CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7.1 **CX/RVDF 16/23/7**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-third Session

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DISCUSSION PAPER ON UNINTENDED PRESENCE OF RESIDUES OF VETERINARY DRUGS IN FOOD COMMODITIES RESULTING FROM THE CARRY-OVER OF DRUG RESIDUES INTO FEED

(***Report of the Electronic Working Group on Carryover in Feed***)

(Australia, Brazil, Cameroon, Canada, Chile, Costa Rica, El Salvador, Equatorial Guinea, France, Germany, Ghana, Italy, Japan, Netherlands, New Zealand, Norway, Papua New Guinea, Peru, Philippines, Republic of Korea, Serbia, Spain, Sweden, Thailand, United States, FAO, IAEA, IFIF, HealthforAnimals, and NHF)

Background

1. The 22nd Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF22) established an Electronic Working Group (EWG), co-chaired by the United States of America and Canada, to prepare a discussion paper for consideration by CCRVDF23 addressing the unintended presence of residues of veterinary drugs in food commodities resulting from carryover of veterinary drugs into feed.

2. The EWG was tasked to elaborate a discussion paper articulating a policy to address situations under which a standard may need to be developed (and considerations for developing such standards) when there is carryover of drug residues into feed, as a result of unintended exposure, resulting in residues in foods of animal origin.

3. The EWG was asked to specifically consider the following points, recognizing other points may also need to be considered:

- Scope of what should be covered under this project? What is meant by unintended exposure/carryover in the CCRVDF? What drug-commodity combination?
- Source of unintentional exposure at feed mill or farm level;
- Consider using existing policies/guidelines/codes of practice to establish these standards to the extent possible (example: *Code of Practice on Good Animal Feeding* (CAC/RCP 54 2004));
- Procedural changes that may be required to set these standards as these situations may not meet the current criteria for recommending MRLs;
- Nature of relevant data required for consideration for setting standards in these unique situations (example: monitoring data, GMP data);
- Source of data required, methodology considerations for detection of residues in feed as well as food;
- Consideration of relevant risk management measures from feed to food continuum.

Proceedings of the electronic Working Group

4. The co-chairs piloted an online forum for discussion and communication in the EWG. The discussion paper was developed from responses to two separate sets of questions. In the first step, the EWG members were asked to provide information on the following questions:

A. CCRVDF identified the *Code of Practice on Good Animal Feeding* (CAC/RCP 54 2004) as a Codex guidance relevant to our task. Are there other Codex policies or guidelines that we should consider?

B. Are there national or regional guidelines or policies relevant to this work that may inform the development of a discussion document? If so, please provide them as electronic documents or hyperlinks to the documents online.

C. Under what circumstances should CCRVDF elaborate risk management measures for the unintentional carryover of veterinary drugs in feed resulting in residue in human food? Are there circumstances when CCRVDF should not? In responding to this question, please include in your response thoughts on:

i. What are possible sources of unintentional exposure at feed mill or farm level?

ii. Should a standard be developed when the unintentional carryover is the result of unapproved veterinary drug use? Should a standard be developed when the unintentional carryover is the result of an approved veterinary drug?

iii. Are there circumstances where CCRVDF should not be elaborating a standard for carryover of veterinary drugs in feed?

5. Comments were received from Brazil, Canada, Chile, Germany, Japan, New Zealand, Nigeria, Peru, Philippines, Spain, Thailand, United States, HealthforAnimals, and International Feed Industry Federation.

6. In the second step, the Working Group members were asked to provide information on the following questions:

A. In consideration of relevant risk management measures from feed to food continuum, what type of standard should be elaborated for addressing veterinary drug residues resulting from unintentional carryover in feed?

a. Quantified standards

i. Possible standards

1. Maximum residue limits (MRLs): used for residues from approved uses of veterinary drugs in animal tissues

2. Maximum levels (MLs): generally used for contaminants in food or feed

a. In feed

b. In animal tissues

3. A new term: action levels, working residue levels, carryover residue levels, etc.

ii. Some considerations on setting the concentration in food

1. As low as reasonably achievable (ALARA principle)

2. Statistically based concentration based on residue data (e.g., 95th percentile tolerance upper bound, median value, etc.)

