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FINAL REPORT OF A FACT-FINDING MISSION CARRIED OUT IN GERMANY FROM 19 TO 28 SEPTEMBER 2017 IN ORDER TO GATHER INFORMATION CONCERNING RISK-BASED CONTROLS IN THE FEED SECTOR

In response to information provided by the competent authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a fact-finding mission carried out in Germany from 19 to 28 September 2017 as part of the European Commission's Directorate-General for Health and Food Safety 2017 work programme. The mission is part of a series of fact-finding missions aimed at gathering information on good practices and difficulties faced by the competent authorities in implementing a risk-based approach according to the requirements laid down by Article 3 of Regulation (EC) No 882/2004 when planning and carrying out official controls in the feed sector.

In Germany, the planning of official feed controls, at federal and Länder level, is in general comprehensive and risk-based. Its implementation is supported by a clear system for registration and approval of feed business operators, and a generally sound system of training for staff involved in feed inspection and sampling activities. The system of planning of official feed controls is based on a robust risk categorisation of all feed business operators. These elements facilitate the effective implementation of the plan though opportunities for improvement in the assessment of some of the visited feed business operators' hazard analysis and critical control points' plans and homogeneity and carry-over testing, which had not been identified in the records of previous official controls, indicate that this particular aspect of inspector training and awareness requires attention. For the primary feed producers, the frequency of inspections is normally determined by the frequency of cross-compliance controls where the focus is not specifically on feed-related risk factors.

The control programme including sampling plan is developed by the Federal Government and the Länder and is based on relevant risk factors; the Länder further elaborate the plan adjusting it to the respective Land's *circumstances. The inspectors in general possess good knowledge of the legislative sampling requirements.*

The number of inspections derived from the risk categorisation model/-s and number of samples set by the federal and Länder's *programme is generally met. There are arrangements in place to take timely and efficient action in case of non-compliant results.*

Notwithstanding the opportunities for improvement identified, overall it is concluded that the German system is, in several respects, a good example of how risk-based principles for official feed controls can be applied in practice.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AFU	Animal Feed Working Group of the *Länder* Working Group for Consumer Health Protection (*Arbeitsgruppe Futtermittel*)
AVV RÜb	General Administrative Regulation on compliance with food, wine, feed and tobacco legislation, known as the Framework Control Regulation (*Allgemeine Verwaltungsvorschrift über Grundsätze zur Durchführung der amtlichen Überwachung der Einhaltung der Vorschriften des Lebensmittelrechts, des Rechts der tierischen Nebenprodukte, des Weinrechts, des Futtermittelrechts und des Tabakrechts* (*AVV Rahmen-Überwachung*))
BfR	Federal Institute for Risk Assessment (*Bundesinstitut für Risikobewertung*)
BIP	Border Inspection Post
BMEL	Federal Ministry of Food and Agriculture (*Bundesministerium für Ernährung und Landwirtschaft*)
BTSF	Better Training for Safer Food
BVL	Federal Office of Consumer Protection and Food Safety (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit*)
DG SANTE	The European Commission's Directorate-General for Health and Food Safety
EU	European Union
FeBO	Feed Business Operator
FIS-VL	Technical Information System for Consumer Protection and Food (*Fachinformationssystem Verbraucherschutz und Lebensmittelsicherheit*)
FMV	Feed Regulation (*Futtermittelverordnung*)
FuttMKontrV	Regulation on the Technical Requirements for the Inspectors Involved in Feed Monitoring (*Futtermittelkontrolleur-Verordnung*)
HACCP	Hazard Analysis and Critical Control Points
LFGB	Food, Feed and Consumer Goods Code (*Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch*)
MANCP	Multi-annual National Control Plan
RASFF	Rapid Alert System for Food and Feed
RBA	Risk Mode

1 INTRODUCTION

The mission took place in Germany from 19 to 28 September 2017 as part of the European Commission's Directorate General for Health and Food Safety (DG SANTE) 2017 work programme. The mission team comprised two auditors and was accompanied by a representative from the Federal Office of Consumer Protection and Food Safety (BVL).

An opening meeting with the competent authorities was held on 19 September 2017, during which the objectives, itinerary and the reporting procedures for the mission were confirmed.

2 LEGAL BASIS

The mission was carried out under the general provisions of European Union (EU) legislation and, in particular, Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council. Full legal references are provided in the Annex. Legal acts quoted in this report refer, where applicable, to the last amended version.

3 OBJECTIVES AND SCOPE OF THE MISSION

The mission is part of a series of fact-finding missions aimed at gathering information on good practices and difficulties faced by the competent authorities in implementing a risk-based approach according to the requirements laid down by Article 3 of Regulation (EC) No 882/2004 when planning and carrying out official controls in the feed sector.

