CODEX ALIMENTARIUS COMMISSION





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REP13/AF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX ALIMENTARIUS COMMISSION

Thirty sixth Session Rome, Italy, 1-5 July 2013

REPORT OF THE SEVENTH SESSION OF THE AD-HOC INTERGOVERNMENTAL CODEX TASK FORCE ON ANIMAL FEEDING

Bern, Switzerland 4-8 February 2013

NOTE: This report contains Codex Circular Letter CL 2013/3-AF

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Organization

To: Codex Contact Points

Interested International Organizations

From: Secretariat,

Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme

Viale delle Terme di Caracalla

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Subject: Distribution of the Report of the Seventh Session of the Ad Hoc Intergovernmental

Codex Task Force on Animal Feeding (REP13/AF)

The report of the Seventh Session of the *Ad Hoc* Intergovernmental Codex Task Force on Animal Feeding will be considered by the 36th Session of the Codex Alimentarius Commission (Rome, Italy, 1-5 July 2013)

MATTERS FOR ADOPTION BY THE 36TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

<u>Draft and Proposed Draft Standards and Related Texts at Step 8 and 5/8 of the Procedure</u>

Draft Guidelines on Application of Risk Assessment for Feed at Step 8 (para. 27 and Appendix II).

Proposed draft Guidance on Prioritizing Hazards in Feed at Step 5/8 (para. 62 and Appendix III).

Governments and international organizations wishing to submit comment on the above texts should do so in writing to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (e-mail: codex@fao.org) before 31 May 2013.

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SUMMARY AND CONCLUSIONS

The Seventh Session of the *Ad Hoc* Intergovernmental Codex Task Force on Animal Feeding reached the following conclusions:

Matters for the 36th Session of the Codex Alimentarius Commission

Matters for adoption

Draft and proposed draft Standards and Related Texts at Step 8 and 5/8 of the Procedure

The Task Force agreed to forward the draft Guidelines on Application of Risk Assessment for Feed and the renamed proposed draft Guidance on Prioritizing Hazards in Feed to the Commission for adoption at Step 8 and 5/8 respectively (see para 27 and 62 and Appendices II and III).

INTRODUCTION

1. The *ad hoc* Intergovernmental Codex Task Force on Animal Feeding (TFAF) held its Seventh Session in Bern, Switzerland, from 4 to 8 February 2013, at the kind invitation of the Government of Switzerland. Dr Eva Reinhard, Assistant Director-General of the Swiss Federal Office for Agriculture (FOAG), chaired the Session. The Session was attended by 101 delegates from 40 Member countries and one Member organization and seven international governmental and non-governmental organizations, including FAO and WHO. The list of participants, including the Secretariats, is given in Appendix I to this report.

OPENING OF THE SESSION

- 2. The Session was opened by Mr Jacques Chavaz, Deputy Director-General of the Swiss Federal Office for Agriculture. In his keynote address, Mr Chavaz emphasized the global need to ensure the safety of food of animal original along the food chain and hence the need to finalize the documents under discussion, which could contribute to this endeavour and that Switzerland was committed to achieving this. He noted that this was a shared responsibility and acknowledged the contribution of all in achieving progress to date. He informed the Task Force that livestock was one of the priority areas for the Switzerland support programme to FAO of which a key component was the development of the Global Agenda of Action in support of sustainable livestock sector development, a multi-stakeholder partnership, which would be launched at the FAO Conference in June 2013.
- 3. Mr Chavaz expressed his thanks to the three Ministries involved in the organization of the session and to the Codex Secretariat for their support, and wished the Task Force every success in finalisation of its work.

Division of Competence¹

4. The Task Force noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of the Codex Alimentarius Commission, as presented in CRD 1.