b. Non-quantified standards

i. Risk Management Recommendations (RMRs)

ii. Other non-quantified standards that mitigate exposure of food producing animals to feed with unintentional carryover of a particular veterinary drug residue

c. Code of practice for the unintentional carryover of veterinary drug residues in feed

i. Development of a new code of practice specifically to address the unintentional carryover of residues of veterinary drugs into feed intended for food producing animals

ii. Modification of the existing Codex code of practice (CAC/RCP 54 2004) to specifically address the unintentional carryover of residues of veterinary drugs into feed intended for food producing animals

B. What is the nature of the relevant data that would be required for consideration for setting standards in these unique situations (e.g. monitoring data, GMP data)?

a. Compliance program monitoring data from national authorities providing information on carryover concentrations

b. Studies (GLP?) showing concentration in feed as a result of test studies in carryover under routine good manufacturing conditions

c. Residue studies in animals showing tissue residue concentration as a consequence of carryover in feed

C. What is the source of the required data, methodology for detection of residues in feed as well as food?

a. Pharmaceutical drug sponsor

b. National authorities

c. Other sources

D. Are there any procedural changes that may be required to set these standards as these situations may not meet the current criteria for recommending MRLs (i.e., good practice of veterinary drugs)?

7. Comments were received on the second round of consultation from Brazil, Canada, Chile, Germany, Japan, Norway, Spain, Sweden, Thailand, United States of America, HealthforAnimals and International Feed Industry Federation.

Scope of the Project

8. CCRVDF22 discussed the issue of carryover in terms of a registered veterinary drug added intentionally to one feed batch that unintentionally carries-over to a subsequent feed batch where the drug should not be used and it ends up as drug residues in food.

9. One member noted that countries may define products differently which relate to the same issue of carryover. One country may regulate a product as a veterinary drug while another country regulates the same product as a feed additive.

10. One member questioned whether carryover was also considered for animal drugs added to water.

11. Another member considered whether carryover would also include feed ingredients of animal origin which contain veterinary drug residues.

12. Another member suggested that the scope should be made specific to situations that will have an impact on international trade.

13. A couple of members suggested that the scope could include that at low concentrations some of the antimicrobial drugs could have an impact on antimicrobial resistance selection.

14. **Comments from the Co-chairs**: Given the directions from the committee, the scope of this particular project is very specific and entails elaborating risk management recommendations in situations when low level residue of a registered veterinary drug is detected regularly in certain foods of animal origin (which is known to be an international trade irritant or domestic compliance issue), and trace-back inspections confirm the source to be unintended carryover residues in feed (even after following a recommended good medicated-feed manufacturing/cleaning procedure).

Considerations for Elaborating Risk Management Measures of Unintentional Carryover

15. The EWG discussed the circumstances under which CCRVDF should elaborate risk management measures for the unintentional carryover of veterinary drugs into feed resulting in residues in foods of animal origin.

Existing Guidelines

16. CCRVDF22 identified the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004) as an existing guideline that may be considered in the issue of unintentional carryover. The co-chairs of the EWG requested information on other existing international and country/regional guidelines. The members of the EWG provided references to many relevant policy documents and guidelines. These resources are listed in the appendix.

17. Several members noted that the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004) includes discussion on the importance of manufacturing controls for medicated feed. The Code highlights the need to have procedures in place to avoid cross-contamination between batches of feed and feed ingredients, such as flushing, sequencing, and physical clean-out. The Code further notes, "In cases where the food safety risk associated with cross-contamination is high and the use of proper flushing and cleaning methods is deemed insufficient, consideration should be given to the use of completely separate production lines, transfer, storage and delivery equipment." The Code also notes "Chemical fertilizers, pesticides and other materials not intended for use in feed and feed ingredients should be stored separately from feed and feed ingredients to avoid the potential for manufacturing errors and contamination of feed and feed ingredients."

18. Some members suggested developing a new Code of Practice that specifically addresses the carryover residues issue while a majority was of the opinion that the current *Code of Practice on Good Animal Feeding* provides an overarching principle that could cover the carryover residue management. Some revisions to this Code, either in the text or more specifically as an annex, could be considered.