In terms of scope the mission included official controls on feed safety requirements throughout the feed chain (primary producers included) and imported feed of non-animal origin, excluding the part concerning requirements laid down by Commission Regulation (EC) No 669/2009. The itinerary of the mission included the following visits:

Visit/meetings		**No**	**Comments**
Competent authority	Federal	2	Opening and closing meetings
	Land	3	Meetings with competent authorities in the *Länder*
Compound feed producer		2	One approved for using coccidiostats
Food business operator marketing by-products of non-animal origin as feed material		1	Milling by-products
Food business operator marketing former foodstuffs of non-animal origin as feed material		1	Former foodstuffs from bakery production
Establishment collecting/recycling former foodstuffs of non-animal origin and marketing them as feed material		1	Former foodstuffs collected from bakery production and processed
Producer of feed additives		1	Broad range of feed additives
Primary feed producer		2	

4 BACKGROUND AND RATIONALE FOR THE MISSION SERIES

As highlighted in the Overview Report DG(SANTE) 2016-8965 issued following the last series of audits in the feed sector carried out between 2012 and 2014[1], in a general context of resource constraints, the risk prioritisation of official controls at that time was weak or at an early stage of development in many Member States. In some cases competent authorities faced difficulties in taking into account the reliability of operators' own checks, and in other cases risks such as those linked to the use of former foodstuffs/food by-products, mineral feed/feed additives were not adequately taken into account by the competent authorities. However, some Member States had succeeded in putting in place mechanisms to prioritise official controls and such mechanisms could be useful for other Member States.

In this context, the current fact-finding series of missions aims at updating the Directorate's knowledge on the risk-based approach implemented by competent authorities for the organisation of official feed controls. Data gathered will be analysed to identify, at EU level, the remaining difficulties faced by the authorities in applying risk-based principles and any examples of good practice or mechanisms which, if adopted by more Member States, may improve the risk basis for feed controls.

5 FINDINGS

5.1 ROLES, RESPONSIBILITIES AND TRAINING OF COMPETENT AUTHORITIES

Legal requirements

Articles 4, 5 and 6 of Regulation (EC) No 882/2004.

Findings

1. The organisation of official controls of feed business operators (FeBOs) is described in the Commission services' country profile for Germany[2].

2. In short, in the feed area, the Federal Ministry of Food and Agriculture (BMEL) is the central competent authority and is responsible for drafting legislation at the federal level and for coordinating implementation by the *Länder*. The BVL assists the BMEL in this. In particular, the BVL supports the BMEL in coordinating and drafting guidelines in order to ensure that legal provisions regarding feed and implementation of the control programmes are enforced in a harmonised manner.

3. Within the BMEL, Division 315 is responsible for feed safety and animal nutrition. In the BVL, Department 102 is responsible for animal feed.

4. Other relevant bodies in the feed area are the Federal Institute for Risk Assessment (BfR), which is responsible both for the assessment and communication of risks to

[1] Available at: http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=100

[2] Available at: http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=DE

public health in respect of feed, and the Friedrich Loeffler Institute, which is responsible for the assessment of risks/benefits related to animal feed.

5. At the *Länder* level, there is a clear designation of roles and responsibilities related to the organisation and implementation of the official feed controls.

6. The Regulation on the Technical Requirements for the Inspectors Involved in Feed Monitoring (*Futtermittelkontrolleur-Verordnung*, hereinafter: FuttMKontrV) establishes the requirements for feed inspectors, in particular with regard to qualifications, experience and training. According to the Regulation, all inspectors conducting official feed controls are obliged to complete studies in the field of agricultural economics, nutrition, food chemistry and veterinary medicine or, under certain circumstances, to have working experience of the feed industry.

7. The feed inspectors are, *inter alia*, required to have sufficient knowledge of the relevant parts of Regulation (EC) No 882/2004 and a comprehensive understanding of Regulation (EC) No 183/2005 of the European Parliament and of the Council.

8. FuttMKontrV requires that feed inspectors receive at least one week of relevant training within every two-year cycle.

9. The mission team was informed that the feed inspectors regularly participate as information disseminators in relevant Better Training for Safer Food (BTSF) courses (insofar as the quotas for Germany allow). In addition, there are yearly three-day conference of feed safety officers arranged in cooperation between the federal and *Länder* authorities. The mission team was presented with a list of the conferences arranged during 2013-2017. At every occasion, about 200 individuals took part. Moreover, relevant training courses for feed safety officers are carried out at Land level.

10. The training programmes and other relevant information are available through the non-public Technical Information System for Consumer Protection and Food (*Fachinformationssystem Verbraucherschutz und Lebensmittelsicherheit*, hereinafter: FIS-VL) which is accessible to the federal and the *Länder* authorities.