ADOPTION OF THE AGENDA (Agenda Item 1)²

5. The Task Force adopted the Provisional Agenda as its Agenda for the Session.

MATTERS REFERRED TO THE TASK FORCE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES (Agenda Item 2) 3

6. The Task Force noted relevant decisions of the 35th Session of the Codex Alimentarius Commission regarding the adoption at Step 5 and advancement to Step 6 of the draft Guidelines on Application of Risk Assessment for Feed and the status of the ongoing review of the existing Codex texts as to their applicability to animal feed. In particular, the Task Force noted the adoption of the revised definition for "contaminant" which now took into account feed.

REPORT ON ACTIVITIES OF FAO, WHO AND OTHER INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS (Agenda Item 3)⁴

Report of Activities of FAO and WHO

- 7. The FAO Representative drew the attention of the Task Force to the information in CX/AF 13/7/3 and provided information on the FAO capacity development activities in the areas of animal nutrition, feeding and feed safety to support the sustainable development of the livestock sector. In this context FAO has linked animal feeding and feed safety not only to public health and food safety, but also to other important areas of work for FAO, such as animal health and welfare, the mitigation of possible negative impacts of livestock on the environment and climate change, food security and sustainable diets and the reduction of food losses and wastes.
- 8. The FAO Representative informed the Task Force of the recently produced Feedipedia⁵, an on-line encyclopaedia of animal feed, developed in collaboration with the French National Institute for Agricultural Research (INRA), the Centre for Agricultural Research for Development (CIRAD) and the French Animal

¹ CRD 1 (Annotated Agenda – Division of competence between the European Union and its Member States)

² CX/AF 13/7/1

³ CX/AF 13/7/2

CX/AF 13/7/3;CX/AF 13/7/3 Add.1

Available at http://www.feedipedia.org

Production Association (AFZ) and of the launch of an FAO Animal Feeding Twitter account⁶ and a series of dedicated podcasts⁷.

- 9. In addition the Representative referred to the FAO's strong collaboration with a wide range of stakeholders, in particular with the International Feed Industry Federation (IFIF), to develop the capacities of the sector players to ensure feed safety.
- 10. The Representative of WHO provided information on WHO activities on antimicrobial resistance, including the development and regular updating of a list of Critically Important Antimicrobials (CIA); the activities of the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (WHO-AGISAR) and the recent FAO and WHO whole food chain studies to assess and quantify microbial contamination and antimicrobial resistance in some developing countries.
- 11. The Representative also provided information on a web-based tool developed by FAO and WHO to assess the performance of sampling plans for microbiological hazards in food and feed ⁸. She further informed on the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Expert Meeting on Pesticide Residues (JMPR) activities related to the risk assessment of chemical substances and contaminants in food, which take into consideration the implication of contamination of animal feed or feed ingredients as appropriate.
- 12. The Representative informed the Task Force that the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN) has enhanced its coordination with the animal production sector to strengthen its capacity to address issues such as feed safety and has also been addressing food safety events related to animal feed and pet food.
- 13. Given the Task Force's work on the development of Guidance for the Prioritization of Hazards in Feed (Agenda Item 5), the FAO Representative made a presentation on the ranking approach that had been applied by FAO and WHO in the ranking of foodborne parasites. The presentation focused on the approach taken, the steps therein and the challenges and lessons learned. A copy of the presentation is available on the Codex ftp site⁹.

World Organisation for Animal Health (OIE)

14. The Codex Secretariat drew the attention of the Task Force to document CX/AF 13/7/3 Add.1 which provided a brief update on relevant OIE activities. In particular, the OIE had adopted standards in the *Terrestrial Animal Health Code* and the *Aquatic Animal Health Code* on the control of hazards of animal health and public health importance in animal feed and on the responsible and prudent use of antimicrobial agents.

Conclusion

15. The Task Force acknowledged and thanked FAO, WHO and OIE for their contribution.

PROPOSED DRAFT GUIDELINES ON APPLICATION OF RISK ASSESSMENT FOR FEED (Agenda Item 4)¹⁰

- 16. The Chairperson introduced the report of the physical Working Group (pWG), which met on 3 February 2013, to consider the draft Guidelines on Application of Risk Assessment for Feed (see CRD 2). The Task Force noted that the pWG had revised the document and, in particular: clarified the text and definitions; added the Codex definition for food; complemented Figure 1; made some changes in the sections on risk assessment procedure, hazard characterization and exposure assessment; and revised Annex 1.
- 17. The Task Force agreed to consider the revised draft Guidelines, as in the Annex of CRD 2, and to consider a proposal of the Netherlands for the Sections on Exposure Assessment and Risk Characterization, as in CRD 5.