Sources of Carryover in Feed

19. Members noted that there are many possible sources of unintentional carryover at the feed mill or farm level. Cross-utilization of equipment for feed manufacture, storage, and transportation can lead to carryover of veterinary drug between feed batches. Improper storage of raw materials or finished medicated feed may lead to carryover. Human error in adding veterinary drug to feed may be a source of unintentional contamination. Another source of possible unintentional contamination may be from using animal protein in feed that contain residues of veterinary drugs. Many other possible sources were identified, but most members stated that following good feed manufacturing practices and developing Hazard Analysis Critical Control Point (HAACP) plans would greatly reduce the risk of unintentional carryover.

Considerations on elaborating an appropriate risk management Standard

20. CCRVDF has traditionally established maximum residue limits (MRLs) for residues resulting from approved uses of veterinary drugs in food-producing animals. Recently, CCRVDF has begun establishing Risk Management Recommendations (RMRs), which are non-quantitative standards, for veterinary drugs for which JECFA has been unable to establish an ADI or recommend MRLs based on specific human health concerns. The CCRVDF terms of reference also allow the development of codes of practice as may be needed.

21. Many members supported development of risk management standards for unintentional carryover, while others suggested that a code of practice should be developed regarding the risk of unintentional carryover and approaches to prevent it. However, there is general consensus that while code of practice should be the principle guideline to minimize carryover contamination, quantitative standards may need to be established under certain circumstances.

22. One member suggested that for clarity the terms used in the discussion document or in future guidelines should be well defined to avoid confusion.

23. Many members supported development of quantitative standards for residues of veterinary drugs in foods due to unintentional carryover of veterinary drugs in feed. One member noted that establishment of standards would unify criteria between countries. Another member suggested that standards should focus on approved veterinary drugs as these are more likely to be manufactured in bulk, introducing a greater potential for error and cross-contamination. Some members suggested that establishing standards would be especially important for antimicrobials to help prevent development of antimicrobial resistance.

24. One member suggested that maximum residue limits (MRLs) should be reserved for residue standards resulting from approved, intentional drug use. One member recommended that another quantitative standard should be used for residues resulting from unintentional carryover, noting action levels can be used to quantify a safe concentration in food resulting from unintentional carryover. Another option may be to establish a new name for a quantitative standard for residues resulting from unintentional carryover of veterinary drug in feed. On discussing these proposals, the co-chairs noted some potential difficulties in the use of MRLs for unintentional carryover of veterinary drugs in feed, since MRLs are predicated on the good practice on the use of veterinary drugs and so would not encompass unintentional carryover. They further noted that maximum levels (MLs) are typically used in Codex for contaminants in food or feed and could be considered for this purpose.

25. Two members cited the definition of contaminants from the Codex Procedural Manual "Contaminants means any substance not intentionally added to food or feed for food producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter." Consequently, it was proposed that Maximum Levels (MLs) could be established for residues of veterinary drugs in foods resulting from carryover residues in feeds. However, a few other members suggested that MLs are already used for contaminants and therefore their use may be limited to the work of CCCF, and an alternative name would be more appropriate.

26. One member suggested that a pragmatic approach (e.g. 1% compared to the authorised maximum content) may be adopted to set such standards. Another member suggested that such an approach may be solicited as a specific risk management recommendation from JECFA. The co-chairs however note that prior consultation with JECFA would be necessary before CCRVDF makes a decision on this approach. Some members expressed concern that standards for unintentional carryover may not be within the terms of reference of the CCRVDF. Some members suggested that establishing quantitative standards would encourage manufacturers to produce medicated feed that may be contaminated up to the standard rather than following good feed manufacturing practices to minimize carryover. Some members suggested that quantitative standards should not be established for carryover because carryover of veterinary medicines has not been a major trade issue either in feed or food, carryover is unintentional contamination, many veterinary drugs in feed do not have a JECFA ADI, and validated analytical methods are lacking for contamination in feed.

27. Some members suggested that a code of practice or appendix to an existing code of practice would be a better approach to control unintentional carryover than individual standards. One member suggested that a code of practice may be used to encourage competent authorities to educate feed manufacturers on good manufacturing practices to minimize potential carryover. Competent authorities should also implement enforcement actions for violations.

28. Some members considered that if a standard for carryover residue is established in foods, standards for feeds may also be required, while others considered it to be rather complicated and were not in favour of setting standards in feeds.