11. The mission team noted deficiencies in the knowledge of a few feed inspectors with regard to the assessment of FeBOs' hazard analysis and critical control points (HACCP) plans. Inspectors interviewed (at the FeBOs where mixing was a part of the feed production cycle) demonstrated deficient knowledge on assessment of homogeneity and carry-over testing and stated that they had not received relevant training on those specific technical topics (see findings 66 and 67).

5.2 LIST OF FEED BUSINESS OPERATORS AND THEIR ACTIVITIES

Legal requirements

Articles 9 to 19 of Regulation (EC) No 183/2005.

Findings

12. The system of registration and approval of establishments and intermediaries is described in part 2.4 of the country profile.

13. The *Länder* authorities are responsible for registration and, when necessary, approval of FeBOs. To facilitate the procedure, there are relevant forms and comprehensive information on the *Länder* websites. In addition, the Federal Government and the *Länder* have prepared fine-tuned and published guides and factsheets, for this purpose[3].

14. The BMEL stated that the basic principle is that every business operator which sells feed is obliged to be registered. In one *Land*, the mission team was informed that pure brokers are not obliged to be registered as FeBOs.

15. In Germany, in 2016, there were 302,769 primary production FeBOs, 204 producers of premixtures, 138 producers of feed additives, 1,942 producers of compound feed, 4,046 producers of feed materials, 238 feed importers and representatives of relevant FeBOs from non-EU countries, 15,294 feed traders, 5,394 feed warehouses and transporters, and one decontamination plant.

16. The mission team noted that FeBOs applying direct drying – as a main activity – are obliged to be approved; this is a requirement laid down by the Feed Regulation (*Futtermittelverordnung*, hereinafter: FMV). Approval applies solely to operators who, uses direct influence of combustion gases, dry green fodder, food or food scraps for the purpose of producing feed material. At one compound feed producer, the mission team noted that the direct drying used for drying of feed materials (cereals) was not considered as a main activity (see also finding 25). The drying of cereal does not fall under the aforementioned approval obligation, nor is it classified as a main activity of compound feed producers.

17. The information available in the authorities' FeBOs register is checked during inspections and, if necessary, the register is updated.

18. In accordance with the requirements laid down by Article 9(2) of Regulation (EC) No 183/2005, FeBOs are obliged to provide the relevant authority with up-to-date information on, *inter alia*, any significant change in activities and any closure of an existing establishment. The mission team was informed by the competent authorities in the *Länder* that primary production FeBOs do not always respect this reporting requirement.

19. In one *Land*, the mission team noted two cases where FeBOs were *de-facto* inactive as FeBOs but continued to be registered as active FeBOs. These FeBOs were thus inspected as active FeBOs even though they did not have active feed-related activities (manufacturing of feed additives). The authority clarified that the operators intentionally

[3] Available at: http://www.bmel.de/DE/Tier/Tierernaehrung/tierernaehrung_node.html

keep the FeBO registration since feed production may arise in the future depending on the market demand (see also finding 79).

20. Once per year, the BVL publishes the updated list of registered and approved FeBOs in the electronic Federal Gazette. The latest publication was on 22 March 2017[4].

5.3 GENERAL CRITERIA FOR THE PLANNING OF OFFICIAL FEED CONTROLS

Legal requirements

Articles 3, 8, 10, 15, 16, 54 and 55 of Regulation (EC) No 882/2004.
Article 1 of, and Annex I to, Commission Regulation (EC) No 152/2009.
Article 3 of, and Annex I to, Directive 2002/32/EC of the European Parliament and of the Council.

Findings

5.3.1 Planning of inspections and audits

21. Federal legislation – General Administrative Regulation on compliance with food, wine, feed and tobacco legislation, known as the Framework Control Regulation (*Allgemeine Verwaltungsvorschrift über Grundsätze zur Durchführung der amtlichen Überwachung der Einhaltung der Vorschriften des Lebensmittelrechts, des Rechts der tierischen Nebenprodukte, des Weinrechts, des Futtermittelrechts und des Tabakrechts* (*AVV Rahmen-Überwachung*, hereinafter: AVV RÜb)[5] – establishes requirements for a system for the determination of risk-oriented frequency of official feed inspections at FeBOs. This requires risk categorisation of all FeBOs and the AVV RÜb provides an exemplary model for such risk categorisation. The *Länder* are obliged to carry out the risk categorisation for all FeBOs registered (other than those at the level of primary production of feed) and may create their own models for this.

22. The AVV RÜb proposes an equation (comprising two main components) to calculate the overall risk score R_B for every individual FeBO. Based on this, a minimum inspection frequency is determined.

23. The first component of the overall risk score R_B is the risk mode (RBA) based on the risk potential of the activities carried out in the field of production, storage, transport, placing on the market and use of feed. The allocation of the RBA is agreed between the federal government and the *Länder*. The allocation of RBAs is established by Annex I of the AVV RÜb.