8 Available at <u>www.mramodels.org/sampling</u>

ftp://ftp.fao.org/codex/Meetings/TFAF/tfaf7/Risk%20ranking%20approach/

https://twitter.com/FAOafeeding

http://vimeo.com/faocast

REP12/AF Appendix II; CL 2012/22-AF; CX/AF 13/7/4 (Comments of Argentina, Canada, Chile, European Union, India, Iran, New Zealand, Philippines, United States of America and IFIF); CX/AF 13/7/4 Add.1 (Comments of India and OIE); CRD 2 (Report of the physical Working Group); CRD 3 (Comments of Ghana, Indonesia, Kenya, Nigeria, Republic of Korea and Thailand); CRD 5 (Proposals of the Netherland for paras 39-43)

Specific comments

18. The Task Force accepted the majority of the changes proposed and, in addition to some editorial changes to improve clarity and consistency with other Codex documents, made the following changes and comments.

Definitions

19. The Task Force agreed that the definitions included in the document, the proposed draft Guidance for Governments on Prioritizing Hazards in Feed (Agenda Item 5) and the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004) should be consistent, and to delete the definitions of the terms which were not used in the two documents under development.

Risk Assessment in the Codex Risk Analysis Framework

- 20. The Task Force noted that preliminary risk management activities encompassed all those activities that would lead to a risk management decision and were, therefore, an integral part of the risk management process.
- 21. The Task Force added: (i) "definition of the output form of the risk assessment" to the list of preliminary risk management activities, consistent with the *Working Principle for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007); and (ii) a reference to the Guidance for Governments on Prioritizing Hazards in Feed (Agenda Item 5) to activity "ranking of the hazard for risk assessment and risk management priority" to establish a link between the risk assessment and the prioritization documents.
- 22. The Task Force complemented Figure 1 to ensure that the list of preliminary risk management activities was consistent with those listed in the text.

Exposure assessment

23. The Task Force agreed to merge the two paragraphs on sampling plans and analytical laboratory methods since both referred to data generation, and to introduce the word "testing" to the introductory sentence to give context to the paragraph.

Risk Characterization

- 24. The Task Force agreed with the proposal in CRD 5 to revise the Sections on Exposure Assessment and Risk Characterization to: better distinguish between the risk characterization and exposure assessment activities; clarify that the feed risk assessment derives a risk estimate for food safety and does not imply a full human risk assessment; and to illustrate the need for the risk characterization and subsequent risk management options to take into account exposure assessment of a hazard from sources other than feed (e.g. from the environment or food of non-animal origin).
- 25. The Task Force included a new paragraph which illustrated that an initial output of risk assessment might be a comparison of the estimated feed hazard in the edible products with an already existing limit in food, before taking a risk management decision related to the control of the hazard in the feed.

Conclusion

26. The Task Force agreed that the document was complete and that no further issues were outstanding.

Status of the proposed draft Guidelines on Application of Risk Assessment for Feed

27. The Task Force agreed to forward the draft Guidelines to the 36th Session of the Commission for adoption at Step 8 (see Appendix II).

