to design the official sampling programme, in the Member States visited it was observed that the decision on which individual establishment to sample was left to the local inspectors and was generally based on the availability of the specific type of feed to sample. As a consequence, in most cases, samples tended to be taken from large operators, where there was usually a much wider variety of feed types available.

In all of the Member States visited, the official samples were analysed by official laboratories (both public and private) accredited to EN ISO/IEC 17025.

3.5 OVERALL CONCLUSIONS ON MEMBER STATES' PLANNING OF OFFICIAL CONTROLS

The audits found that the systems for planning official controls (inspections and sampling) were comprehensive and risk-based. Planning was supported by adequate approval/registration procedures ensuring that the competent authorities had access to a complete list of feed business operators for the planning purposes. Centrally organised training programmes and guidance documents further supported inspectors in their work. Whilst there were different risk factors and models used by Member States during their planning process, all were in line with EU requirements and were appropriate for decisions on the frequency of inspections on feed additives and premixtures.

4 IMPLEMENTATION OF OFFICIAL CONTROLS

4.1 OFFICIAL INSPECTIONS

All of the Member States audited had prepared comprehensive sets of guidance documents and checklists to ensure that official inspections were carried out in a consistent manner. Local inspectors were trained to make use of these documents. In the majority of the Member States visited, the planned inspection frequencies were complied with in the two years preceding the audit series. Generally, official inspections could adequately verify the operators' fulfilment of the EU requirements concerning hygiene, facilities, equipment and maintenance.

However, in the majority of the Member States visited, despite the fact that training had been provided, local inspectors did not demonstrate that they possessed sufficient knowledge on how to assess operators' HACCP systems, in particular hazards relating to feed additives (e.g. whether the approved strains of microorganisms were used for fermentation, whether the products of mineral origin do not contain unacceptably high levels of heavy metals, etc.). In addition, in several cases inspectors were not able to verify that operators' tests to demonstrate homogeneity of the product and/or demonstrate that measures to minimise carry-over of certain feed additives (e.g. coccidiostats) to non-target feed were fit for purpose and effective, although it should be noted that in some cases local inspectors had not received training on these specific topics. In a few Member States, the assessment of operators' HACCP systems was not part of the routine inspections but was carried out regularly but less frequently than the routine inspections by a specialised team of inspectors. In these Member States, the official inspection of operators' HACCP systems was more effective than in the others.

In all of the Member States visited, inspectors identified non-compliances during their official inspections. These non-compliances were recorded in the reports of these inspections. However, in several cases in majority of the Member States visited the reports and other communications with the feed business operators did not specify a timeframe for the operators to remedy the situation and, in addition, the follow-up of these non-compliances was either not carried out comprehensively or not at all.

4.2 OFFICIAL CONTROLS ON TRACEABILITY

Checks on traceability were included in the routine inspections in all of the Member States audited. In the establishments visited, local inspectors had sufficient expertise to assess operators' documentation (e.g. product specifications, recipes, production sheets, labels, results of laboratory analysis, delivery documents, etc.) on traceability and to evaluate the effectiveness of the operators' traceability systems. In many of the Member States, there were centrally prepared comprehensive guidance documents and checklists supporting the implementation of the controls on traceability.

As regards controls on retained samples (i.e. samples of ingredients and final products manufactured taken and kept by the operators as required by EU legislation ([6])), the audits identified common problems relating to the collection and storage of these samples. These included operators not having written procedures describing how samples should be taken, stored and how much should be taken and an absence of proper sealing of the samples. In general, retained samples were taken from final products but not always from the ingredients (e.g. feed additives, premixtures, certain feed materials, carriers, etc.) used during the production of premixtures and/or compound feed.

4.3 OFFICIAL CONTROLS ON LABELLING

Checks on labelling were normally included in the routine inspections and included controls on labels of feed additives and premixtures. In all of the Member States audited, comprehensive guidance documents and checklists helped inspectors to carry out the label controls effectively. The central competent authorities during their training programmes paid particular attention to the requirements for feed labelling, including requirements for the labels of feed additives and premixtures.

Nonetheless, in the feed business operator establishments visited during the audits, numerous labelling shortcomings were seen by the audit teams. These concerned primarily the absence of the name of the functional group, the directions for use and/or the safety recommendations, the identification number, the batch number and/or the date of manufacture, the word "premixture", the active substance concentration/inclusion rate, information on the other substances contained in the preparation, and the absence of or incorrect dosage instructions.

It should be noted that many of the shortcomings above have no direct effect on the safe use of the feed additives or premixtures in question. However, some instances (e.g. absence of (i) active substance concentration/inclusion rate, (ii) name of other substances contained in the preparation, and (iii) dosage instruction) may have an effect on animal/public health and/or the environment, and the absence of safety instructions can constitute a risk for the users of these additives.