24. There are five RBAs where RBA1 corresponds to very low risk and RBA5, to the highest risk. For every RBA, there are a number of starting points S_{RBA} used to

[4] Available at: https://www.bundesanzeiger.de/ebanzwww/wexsservlet?page.navid=to_bookmark_officialsite&genericsearch_param.edition=BAnz+AT+22.03.2017&global_data.language
[5] Available at: http://www.verwaltungsvorschriften-im-internet.de/bsvwvbund_03062008_3158100140002.htm

determine inspection frequency *before* the individual risk score R_I can be established. Under certain circumstances, for example, production of only simple compound feed, the RBA may be corrected (in general, one class up or down).

25. In accordance with model laid down by the AVV RÜb, where several feed-related activities being carried out by a FeBO, the AVV RÜb proposes that the riskiest one is taken for establishing the RBA. In two *Länder* visited, the mission team noted this approach had been adopted. In another *Land*, the authority stated that it rather took the main activity into consideration (see also finding 16).

26. After the first inspection of the FeBO, the second component of the overall risk score R_B – the individual risk score R_I – is determined based on the following criteria:

    I. Production/trade volume and production spectrum
        i. Production scope and spectrum
        ii. Volume of trade
        iii. Sales territory
        iv. Critical product changes per production line/risk of carry-over
        v. Formulation types
        vi. Origin of the raw materials/additives
        vii. Perishability of the product
    II. Production and operational structure
        i. Production
        ii. Construction and technical condition
        iii. Contamination risk ("non-feed" only)
    III. Quality control system
        i. Documentation and traceability
        ii. Application of HACCP
        iii. Operational controls (own-checks)
        iv. Responsiveness of the system in case of deviations/non-compliances identified by own-checks
        v. Organisational structure of the FeBO
    IV. Assessment of results of official feed controls
        i. Previous complaints/non-compliances (mainly regarding undesirable substances and labelling)
        ii. Previous deficiencies other than in part IV.i (for example, structural deficiencies of the establishment).

27. For each criteria and gradation, the AVV RÜb provides detailed and clear guidance.

28. For all the criteria outlined, there are weighting factors (1, 2 or 3) allowing for further differentiation between FeBOs and thus strengthening the risk-based approach in the planning of the inspections.

29. When both components – the RBA and the R_I – are available, the equation provided by the AVV RÜb is applied (i) to determine the overall risk score R_B of the FeBO, (ii)

assign the corresponding risk category to the FeBO and (iii) thus establish the inspection frequency (excluding sampling) of the FeBO.

30. There are seven risk categories with the following minimum inspection frequencies:

    I. Suggested as " ≥ three years" (the mission team noted that the general practice for this category (excluding primary producers of feed), is once per five years)
    II. Once every three years
    III. Once every two years
    IV. Once a year
    V. Once every nine months
    VI. Once every six months
    VII. Once every three months

31. In case the minimum inspection frequency is not followed, the AVV RÜb requires a written justification for this.

32. The mission team noted different approaches in the risk categorisation of the FeBOs in the three *Länder* visited:

    1) In one *Land*, the AVV RÜb model was only slightly modified, mainly to omit some gradations in certain criteria. This does not seem to have any impact on the inspection frequency compared to the AVV RÜb model.

    2) In another *Land*, a new model – based on the major principles of the AVV RÜb model – is under development and foreseen to be implemented from 2018. Some additional criteria have been added and more risk categories are considered, which will allow for better differentiation of the FeBOs and thus will further strengthen the risk-based approach in the planning of the inspections. This new system will be presented at the coming AFU meeting in October 2017. The mission team noted that during the transition period (2017), the planning of the inspections was based only on the activities of the FeBOs, with no individual risk scoring being taken into account.

    3) In the third *Land*, the AVV RÜb model is applied without any changes/modifications.

33. There is no specific planning for feed importers not subject to the special import conditions established by Commission Regulation (EC) No 669/2009 and other relevant safeguard acts, except for third country representatives. However, the origin of feed materials and additives is supposed to be taken into consideration in point I.vi of the AVV RÜb risk categorisation model – although with limited impact on the inspection frequency. The vast majority of imported feed is therefore controlled during routine inspections of FeBOs at whatever frequency has been defined in their risk categorisation.

34. Private certification schemes can be taken into consideration in point III.iii of the AVV RÜb risk categorisation model; this appears though to have a very limited impact on the inspection frequency.

35. The AVV RÜb proposes that the risk-categorisation model can be used for primary production FeBOs. The mission team did not see any evidence of this approach being adopted in the three *Länder* visited:

    1) In two *Länder*, the inspection frequency for primary production FeBOs is solely based on the frequency of cross-compliance inspections in accordance with the requirements laid down by Regulation (EC) No 1306/2013 of the European Parliament and of the Council. These do not include some specific feed-related criteria (for example, origin of feed materials, use of feed additives, type of feed production, etc.). The mission team was informed that the inspection frequency is 1-2% of the registered primary production FeBOs per year and that the inspections are normally not focused exclusively on feed but rather include all aspects of cross-compliance.