PROPOSED DRAFT GUIDANCE FOR USE BY GOVERNMENTS IN PRIORITISING THEIR NATIONAL FEED HAZARDS (Agenda Item 5)¹¹

28. The Delegation of Switzerland introduced the report of the electronic Working Group (eWG) and explained the relationship between prioritization and risk assessment. It was clarified that prioritization was a

CX/AF 13/7/5; CX/AF 13/7/5 Add.1 (Comments of Argentina, Brazil, Canada, Chile, Colombia, Egypt, European Union, Iran, Japan, Norway, Philippines and United States of America); CX/AF 13/7/5 Add.2 (Comments of India, IFIF and OIE); CRD 2 (Report of the physical Working Group); CRD 4 (Comments of Ghana, Kenya, Nigeria, Republic of Korea, Thailand and IDF), CRD 6 (Proposed Draft Guidance for Governments on Prioritizing Hazards in Feed prepared by Switzerland); CRD 7 (Draft Guidelines for Governments on Prioritizing Hazards in Feed, proposal of 5 February 2013)

risk management step, the purpose of which in many or most cases was to establish which risk assessments needed to be done.

- 29. The Delegation highlighted the key tasks undertaken as given by the previous session of the Task Force. It was explained that the eWG had further revised the document to provide a globally applicable step-by-step guidance for prioritization, which would enable national risk managers to prioritize feed hazards in a multitude of situations. The document included two annexes on examples of hazards and a partially completed example of the prioritization process.
- 30. To facilitate discussion at the Session, the Delegation of Switzerland had prepared a revised document (CRD 6), which took into account the written comments received and the FAO/WHO report on ranking of foodborne parasites (see Agenda Item 3). The Delegation noted that this approach to prioritization was a first and innovative attempt in Codex.
- 31. The Delegation of Switzerland presented this revision and explained the key change was the use of the multi-criteria analysis approach, which included the following steps: identification of hazard/feed/edible product combinations; identification and definition of the criteria by which each selected combination is quantified; assignment of the criterion-based values to the combinations; normalization of these values to make them comparable between criteria; weighting of the criteria to reflect their relative importance; combining the weighted normalised values for each combination to produce a score and ranking of the scores; and reporting. The risk-profiling step was removed as this was not a part of the prioritization process and was also not used by FAO/WHO in their work on parasites in food.
- 32. It was further explained that the example of prioritization in the annex was generic and for illustrative purposes only and did not apply to a specific hazard/feed/edible product combination. However, since it was based on the FAO/WHO parasite report, the example needed to be revised to apply to feed.
- 33. The Committee agreed to consider CRD 6 as the basis for discussion.

General discussion

34. The Task Force agreed that the revised document was a good basis for discussion, but that further work was needed on the example in the Annex, in particular to ensure its applicability to feed.

Specific comments

35. The Task Force accepted the majority of the changes proposed and, in addition to some editorial changes to improve clarity and consistency with the document on risk assessment (Agenda Item 4), made the following changes and comments.

Title, Introduction and Scope

- 36. The Task Force agreed with the revised more concise title that is "Guidance for Governments on Prioritizing Hazards in Feeds".
- 37. The Introduction was amended to make clear that "preliminary risk management activities" are part of the risk management process and provide inputs leading to a risk management decision.
- 38. The Task Force amended the scope to indicate that approaches other than the multi-criteria analysis approach could also be used for prioritization.

Definitions

- 39. Consistent with the earlier decision on definitions in the risk assessment document (Agenda Item 4), the Task Force agreed: to revise the definitions to ensure consistency with other texts related to animal feed; to use to the extent possible Codex definitions; and to limit the list of definitions to only those terms which appear in the document.
- 40. The Task Force agreed to use the definition of "processing aid" for food from the Procedural Manual and to indicate that it was also applicable to feed.
- 41. The Task Force noted that the term "carry-over" when translated into French and Spanish did not clearly differentiate between "carry-over" and "cross-contamination" and could cause confusion. The Task Force therefore agreed to delete the definition for "carry-over" and to broaden the definition of "cross-contamination" to also cover contamination of feed originating from previous use of equipment.

Prioritization of hazards in the framework of Codex risk analysis

42. The Task Force agreed to amend this section to clarify that prioritization could also be undertaken at any point of the risk analysis process.

Prioritization Process

43. The Task Force introduced an introductory paragraph to explain the aim of prioritization.

Steps of the Prioritization Process

44. The Task Force introduced a reference to the risk assessment document (Agenda Item 4) to explain the link between the two documents.