29. **Comments from the co-chairs:** Although some members preferred to have a completely new code of practice specifically for carryover residue management, there was a general consensus that the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004) provides the necessary guidelines to minimize carryover residues of veterinary drugs in feeds and that this could be specifically amended to address this issue. Further, overall comments indicate that setting a quantified standard should only be considered when carryover residues in food is an identified issue (e.g. for compliance/enforcement purpose or international trade) even when feed is manufactured following GMP principles and the *Code of Practice for Good Animal Feeding*. Such a standard in food should not be called "MRL" as it meets the definition of a contaminant, and hence should preferably be called an "ML". However, not all members agreed on the term ML. It also needs to be explored whether using the term ML by CCRVDF will be acceptable as until now it has been used only by the CCCF. The co-chairs note that the principles used for establishing a ML (maximum level that does not pose health risk) may need to be established for residue standard resulting from carryover residues in feeds

Criteria for Establishing a Standard

30. Many members supported establishment of a standard for residues in foods resulting from unintentional carryover of veterinary drugs in feed for both approved and unapproved veterinary drugs. One member suggested that approved and unapproved veterinary drugs may need to be defined, while many members provided definitions in their responses. It was suggested that an approved veterinary drug is one which has been officially authorized or recognized by a competent authority and which is used according to the product labelling. An unapproved veterinary drug would be a drug used off-label or extra-label or use of a prohibited substance.

31. Many members agreed that a standard should only be established when JECFA has established an acceptable daily intake (ADI). Likewise, members suggested that standards for carryover residues should not be established for veterinary drugs for which JECFA was unable to establish an ADI or recommend MRLs due to specific human health concerns. In line with the goal of Codex, some members opined that standards should only be established when they are needed to protect the health of consumers and ensure fair practices in the food trade.

32. Many members suggested possible criteria for establishing a standard for carryover in feed. It was suggested that a standard should only be developed where unintentional carryover occurred despite following good feed manufacturing practices. To ensure this was the case, several members suggested that a standard should be established following the "as low as reasonably achievable" (ALARA) principle. One member suggested that data may be needed showing the occurrence of carryover even when good feed manufacturing practices are followed. Additionally, there was some support that setting standards should also consider statistical distribution of incurred tissue residues following exposure of animals to feed with carryover residues (or feed with drug mixed at expected carryover concentrations).

Data Requirements for Establishing a Standard

33. Depending on the type of standard established for residues resulting from unintentional carryover in feed, data will be required to allow JECFA to evaluate the risk and make a recommendation. Some members suggested the kinds of data that may be necessary to allow JECFA evaluation. Data for establishing a standard may include residue data in food commodities showing a low level residue in food to be common which would be an issue for compliance and enforcement or international trade. Additional data may be needed to estimate transfer factors (transfer rate of drug residues from feed to animal tissues), marker to total ratio in food commodity for the drug in question, distribution of residues in feed resulting from unintended carryover in feed under good feed manufacturing practices, validated analytical method in the feed and in food in which the standard is to be set, etc. JECFA may consider further elaboration of policies for such evaluation including but not limited to use of an additional uncertainty factor.

34. Several members suggested that relevant data could be generated by the drug sponsor, feed mills (e.g. data from quality plan and HACCP), academia or national authorities. All data available may not be generated according to principles of Good Laboratory Practices (GLP). However, if the data meets minimum quality standards, data from different sources could be pooled and analyzed (including modelling). It was suggested that national residue monitoring programs, with proper trace back investigations, could provide substantial information on expected residue distribution. While several members expressed that quality data may not be available, the organization representing drug sponsors suggested that its members could generate data required to establish a numerical standard when this is warranted. There were several comments noting that an analytical method would be very important to any standard that might be established. One member noted that the analytical method established for an MRL would be insufficient for detecting such low levels of residue as might be expected from unintentional carryover. Some members expressed concern that development of methods to detect carryover residue could be costly, require more research, and questioned the source of such data.

Considerations for Potential Procedural changes:

35. Many members considered that changes in the procedural manual would be required for CCRVDF and JECFA to establish numerical standards for residues of veterinary drugs in foods resulting from unintentional carryover residues in feeds. One member suggested that the inability of JECFA to recommend a standard in food from carryover residues in feed was the reason for formation of this EWG.