    2) In one *Land*, there is an ongoing attempt to create a separate risk categorisation system for primary production FeBOs. Based on their activities, all primary production FeBOs will be divided into four risk categories (no scoring system is planned):

        a) For categories 1 and 2 (mixing of basic feed materials without additives for the own holding only): the cross-compliance frequency is proposed to be used, i.e. 1% of all registered primary production FeBOs in these categories;
        b) For category 3 (using feed additives and/or applying direct drying of feed materials for the own holding only): 5-10% of all registered primary production FeBOs in this category are proposed to be inspected;
        c) For category 4 (in addition to the activities described in categories 1-3 above, trade, storage and transport, including for third parties, can occur): 10% of all registered primary production FeBOs in this category are proposed to be inspected.

36. The mission team observed two different types of software being used by the *Länder* to carry out the calculations for the purpose of the risk categorisation.

5.3.2 Planning of the official sampling programme

37. The BMEL, in cooperation with the BVL, the BfR and the *Länder*, prepares a five-year programme on the planning of the official feed checks; this programme also covers feed sampling. The current version is in the "Control Programme for Feed 2017 to 2021"[6]. The programme is a part of the Multi-Annual National Control Plan (MANCP).

[6]Available at: http://www.bmel.de/DE/Tier/Tierernaehrung/tierernaehrung_node.html;jsessionid=9D0D0780BADC87E98FFD1C0BD22F67B1.1_cid358

38. The Control Programme includes undesirable substances as referred to in Directive 2002/32/EC, pesticide residues as referred to in Regulation (EC) No 396/2005 of the European Parliament and of the Council, unauthorised substances (for example, veterinary medicinal products), prohibited materials as referred to in Annex III of Regulation (EC) No 767/2009 of the European Parliament and of the Council, genetically modified organisms, and microbiological contamination, primarily *Salmonella* spp. In the Control Programme, a comprehensive and clear guidance on the parameters outlined is provided for the use by the *Länder*'s competent authorities. The official sampling covers the whole feed chain.

39. There are two main types of official samples in the Control Programme:

    1) Product control samples (primarily parameters and analytes of relevance for feed safety)

    2) Labelling control samples (for example, composition of compound feed, verification of declared levels of feed additives, etc.)

40. The Control Programme establishes the target number of samples, the types of analytes, the types of feed and the categories of FeBOs to be sampled; these are determined on the basis of the following risk criteria: legislative EU (and federal, when applicable) requirements, previous years' sampling results, Rapid Alert System for Food and Feed (RASFF) notifications, suggestions from the AFU, scientific studies/statistical data, etc.

41. The Control Programme proposes a target number of official samples for every *Land* based on its respective share of:

    1) arable land,
    2) permanent grassland,
    3) number of primary producers of feed,
    4) volume of compound feed production,
    5) number of compound feed producers,
    6) amount of feed materials of plant origin at entry points with an yearly amount > 100 000 tonnes of plant-based feed materials at least.
    7) key compound feed (taking into account number of approved compound feed producers and production volumes of large compound feed producers),
    8) number of manufacturers of pre-mixtures,
    9) number of manufacturers of additives.

42. Based on the Control Programme, each *Land* develops its own sampling plan. The mission team noted that in general the *Länder* observe the distribution of samples suggested by the Control Programme. The *Länder* are also free to amend the number of samples planned (either decrease or increase, the latter case being the most common) if deemed necessary.

43. The decision on which a specific FeBO is chosen for official sampling and the feed type to be sampled and the contaminant to be tested for is normally left to the discretion of

the *Länder*'s feed inspectors who can, when necessary, seek advice/support from the relevant authority within the *Land*'s organisation. The main criteria applied by the *Länder* are the production volumes and availability of certain types of FeBOs in their respective *Land*. The federal Control Programme contains clear guidance on most relevant feed types and contaminants.

44. In one *Land* visited, the mission team observed that in addition to individual risk assessment on the premises of compound feed producers, the production volumes are taken into consideration by developing specific weighting factors. In practice, it means that no official samples are planned for the producers with annual volumes up to 500 t (although samples can still be taken by the inspectors, if deemed necessary). For the producers with annual volumes exceeding 50,000 t, there are weighting factors between 2.0-2.8, thus increasing the number of official samples planned. In this *Land*, 75% of all official feed samples are taken from producing FeBOs, 20% from traders, transporters and other non-producers, and 5% from primary producers of feed.

45. In one *Land* visited, the authority informed the mission team that the official feed samples can be taken only from the FeBOs chosen for the inspections thus limiting the number of establishments available for official sampling.