- 45. The Task Force agreed to better describe Step 2 "Identification and definition of the criteria" using the information from the example. The Task Force agreed that the criteria which could be considered included: those related to the extent of the occurrence of the hazard; effect on human health; and other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.
- 46. The Task Force agreed to amend Step 5 "Criterion weighting" to explain that weighting of criteria is typically done by the risk manager with support of experts when required; and introduced a new paragraph under Step 6 "Ranking of the hazard/feed/edible product combinations" to emphasize the need to demonstrate the impact of assumptions on the ranking.
- 47. The Task Force supported the deletion of the risk-profiling step, as it was a separate element of the preliminary risk management activities.

Annex 1: Examples of Hazards in Feed with Potential Relevance for Human Health

- 48. The Task Force discussed the need for this Annex. A number of delegations considered that the Annex was useful and that it made the document more complete and self-contained. The Annex provided, even though not exhaustive, a wide list of hazards in feed and information that countries could consider when starting their prioritization process. It was considered that this useful information could also contribute to a common understanding of these hazards in feed. These delegations also noted that the language used in the Annex was not prescriptive and that the introduction made it clear that its purpose was only to provide examples.
- 49. Some other delegations were not in favour of retaining the Annex. They pointed out that the information provided was not complete and would be difficult to maintain and update; and that the 2008 report of the FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety already included information on hazards in feed. These delegations also questioned the validity of some of the information and expressed concern that countries could misinterpret the purpose of the Annex and use the examples as unjustified barriers to trade.
- 50. In view of the support by a large number of delegations to retain the Annex, the Task Force considered it in detail with a view to identifying and addressing those parts that could be of concern. It was agreed to focus on the information provided and not to add new information that could not be verified.
- 51. In particular, the Task Force amended the Title to only refer to hazards in feed to better reflect its content. The introductory section was revised to make it clearer that the Annex was not a comprehensive description of different situations related to feed and food safety; that the information might need to be updated; that the Annex was intended to provide only information for the initial steps of the prioritization process and should not be considered as a risk assessment of the cases mentioned; that the examples illustrated might not be relevant everywhere or at all times; and that the Annex was not covering rare and emerging hazards.
- 52. The Task Force further corrected some inaccuracies, such as: replacing *Cysticercus* spp with *Taenia* spp and deleting the example of *Trichinella*. It also deleted the section on viruses, which was relevant to animal health rather than feed, and included zearalenone as an example of mycotoxins, noting that it was not a major contaminant of edible products as it was rapidly metabolised and/or excreted.
- 53. The Task Force amended the section on organic chemicals to distinguish between dioxins and polychlorinated biphenyls (PCBs) and added the example of medicated feed as a potential source of cross-contamination of feed in the Section on pesticides, veterinary drugs, feed additives and processing aids.
- 54. In view of these amendments, the Task Force agreed to retain the Annex.
- 55. The delegations of Argentina, Brazil and Costa Rica expressed their reservation to the inclusion of the Annex in the Guidance noting that: the Annex could not be easily updated; the FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety, published in 2008, addressed feed hazards of relevance to food safety; and that competent authorities could misinterpret the purpose of the Annex and use the information therein as unnecessary sanitary requirements that could compromise trade.
- 56. The Task Force recognizing that new information on hazards in feed of relevance to human health had become available since the FAO/WHO Expert Meeting (2008), requested FAO and WHO to provide updated

information. It was noted that FAO and WHO would consider this request in light of their work plans and availability of resources.

Annex 2: Example of the Prioritization Process

- 57. The Task Force agreed that it would be useful to have an example to illustrate the steps of prioritization and established an in-session working group to prepare a revised example more applicable to feed.
- 58. The Task Force considered the proposal of the in-session WG (CRD 7), which was based on fictitious hazard/feed/edible product combinations, applicable criteria, and hypothetical criterion-based values.
- 59. The Task Force revised the introductory part to indicate that the example was fictitious and that its only purpose was to illustrate the steps of the prioritization process; that the criteria used were applicable but not exhaustive; and the values used were illustrative.
- 60. The Task Force supported the example and made some editorial amendments to improve its readability and clarity and further agreed to re-order the two annexes for better flow of the document.