In some Member States, staff of the official laboratories were also required to assess the labels of those official feed samples which were sent to the laboratories for analysis. These additional controls led to an increase in the number of the feed labels that were checked and, overall, also increased the effectiveness of this type of control.

4.4 OFFICIAL SAMPLING

In the majority of the Member States audited, the number and type of official samples planned were actually taken in each of the two years preceding the audit series.

Nevertheless, in all of the Member States visited, the audit teams noted that the inspectors experienced difficulties with implementation of official sampling. Despite the fact that in most Member States the central competent authorities had provided training for inspectors on the practical implementation of the EU legal requirements for official sampling ([8]), inspectors were not able to fully follow these requirements. In general, samplers could not correctly identify the size of the sampled portion ([15]) which in turn resulted in errors in the identification of the minimum number of incremental samples ([16]) to be taken. In certain cases, inspectors could not correctly identify the distribution pattern of the undesirable substances (i.e. uniform vs non-uniform distribution) resulting in an erroneous calculation of the number of incremental samples required. In addition, in several cases inspectors used alternative methods of sampling but this was not fully described and documented in the sampling protocol as required by EU legislation ([17]). In many of the Member States visited, inspectors were not equipped with sampling spears and dividers (the latter are necessary for preparation of the final samples for those substances likely to be distributed non-uniformly).

In one Member State visited, the central competent authority had established a specially trained group of feed samplers thus significantly increasing the effectiveness of official sampling. In another Member State, the central competent authority had developed an application for mobile phones which supported inspectors on-the-spot with the relevant calculations on the number of incremental samples to be taken.

As for the interpretation of analytical results, there were generally two approaches followed. The official laboratory either communicated the laboratory results to the inspector(s) who had full responsibility to assess whether the laboratory result was in line with the legal requirements, or the official laboratory made the full assessment of the result obtained and provided the assessment to the inspector(s).

In all of the Member States visited, the audit teams noted that the analytical reports seen did not contain clear information, necessary when the result of the analysis was equal or exceeded 50% of the specification to be controlled, whether the result reported (i) was the mean of two determinations, (ii) was corrected for the moisture content of the final sample prior to preparation, and (iii) was corrected for analytical recovery. Knowledge of these parameters is essential, and is required by relevant legislation ([8]), to ensure that the analytical values reported have been determined beyond reasonable doubt. Thus, the information provided in the analytical reports seen in cases where the result was equal or exceeded 50% of the specification to be controlled (however low number of samples compared to the total number of all official samples), questions whether the assessment(s) were made in line with

([15]) Sampled portion: A lot or an identified part of the lot or sub-lot.
([16]) Incremental sample: A quantity taken from one point in the sampled portion.
([17]) Part 5 of Annex I to Regulation (EC) No 152/2009.

legal requirements. It is to note that official feed laboratories were not visited in course of the audits and the related findings were made based on the laboratory reports seen.

4.5 OVERALL CONCLUSIONS ON MEMBER STATES' IMPLEMENTATION OF OFFICIAL CONTROLS

The overall picture on the implementation of official controls was somewhat mixed. On the positive side, inspections took place in line with the planned frequencies and they were largely suitable for verifying operators' fulfilment of the relevant requirements concerning hygiene, facilities, equipment, maintenance and traceability.

However, the effectiveness of the various control systems was weakened by several factors: (i) insufficient official assessment of feed business operators' HACCP systems, (ii) inadequate follow-up of non-compliances, (iii) insufficient official controls on retained samples, (iv) insufficient official controls on labelling, and (v) inadequate official sampling and interpretation of analytical results.

5 IMPORTS AND EXPORTS OF FEED ADDITIVES AND PREMIXTURES

A substantial quantity of feed additives and ingredients for their production are sourced from third countries and it is thus paramount to ensure that the feed additives and ingredients for their production are fit to produce safe feedingstuffs.

From 2010 until the end of 2019, there were 177 notifications issued for feed additives and premixtures under the Rapid Alert System for Food and Feed for the presence of, *inter alia,* non-authorised genetically modified organisms, dioxins, heavy metals, veterinary medicinal products, microbiological contaminants and other non-specified hazards. Most of these were for imported feed additives and ingredients for their production.

5.1 OFFICIAL CONTROLS ON IMPORTS OF FEED ADDITIVES AND PREMIXTURES

Imported feed additives and premixtures are subject to feed operators' own-checks and to official controls carried out by competent authorities on feed importers and/or manufacturers using imported feedingstuffs. Member States' competent authorities have different approaches on how to assess whether an imported feed additive and the commercial documentation accompanying it (product specifications, certificates of analyses, etc.) provides sufficient guarantees that the imported product satisfies EU requirements. For example, when carrying out documentary checks, several Member States do not check/require that the method used for the analysis is the one mentioned in respective Regulation for the authorisation of the feed additive and/or that the laboratory that provides the certificate of analyses is accredited to ISO/IEC 17025. Some Member States only accept certificates of analysis if the laboratory and/or the method is accredited and the feed business operator can provide adequate evidence. Finally, while some Member States limit the controls on imported additives to checks of the accompanying commercial documents, others carry out physical checks and take samples for analysis.