46. As for imported feedingstuffs which are not subject to special import conditions, the federal Control Programme states that "*the results of control work from recent years have shown that feed (material) imported in particular from non-EU countries may constitute a higher risk*". In this respect, the Control Programme recommends that the *Länder* take additional samples from imported feed materials of plant origin when annual import volumes are more than 100,000 t per point of entry. However the Control Programme does not show the target number of samples specifically for imported feed materials per entry point.

47. Residues of packaging materials in former foodstuffs which are processed and placed on the market as feed materials are sorted under the group of prohibited substances. The German authorities emphasised that there is no tolerance for the presence of packaging material in feed in German legislation. As it was noted in the DG SANTE report 2009-8322[7], in 2005 the BfR issued a "Statement on the expert opinion on foreign materials in recycled animal feed (made from by-products of the manufacture of bread/baked products and confectionary)" stating that "*... it is possible to restrict the level of unavoidable admixtures according to the state-of-the-art to levels ranging from 0.15 to 0.20 percent*". This is applied as an enforcement threshold in Germany. The official laboratories possess a relevant analytical method.

5.3.3 Procedures and guidance for official controls

48. To facilitate and standardise the *Länder*'s control activities, the Federal Government and the *Länder* drew up and fine-tuned template checklists which may be used during

[7] Available at: http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=2461

official feed controls. The templates are based on relevant requirements laid down by Regulation (EC) No 183/2005 and are available at the FIS-VL information system.

49. The checklists consist of questions related to the applicable legal requirements which require "yes" or "no" answers (compliance or not, provided that the requirement is applicable). The questions are grouped into modules to address certain aspects of the official controls, for example HACCP module, infrastructure module, etc.

50. At all three *Länder* visited, the mission team saw checklists created by the *Länder*, which were mainly based on the templates referred to finding 48. The *Länder*'s checklists contain varying degrees of itemisation.

51. The mission team noted that in Germany, once per year, all feed-related legislation is consolidated and issued as a hardcopy volume available to all *Länder*/feed inspectors thus providing the relevant authorities and the inspectors with updated and detailed information on the current EU feed legislation.

5.3.4 Procedures and guidance for the follow-up of non-compliances

52. Two federal legislative acts set out provisions on dealing with non-compliances; those are the Food, Feed and Consumer Goods Code (*Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch*, hereinafter: LFGB) and the FMV.

53. The LFGB and the FMV contain general requirements for the actions to be taken in the event of non-compliances being detected either during inspections and/or as a result of official sampling. The key requirement is that handling of all non-compliances is based on the risk posed.

54. If a non-compliance is detected during an inspection, the inspector notes this in the control report and, where appropriate, in the relevant checklist and informs the FeBO about the finding.. The non-compliance note for the FeBO comprises the following information – the type and nature of the non-compliance, the corrective measures to be put in place and time-frame for this.

55. For non-compliances related to feed, the LFGB and the FMV provide for financial sanctions and suspension of the FeBO's registration/approval. In the event of severe and/or repeated non-compliances, there is a provision for revocation of the FeBO's registration/approval according to Article 15 of Regulation (EC) No 183/2005.

56. In case of any suspected severe risk to human and animal health or to the environment, a RASFF notification must be immediately triggered, following the federal guideline on RASFF.

57. The general enforcement measures are established by the LFGB and the FMV. Those acts require that the final choice of the most appropriate measure depend on the type of non-compliance and its gravity and shall be based on an appropriate risk assessment.

58. In two *Länder*, the mission team studied two cases of non-compliances, one for a labelling issue and another regarded a feed safety parameter:

    1) In the feed safety parameter case, the handling was satisfactory, the documentation provided allowed for detailed tracking of the actions taken and decisions made, including verification of the destruction of the consignment.

    2) In the labelling case, the mission team noted that the time gap between obtaining the final laboratory protocol and notifying the FeBO was two months. The mission team was not provided with information on the reasons for the delay.

5.3.5 Review of the risk-based planning of official feed controls

Legal requirements

Articles 4 and 8(3) of Regulation (EC) No 882/2004.

Findings

59. As regards the risk categorisation of FeBOs and establishing the official feed controls frequency, the AVV RÜb contains a provision for the system to be periodically reviewed. The common forum for relevant discussions with the federal authorities and the *Länder* is the AFU group; the normal meeting frequency is at least twice per year. As an example, the mission team noted that the risk categorisation model developed by one *Land* (see finding 32(2)) is to be discussed at the coming AFU group meeting. In between the ordinary AFU group meetings, there is a regular information exchange between the federal authorities and the *Länder*.