Conclusion

61. The Task Force noted the progress made on the text and that there were no outstanding issues that needed to be addressed and agreed to advance the proposed draft Guidance for Governments on Prioritizing Hazards in Feed to Step 5/8. The Task Force noted that Argentina, Brazil, Costa Rica, Saudi Arabia and Thailand required time to consult at national level on the changes made to the document.

Status of the proposed draft Guidance for Use by Governments in Prioritizing their National Feed Hazards

62. The Task Force agreed to forward the renamed proposed draft Guidance on Prioritizing Hazards in Feed to the 36th Session of the Commission for adoption at Step 5/8 with the omission of Steps 6 and 7 (*see* Appendix III).

OTHER BUSINESS (Agenda Item 6)

- 63. The Task Force noted that no other business had been put forward.
- 64. The Chairperson congratulated all delegations, which had actively contributed through the two sessions to develop comprehensive guidance documents for governments on the application of risk assessments of feed and on prioritization of feed hazards. The Chairperson further noted that, with the completion of these two documents, the Task Force had completed the task assigned to it by the 33rd Session of the Commission.

SUMMARY STATUS OF WORK

| Subject Matter | Step | Action by: | Document Reference (REP13/AF) |
|---|------|----------------------|----------------------------------|
| Draft Guidelines on application of risk assessment for feed | 8 | 36 th CAC | Para. 27 and Appendix II |
| Proposed draft Guidance for use by governments in prioritizing the national feed hazards (renamed Guidance on Prioritizing Hazards in Feed) | 5/8 | 36 th CAC | Para. 62 and Appendix III |

Appendix I

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Appendix II

DRAFT GUIDELINES ON THE APPLICATION OF RISK ASSESSMENT FOR FEED (at Step 8 of the Procedure)

INTRODUCTION

- 1. These guidelines provide guidance for feed and feed ingredients risk assessment by governments in accordance with Codex principles for risk analysis. They address the potential risks to human health associated with the presence of hazards in the feed of food-producing animals and the subsequent transfer of hazards to edible products.
- 2. These guidelines should enable risk assessment of hazards in feed based upon local conditions considering the impact on food safety and human health. The application of these guidelines should also enable international comparability of feed risk assessments and thereby promote fair practices in food and feed trade.
- 3. Implementation of these guidelines requires specialised support and training of experts on animal feeding and risk analysis.
- 4. These guidelines should be read in conjunction with the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004).
- 5. Codex guidance on risk assessment of food additives, food contaminants, natural toxicants, residues of pesticides and veterinary drugs, and microbiological hazards is also provided in:
 - Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius²;
 - Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods²;
 - Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues²;
 - Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods²;
 - Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007);
 - Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007);
 - Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77-2011);
 - Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30- 1999).
- 6. Further information is provided in the WHO Principles and Methods for the Risk Assessment of Chemicals in Food³ and the FAO/WHO Microbiological Risk Assessment Series (MRA)⁴.
- 7. Annex 1 lists other references that have been used when developing this document.

SCOPE

- 8. These guidelines are applicable to all hazards in the feed of food-producing animals, which may adversely affect human health. Agents which may adversely affect animal health but which have no impact on food safety are not considered in these guidelines, as they are not within the scope of the Codex Alimentarius.
- 9. Direct human exposure to hazards in feed, for example occupational exposure during feed production and processing, is not considered as it is not within the scope of the Codex Alimentarius.

DEFINITIONS

10. The following definitions are included to establish a common understanding of the terms used in these guidelines.

¹ Throughout the text the term "feed" refers to both feed and feed ingredients, unless otherwise stated

² Codex Alimentarius Commission: Procedural Manual

³ http://www.who.int/foodsafety/chem/principles/en/index1.html

http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/

Biotransformation product: Product resulting from the transformation of a chemical or biological agent in the body of the food-producing animal (e.g. via metabolic processes).