36. However, another member noted that the terms of reference for the CCRVDF include "(b) to recommend maximum levels of such substances; (c) to develop codes of practice as may be required". Hence, it allows the Committee to establish MLs in foods resulting from the carryover residues in feeds. Yet another member suggested that while the "maximum levels" could be interpreted to include both MRLs and MLs, JECFA's terms of reference may not allow it to establish the standards for residues in food resulting from carryover residues in feed:

37. The terms of reference for JECFA (veterinary drugs) state that JECFA:

- Elaborates principles for evaluating their safety and for quantifying their risks;
- Establishes ADIs for chronic exposure and other guidance values for acute exposure;
- Recommends maximum residue limits (MRLs) for target tissues; and
- Determines appropriate criteria for and evaluates methods of analysis for detecting and/or quantifying residues in food.

38. In its assessment, JECFA considers residues of veterinary drugs arising from use according to good practice in the use of veterinary drugs (GPVD).

39. Another member suggested that changes to the Procedural Manual may not be required if the establishment of MLs for residues resulting from carryover in feed could be considered a type of risk management recommendation (RMR). This could take the form of a specific ML established on an as-needed and case-by-case basis.

40. **Comments from the co-chair:** This topic needs further discussion in the physical working group and at the CCRVDF plenary to define the scope of changes required in the procedural manual, if any.

Overall Conclusions

41. Overall, there was a consensus that this issue needs to be addressed by CCRVDF. Summary of the overall comments provided to the EWG and areas that need further attention are highlighted below.

i. Use the *Code of Practice for Good Animal Feeding* to minimize carryover residues. If necessary, the Code could be revised (within the main text or an additional annex).

ii. A numerical standard setting could be considered if sufficiently justified and will be based on the rationale provided in the priority setting discussion.

iii. A name for the numerical standard needs further discussion to achieve consensus. A majority opinion was to call it a Maximum Level (ML) as the unintentional carryover of residues meets the definition of a contaminant. However, this needs further discussion particularly as this term has so far been exclusively used by CCCF, and the approach of setting a ML in food under a carryover scenario might be different than those used for contaminants. Specific principles may need to be defined should MLs be assigned to set a standard for carryover veterinary drug residues.

iv. Standard setting in foods (resulting from carryover residues in feed) could consider both ALARA principles and statistical approach based on residue data. An alternative could be to use a pragmatic approach and assign the ML in food resulting from carryover residues in feed as a fixed percentage of the MRL established in other edible tissues. JECFA can further elaborate on the data requirements and approaches to be used for such standard setting.

v. Data would be required to set a numerical standard. Good quality data that meets the JECFA's requirements will be required. The source of the data could be the drug sponsor, data from feed mills (quality/verification, HACCP), academic publications or national authority.

vi. There is no agreement on when a standard in food is set for residues resulting from unintentional carryover of drug residues in feed, whether a standard also needs to be established for feed.

vii. Appropriate analytical method(s) that can determine drug residues in foods and feed at carryover levels would be required.

viii. Current Procedural Manual may not allow CCRVDF or JECFA to establish numerical standards for residues of veterinary drugs in foods resulting from unintentional carryover of drug residues in feeds. Further discussion is required on how this could be addressed, and what revisions would be appropriate.

Appendix

International Guidelines

Code of Practice on Good Animal Feeding (CAC/RCP 54-2004)

Guidelines on the Application of Risk Assessment for Feed (CAC/GL 80-2013)

Guidance for Governments on Prioritizing Hazards in Feed (CAC/GL 81-2013)

Joint FAO/WHO Expert Meeting on Hazards Associated with Animal Feed (12-15 May 2015) (http://www.fao.org/3/a-az851e.pdf)

Principle for the establishment of Codex methods of analysis (Codex Alimentarius Commission Procedural Manual (http://www.fao.org/3/a-i3243e.pdf)

Guideline on Analytical Terminology (CAC/GL 72-2009) (http://www.codexalimentarius.org/standards/list-of-standards/)

FAO and IFIF (2010). Good practices for the feed industry – Implementing the Codex Alimentarius Code of Practice on Good Animal Feeding. FAO Animal Production and Health Manual No. 9. Rome. (http://www.fao.org/docrep/012/i1379e/i1379e.pdf)

Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009)

Code of Practice Concerning Source Directed Measures to Reduce Contamination of Foods With Chemicals (CAC/RCP 49-2001)

The Control of Hazards of Animal Health and Public Health Importance in Animal Feed. OIE Terrestrial Animal Health Code. (Chapter 6.3)