60. As for the Control Programme for Feed 2017-2021, the Federal Government and the *Länder* have agreed that the Programme is examined and revised, if deemed necessary, at least once per year in light of developments in the feed sector. In particular, annual statistics on official feed monitoring in Germany and results from special programmes carried out on selected issues are taken into consideration. In general, the factors that can trigger amendments are legislative changes, emerging needs and trends observed, changes in analytical methodology, etc.

5.4 IMPLEMENTATION OF OFFICIAL FEED CONTROLS ACCORDING TO RISK CRITERIA

Legal requirements

Articles 3, 8, 9, 10, 11, 15 and 16 of Regulation (EC) No 882/2004.
Articles 5, 6, and 7 of, and Annexes I, II and III to, Regulation (EC) No 183/2005.
Article 1 of, and Annex I to, Commission Regulation (EC) No 152/2009.
Article 3 of, and Annex I to, Directive 2002/32/EC.

Findings

5.4.1 Performance of inspections

61. As described in the section 5.3.1, the number of inspections is solely determined by the Länder based on the respective risk categorisation model applied under the AVV RÜb. The AVV RÜb was issued by the Federal Government with the agreement of the Länder. The model described in Annex 1b, No 2 of the AVV RÜb on risk-based assessment and determination of inspection frequency for establishments may be applied. The federal authorities have no power to establish, or recommend, the number of inspections to be carried out. The authorities in the Länder are responsible for the Länder's planning and implementation of the inspection programme. Official feed controls are carried out by the Länder's feed inspectors.

62. In Germany's 16 *Länder*, in 2014 there were 19,071 feed inspections carried out (10,331 in the primary sector), in 2015 – 20,351 (11,339 at primary feed producers), and in 2016 – 19,060 (10,321 at primary feed producers). For the FeBOs other than primary producers of feed, this corresponds to approximately 32% of registered/approved FeBOs. For the primary production FeBOs, this corresponds to approximately 3% of registered/approved primary FeBOs.

63. The mission team noted that the inspection frequency derived from the respective risk categorisation models was normally adhered to. In one *Land*, the authority informed the mission team that in some cases (primarily for the FeBOs with high risk scores) one planned inspection can be split into several sub-inspections (up to eight) each focusing on certain modules of the checklist; this is to avoid excessive complexity and duration of the inspections if everything is taken in one go. Thus, in such cases the total number of visits is much higher than that derived from the risk categorisation model. On the other hand, in other *Länder* visited, the mission team was informed that the inspections may focus only on certain modules due to time constraints; this might raise the question as to whether such inspections can be considered comprehensive[8].

64. The ratio of inspections where deficiencies were identified is as follows (for all 16 *Länder*):

    1) 2014: 15.4% (highest rate, 26%, for producers of compound feed, additives and premixtures)
    2) 2015: 12.6% (highest rate, 24.5%, for the same group of FeBOs as above)
    3) 2016: 15.7% (highest rate, 28.6%, for the same group of FeBOs as above)

65. The mission team observed that the inspectors normally used the checklists developed by the *Länder* though in one *Land* visited there were some instances where the checklist was not included in the inspection documentation.

[8] In response to the draft report the central competent authority stated that while focussing on certain priorities, the inspections are extended, where necessary, to other areas in which establishments are involved, in particular where there is evidence of infringements."

66. The mission team visited eight FeBOs and studied inspection documentation for one mobile mixer without visiting it. The mission team noted some shortcomings in three of the FeBOs' HACCP plans; these were not spotted during routine inspections as there was no record in the respective inspection documentation. The shortcomings concerned the following types of FeBO: one food operator supplying former foodstuffs as feed materials, one compound feed producer, and the mobile mixer. In the case of the food operator, there was no feed-related HACCP plan in place.

67. The feed inspectors in the *Länder* visited demonstrated reasonably good knowledge of the general requirements laid down by Regulation (EC) No 183/2005. In some cases, the mission team noted that the inspectors found some of the technical areas to be challenging: (i) the assessment of FeBOs' homogeneity and carry-over tests, and (ii) taking and storing samples of products manufactured and placed on the market (in particular at the food operator supplying former foodstuffs as feed materials).

68. The mission team noted that due to the nature of mobile mixers, it can be challenging to inspect them without prior warning, therefore in some instances announced inspections had to be carried out.

5.4.2 Implementation of the sampling programme

69. The implementation of the sampling programme is the sole responsibility of the *Länder*. The number of samples, analytes and types of feed to sample are based on the Control Programme for Feed 2017-2021. The exact place of sampling and type of feed to sample is at the discretion of the *Länder*'s feed inspectors. In general, the planning suggested by the Control Programme in terms of number of samples and analytes was adhered to.