Contaminant: 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.²

Edible product: Any tissue or product from a food-producing animal which is intended for human consumption, including for example meat, fish, eggs and milk.

Exposure assessment: The qualitative and/or quantitative evaluation of the likely human intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.² In these guidelines, it may also refer to the consideration of the exposure of a food-producing animal to a hazard and to an evaluation of the likely amount of a hazard in feed that can transfer to an edible product.

Feed (Feedingstuff): Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food-producing animals.⁵

Feed additive: Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, that affects the characteristics of feed or animal products (micro- organisms, enzymes, acidity regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration).⁵

Feed ingredient: A component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant, animal or aquatic origin, or other organic or inorganic substances.⁶

Food: Any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs.²

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.² In these guidelines, it refers to an agent in feed, which has the potential to cause an adverse human health effect after transfer into an edible product.

Hazard characterization: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents, which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.²

Hazard identification: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.²

Qualitative risk assessment: A risk assessment based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties permits risk ranking or separation into descriptive categories of risk.⁶

Quantitative risk assessment: A risk assessment that provides numerical expressions of risk and indication of the attendant uncertainties.⁶

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.² In these guidelines, it may also refer to the probability that a hazard in feed eaten by a food-producing animal will transfer to an edible product at a level which may cause an adverse health effect in humans.

Risk analysis: A process consisting of three components: risk assessment, risk management and risk communication.²

Risk assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.²

⁶ Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999)

⁵ Code of Practice on Good Animal Feeding (CAC/RCP 54-2004)

Risk characterization: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.²

Risk communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.²

Risk estimate: The quantitative estimation of risk resulting from risk characterization.²

Risk management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.2

Risk profile: The description of the food safety problem and its context.²

Transfer: Passing of a chemical or biological hazard (including hazardous biotransformation products) from feed of a food-producing animal to an edible product of the animal.

Transparent: Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgements, decisions, limitations and uncertainties of the expressed determination are fully and systematically stated, documented, and accessible for review.⁶

Undesirable substances: Contaminants and other substances, which are present in and/or on feed and feed ingredients and which constitute a risk to consumers' health, including food safety related animal health issues.

RISK ASSESSMENT IN THE CODEX RISK ANALYSIS FRAMEWORK

Risk assessment is one of the three components of the risk analysis framework together with risk management and risk communication. This is illustrated in Figure 1.

Figure 1. Risk analysis framework

Risk management

- o Preliminary risk management activities:
 - · identification of a food safety problem arising from feed:
 - · establishment of a risk profile;
 - · ranking of the hazard for risk assessment and risk
 - management priority;
 determination of a risk assessment policy for the conduct of the risk assessment;
 - · definition of the output form of the risk assessment;
 - · commissioning of the risk assessment;
 - consideration of the possible result of the risk assessment.
- Evaluation of risk management options
- Implementation of risk management options
- Monitoring and review

Risk assessment

- Hazard identification
- Hazard characterization
- Exposure assessment
- Risk characterization

Risk communication

12. A risk assessment is commissioned by the risk manager. Preliminary risk management activities include in particular: identification of a food safety problem arising from feed; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority (for further details see Guidance for Government on Prioritizing Hazards in Feed); determination of a risk assessment policy for the conduct of the risk assessment; definition of the output form of the risk assessment; commissioning of the risk assessment; and consideration of the possible results of the risk assessment.

13. The risk assessment policy should be established by the risk manager in advance of risk assessment in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, documented, unbiased and transparent. The mandate given by the risk manager to the risk assessor should be as clear as possible.