General Guidelines on Sampling (CAC/GL 50-2004)

Glossary of Terms and Definitions (Residues of Veterinary Drugs in Foods) (CAC/MISC 5-1993)

Maximum Residue Limits for Veterinary Drugs in Foods (CAC/MRL 2-2015)

Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 38-1993)

General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)

Code of Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993)

Guidelines for the Control of Veterinary Drug Residues in Food (CAC/GL 16-1993)

Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004)

Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)

Food Safety Practices for Aqua Culture (World Bank etc)

Code of Practice on Responsible Use of Animal Medicines on the Farm (Veterinary Medicine Directorate updated December 2014 eg PVS, NOAH (National Office of Animal Health), AHDA, RUMA (Responsible Use of medicine in Agricultural Alliance, PVS (Pig Veterinary Society), AMTRA (Animal Medicines Training Regulatory Authority)

Terresterial Animal Health Code (OIE, 2015)

Aquatic Animal Health Code (OIE, 2015)

Responsible and Prudent Use of Antimicrobials in Livestock (OIE), Section G, Chapter 6.9, OIE Terrestrial Code

Classification of Foods and Animal Feeds (CAC/MISC 4)

National and Regional Guidelines

Brazil

INSTRUÇÃO NORMATIVA Nº 65, November 21, 2006 – On manufacturing and use procedures of medicated feed.

INSTRUÇÃO NORMATIVA Nº 4, February 23, 2007 – On Good Manufacturing Practices for animal feeding.

DECRETO N.º 5.053, April 22, 2004 – Inspection of Establishments that produce or market veterinary drugs (This decree has been altered in part by the Decree 8448, published in May, 2015).

INSTRUÇÃO NORMATIVA No- 26, July 9, 2009 – On manufacturing, quality control and marketing of antimicrobials of veterinary use.

INSTRUÇÃO NORMATIVA Nº 11, May 5, 2014 – On the National Program of Residues and Contaminants Control (beef, poultry, pork, equine meats, milk, fish, honey and eggs). This document is published every year with the program of the following year.

Canada

Medication Sequencing Guideline for Management of Drug Carryover (http://inspection.gc.ca/animals/feeds/inspection-program/medication-sequencing/eng/1389362488069/1389362490053)

Validation studies for Modification of Sequencing Guidelines (http://inspection.gc.ca/animals/feeds/inspection-program/sequencing-guidelines/eng/1373325944197/1373325944713)

Measurement of Feed Carryover Level (http://inspection.gc.ca/animals/feeds/inspection-program/measurement-of-feed/eng/1373325386112/1373325437132)

Medication Residues Validation Testing Procedures for Equipment Cleanout Procedures (http://inspection.gc.ca/animals/feeds/inspection-program/equipment-cleanout/eng/1373325971995/1373325972541)

Chile

Resolution 5025 exempt: “Establishes scope of the quality assurance program in factories or processors of animal food or suplements and factories of animal food or supplements and factories of animal origin ingredients intended for animal feed” (http://www.leychile.cl/Navegar?idNorma=1005988)

Resolution 5580: "Establish requisites for the operation of animal food and supplements manufacturing factories and plants, and derogates a resolution that indicates” (http://www.bcn.cl/leychile/Navegar?idNorma=243203)

Resolution 2487: "Establish operational and structural requisites of factories of animal ingredients intended for animal feed” (http://www.bcn.cl/leychile/Navegar?idNorma=1002635)

Decree 307: Animal Food Regulation (http://www.leychile.cl/Navegar?idNorma=171845&idParte=0)

Resolution 557 exempt: "Establish payroll and guarantee food ingredients to be used in the manufacture of food supplements for animals” (http://www.bcn.cl/leychile/Navegar?idNorma=279502)

Resolution 1992 exempt: “Establish authorized payroll processing and food manufacturing additives and supplements for animals and repeals resolution stating” (http://www.leychile.cl/Navegar?idNorma=249643)

European Union

COUNCIL DIRECTIVE (90/167/EEC) of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community

DIRECTIVE 2002/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 7 May 2002 on undesirable substances in animal feed (http://eur-lex.europa.eu/legal-content/DE/TXT/HTML/?uri=CELEX:32002L0032&from=DE)

COMMISSION DIRECTIVE 2009/8/EC of 10 February 2009 amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels of unavoidable carryover of coccidiostats or histomonostats in nontarget feed

COMMISSION REGULATION (EC) No 124/2009 of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carryover of these substances in non-target feed

Document EUR-Lex - 52014PC0556
Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND THE COUNCIL on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC (http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52014PC0556&qid=1444290152009&from=DE)

Feed Hygiene Regulation (EC) No 183/2005: Annex II provides among others that "Technical or organisational measures must be taken to avoid or minimise, as necessary, any cross-contamination and errors."