70. In Germany's 16 *Länder*, the following number of official feed samples were taken from FeBOs other than primary producers of feed:

    1) 2014: 17,304 (9.7% of the samples were non-compliant; the highest ratio – 20% – was for the group of mineral feed)
    2) 2015: 16,722 (9.6% of the samples were non-compliant; the highest ratio – 19.2% – was for the group of "feed for other farm animal than poultry, pigs and ruminants")
    3) 2016: 16,223 (9.7% of the samples were non-compliant; the highest ratio – 20.3% – was for the group of pet food)

71. For the primary production FeBOs, the sampling statistics were as follows:

    1) 2014: 29,524 (1.1% of the samples were non-compliant; the highest ratio – 11.5% – was for microbial deterioration)
    2) 2015: 28,947 (0.6% of the samples were non-compliant; the highest ratio – 11.9% – was for microbial deterioration)
    3) 2016: 37,860 (0.8% of the samples were non-compliant; the highest ratio – 8.2% – was for microbial deterioration)

72. Every official feed sample taken is normally tested for several parameters, normally for 5-10, for example dry matter + nutritional composition + certain undesirable substances. This leads to a higher number of analytical determinations than the number of samples taken.

73. The feed inspectors in the three *Länder* visited demonstrated good knowledge of the relevant requirements laid down in Annex I to Commission Regulation (EC) No 152/2009. In one *Land* the inspector failed to comply with the number of incremental samples to be taken under this Regulation with respect to the heterogeneous distribution of mycotoxins in one feed material, resulting in a calculation of a fewer number of incremental samples than required to form a representative sample.

74. The sampling protocols observed by the mission team in the three *Länder* visited were in general satisfactory. In some instances, the mission team noted that the batch number and size of the sampled portion was not recorded.

75. In one *Land*, the mission team noted that the homogenisation of the aggregate samples for the control of constituents likely to be non-uniformly distributed in feed materials was attempted by manual mixing. This could not ensure the preparation of completely homogenised material, which is a requirement of Commission Regulation (EC) No 152/2009. Directly after this finding was communicated to the respective authority, the mission team was informed that the procedure was revised meaning that the whole aggregate samples for the control of constituents likely to be non-uniformly distributed in feed materials would be sent to the official laboratory for the homogenisation with suitable equipment.

76. The official laboratories used for analysing the official feed samples are mainly at *Länder* level, all of which are accredited according to EN ISO 17025 with their respective scopes of accreditation including those analyses/matrices included in the Control Programme for Feed 2017-2021. When necessary, the official feed samples may be sent to other laboratories accredited according to EN ISO 17025.

77. The mission team observed that, in the three *Länder* visited, the agreed turnaround times from sampling to analysis for routine samples are 2-4 weeks. For the samples taken as a result of an emergency or based on a suspicion, the turnaround times are considerably shorter.

5.5 DISCUSSIONS WITH THE COMPETENT AUTHORITIES

78. The competent authorities acknowledged that regular communication between the federal authorities and the *Länder* is a prerequisite for adequate preparation of the control plans in the feed sector and for proper implementation of official feed controls.

79. The competent authorities experience difficulties in getting updated information on feed-related activities from some FeBOs, in particular from the primary producers of feed,

which in turn affects the planning and implementation of the official feed controls (see also finding 19).

6 OVERALL CONCLUSIONS

In Germany, the planning of official feed controls, at federal and *Länder* level, is in general comprehensive and risk-based. Its implementation is supported by a clear system for registration and approval of feed business operators, and a generally sound system of training for staff involved in feed inspection and sampling activities. The system of planning of official feed controls is based on a robust risk categorisation of all feed business operators. These elements facilitate the effective implementation of the plan though opportunities for improvement in the assessment of some of the visited feed business operators' hazard analysis and critical control points' plans and homogeneity and carry-over testing, which had not been identified in the records of previous official controls, indicate that this particular aspect of inspector training and awareness requires attention. For the primary feed producers, the frequency of inspections is normally determined by the frequency of cross-compliance controls where the focus is not specifically on feed-related risk factors.

The control programme including sampling plan is developed by the Federal Government and the *Länder*, and is based on relevant risk factors; the *Länder* further elaborate the plan adjusting it to the respective *Land*'s circumstances. The inspectors in general possess good knowledge of the legislative sampling requirements.

The number of inspections derived from the risk categorisation model/-s and number of samples set by the federal and *Länder*'s programme is generally met. There are arrangements in place to take timely and efficient action in case of non-compliant results.

Notwithstanding the opportunities for improvement identified, overall it is concluded that the German system is, in several respects, a good example of how risk-based principles for official feed controls can be applied in practice.

7 CLOSING MEETING

A closing meeting was held on 28 September 2017 with the representatives of the BMEL, the BVL and the authorities of the *Länder* visited. The main findings of the mission were presented by the mission team. The authorities present did not indicate any major disagreement with these.

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 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. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Reg. 669/2009	OJ L 194, 25.7.2009, p. 11-21	Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC
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. 1306/2013	OJ L 347, 20.12.2013, p. 549–607	Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008

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
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