5.2 OFFICIAL CONTROLS ON THE PRODUCTION/TRADE OF NON-EU AUTHORISED FEED ADDITIVES AND/OR MIXTURES OF THESE ADDITIVES FOR EXPORT OR RE-EXPORT FROM THE EU TO A THIRD COUNTRY

In six of the ten Member States visited, there are relatively low numbers of establishments producing non-EU authorised feed additives/premixtures destined for third countries. Even though EU legislation does not expressly require feed business operators to inform the competent authority of this activity, when the competent authorities know about it, such establishments are approved and are subject to regular official controls.

In one Member State, the central competent authorities stated that they were aware about such activities but at the time of the audit did not have a list of relevant operators. However, there was an ongoing effort to obtain necessary information.

The audit teams noted that the official controls on relevant establishments did not always verify whether the operator producing and exporting the non-EU authorised feed additives/premixtures established that the relevant requirements had been met.

In one Member State, the central competent authority had established a robust system specifically dedicated to controls on operators producing and exporting non-EU authorised products. The system included inspections carried out by joint teams from the central and the local competent authorities, significantly strengthening the effectiveness of the official controls.

6 OVERALL CONCLUSIONS ON MEMBER STATES` COMPETENT AUTHORITIES' PERFORMANCE OF OFFICIAL CONTROLS ON FEED ADDITIVES AND PREMIXTURES

Overall, the audit teams found robust and risk-based systems in place for the planning of official inspections and sampling in the feed additives/premixtures sector. Inspectors generally adhered to this planning and were able to adequately verify operators' fulfilment of the main requirements concerning hygiene, facilities, equipment, maintenance and traceability. Training programmes and guidance documents supported inspectors in carrying out their duties.

Nevertheless, despite the satisfactory planning, some weaknesses in the way official controls were being implemented were noted in key areas, namely insufficient official assessment of (i) feed business operators' hazard analysis and critical control points' systems and (ii) operators' tests on homogeneity and measures to minimise carry-over of certain feed additives; inadequate follow-up of non-compliances; insufficient official controls on retained samples; insufficient official controls on labelling; and inadequate official sampling and interpretation of the results thereof.

In relation to controls on imported feed additives and premixtures, Member States competent authorities' generally satisfied existing EU requirements although the practical approaches on carrying out these controls varied.

Further to these audits, the Commission made a number of recommendations to the respective Member States to improve their control systems, and is actively following up on the corrective actions provided in response to these recommendations. A series of audits in the area of general feed hygiene commenced in 2020 and a planned workshop with Member States' officials will provide further opportunities to share good practice and facilitate the implementation of more effective official controls.

7 WHAT IS COMMISSION DOING TO IMPROVE MEMBER STATES' OFFICIAL CONTROLS ON FEED ADDITIVES AND PREMIXTURES?

The Commission continues to carry out audits to evaluate Member States' implementation of official controls on feed in general. A new series of audits, focusing on the implementation of official controls, and in particular on the weak points highlighted in this report, commenced in 2020 and should be complete by 2022.

As with all audits carried out by the Commission's Health and Food Audits and Analysis Directorate, the actions provided by the competent authorities in response to audit recommendations have been followed-up. Follow-up involves an initial assessment on paper of the likelihood of the proposed actions to effectively address the recommendations made. Further to this, evidence of implementation of the actions is sought – for example, training records for staff, revised/new staff instructions, etc. Definitive proof that actions taken have been effective is always sought in subsequent sectoral and General Follow-up audits.

As regards the lessons learned from the audits covered in this overview report, a three-day workshop with Member States' representatives is planned in 2020 in the framework of the Commission's Better Training for Safer Food initiative. The objective of this workshop is to disseminate the findings and conclusions of the audit series, to discuss common challenges faced by competent authorities, identify common solutions and share good practices and ways to facilitate the implementation of more effective official controls.

Annex

Details of individual audits

Country	**Dates of audit**	**SANTE ref. no.**
Germany	13-22/03/2018	2018-6315
Hungary	20–28/03/2018	2018-6319
Austria	17–24/04/2018	2018-6313
Spain	16–26/10/2018	2018-6316
Greece	24/10–02/11/2018	2018-6318
France	26/03-05/04/2019	2019-6629
Ireland	25/03–03/04/2019	2019-6630
Poland	01–11/10/2019	2019-6632
Lithuania	22–30/10/2019	2019-6631
Portugal	26/11–06/12/2019	2019-6633

ANNEX 1 – LEGAL REFERENCES

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

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