European Feed Manufacturers Guide for good Hygiene Practice for the manufacturing of feed for food producing animals (EFMC): this guide is meant to help operators meeting the requirements of the EU Feed Hygiene Regulation. It includes provisions for the prevention and minimisation of carryover, including guidance for the measurement of premises-bound carryover. This includes also definitions of carryover and cross-contamination.

France

There are two guidelines, one for medicated feed, one for non–medicated feed. Attached are the guidelines for medicated feed (Guide des BPFD Alts med 2012), on page 52, there is a test to be done to measure carryover. Carryover must to be under 5 % for the first batch and under 1 % for the second batch.

Germany

Guidelines for the prudent use of veterinary antimicrobial drugs -with notes for guidance

http://www.bundestierärztekammer.de/index_btk_abll.php?Year=2016

Oral administration of veterinary medicines in the livestock sector through feed or drinking water
http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/Leitfaden-Orale-Medikation.pdf?__blob=publicationFile
http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/Leitfaden-Orale-Medikation-Anlage1.html
http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/Leitfaden-Orale-Medikation-Anlage2.html

Philippines

Republic Act No 8550, otherwise known as the Philippine Fisheries Code of 1998 (http://www.region3.bfar.da.gov.ph/ra8550.pdf)

Republic Act No 1556, otherwise known as Livestock and Poultry Feeds Act (http://www.pvma.com.ph/sites/all/laws/RA1556_main.htm)

Republic Act No 9711, otherwise known as Food and Drug Administration (FDA) Act of 2009 (http://www.fda.gov.ph/issuances/305-others/others-republic-act/29052-republic-act-no-9711)

Republic Act No. 9296, otherwise known as the Meat Inspection Code of the Philippines (http://www.nmis.gov.ph/attachments/article/559/RA.9296.pdf)

Republic Act No 10611 otherwise known as Food Safety Act of 2013 (http://www.gov.ph/2013/08/23/republicact-no-10611/)

Philippine National Standard No. 60:2008 Code of Good Animal Husbandry Practices (GAHP)

Philippine National Standards on Animal Feed Ingredients

Philippine National Standards on Halal Feeds

Philippine National Standard for Fresh Milk

Fisheries Administrative Order No. 214,series of 2001 Code of Practice for Aquaculture which uphold Good Aquaculture Practice (GAqP) (http://www.bfar.da.gov.ph/LAW?id=215-207)

Philippine National Standard Good Agricultural Practices (GAP)

DA AO No 38 Series of 2005 Good Manufacturing Practices (GMP) (http://nmis.gov.ph/attachments/article/469/mc%2002-2005-02.pdf)

HACCP Program (http://www.bafps.da.gov.ph)

Spain

PDOC CNCAA 3/2014-Agreement of the National Commission for Coordinating Committee on Animal Nutrition on the acceptability of checks on homogeneity and cross contamination made by manufacturers of animal feeds and premixes

PDOC CNCAA 1/2010 Criteria for evaluating the effectiveness of self-monitoring in place to determine the level of cross contamination in establishments manufacturing compound feed and premixes.

Regulation (EC) 183/2005 laying down requirements are set on feed hygiene (attached consolidated version).

Directive 90/167 laying down conditions governing the preparation, placing on the market and use of medicated feed (attached consolidated version)

Royal Decree 1409/2009 on the processing, marketing, use and control of medicated feed is regulated

United States

CPG Sec. 680.500 Unsafe Contamination of Animal Feed from Drug Carryover: http://www.fda.gov/ICECI/ComplianceManu ... 074699.htm

CPG Sec. 680.600 Sequencing as a Means to Prevent Unsafe Drug Contamination in the Production, Storage and Distribution of Feeds: http://www.fda.gov/ICECI/ComplianceManu ... 074700.htm