RISK ASSESSMENT PROCEDURE

- 14. The scope and purpose of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined.
- 15. Experts involved in risk assessment should be objective in their scientific work and selected in a transparent manner on the basis of their expertise.
- 16. Risk assessment is a science based process and should follow a structured approach incorporating the following four steps: hazard identification, hazard characterization, exposure assessment and risk characterization.
- 17. Risk assessment should be based on scientific data most relevant to the national context. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.
- 18. Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

Hazard identification

- 19. Hazards in feed can include biological and chemical agents (such as "heavy metals", dioxins, excessive levels of pesticides, veterinary drugs and additives), radionuclides and other undesirable substances. Biotransformation products present in edible products also need to be considered.
- 20. Feed additives, veterinary drugs and pesticides used in feed, which have been assessed for safety and which have been used under stated conditions of use as pre- approved by the competent authorities, should not be *prima facie* considered as hazards.
- 21. Physical agents in feed are not known to be hazards reasonably likely to cause food safety risks, but rather may cause a risk to animal health, which is outside the scope of these guidelines.
- 22. Factors to be considered include those which can markedly influence the occurrence of a given hazard in feed and which may be specific to a locale, country, or region, include environmental conditions and interactions with other materials during growth, harvesting, drying, processing, storage, handling and transport.
- 23. Useful information on the presence of the hazard in feed may be obtained from regulatory surveillance samples and investigative work, published data from government agencies and scientific peer-reviewed publications, and from international programs such as the WHO Global Environment Monitoring System (GEMS/Food), the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN), and other reliable rapid alert systems, and industry self-monitoring programmes.
- 24. In order to evaluate which feed ingredients may contain a given hazard, consideration should be given to the source of feed ingredients and environmental conditions and interactions, and the potential for introduction of hazards during their manufacture, preparation, transportation, handling, storage and use. Many feed ingredients are produced as co-products or by-products from other production processes, including industrial processes, and an evaluation may need to be made of these processes and their potential for introducing hazards in feed.

Hazard characterization

25. Hazard characterization refers to the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with hazards in feed, which may be present in edible products as a result of transfer. For any hazard identified, including biotransformation products, a hazard characterization should be conducted.

- 26. Information on characterization of specific hazards may be obtained in international reports and monographs from risk assessment bodies and/or in peer-reviewed scientific literature. Sources of information should be documented.
- 27. For the hazard characterization of chemicals the relevant reference value especially for an oral route of exposure is identified, e.g. Acceptable Daily Intake (ADI), Tolerable Daily Intake (TDI), Acute Reference Dose (ARfD). For biological hazards, a dose-response relationship is established if possible.
- 28. If available scientific data are inadequate to characterize a hazard, it may be necessary to consider generating such data. The risk manager may request action to resolve the data gaps. Any generation of new data should be based on relevant scientific principles and procedures.

Exposure assessment

- 29. Human exposure assessment is the qualitative and/or quantitative evaluation of the likely intake of the hazard(s) via food. The aim of the exposure assessment in feed risk assessment is to estimate the level or prevalence of hazard(s) in edible product(s) after transfer from feed. Subsequently, these estimated levels of hazard in edible product arising from feed are used as input for human exposure assessment.
- 30. The final edible product(s) in the exposure assessment should be defined as precisely as necessary.
- 31. Exposure assessment should use quantitative data on the level of hazard(s) or prevalence in feed and/or edible product(s). If quantitative data are not available, a semi-quantitative or qualitative risk assessment approach may be useful in assessing the potential food safety risk. If necessary, the assessment should be reconsidered when scientific quantitative data are obtained.
- 32. Data obtained from sampling and testing of feed and edible product may be useful for quantifying the exposure. Sampling plans for feed and edible products should use scientifically recognized principles and procedures in accordance with the *General Guidelines on Sampling* (CAC/GL 50-2004). The sampling plan should take into consideration possible non-homogeneous distribution of the hazard. Analytical laboratory methods should be validated using scientifically recognized principles and procedures in accordance with the *General Criteria for the Selection of Methods of Analysis Using the Criteria Approach*¹.
- 33. Exposure assessment for a hazard in feed is a two-step process. The first step concerns the exposure of the food-producing animal to hazard(s) through feed. If such exposure is present, the second step is to evaluate the transfer of hazard(s) to edible product(s) of the food-producing animal.

First Step: Animal exposure assessment

- 34. The first step involves:
 - (a) Identification of feeds which may contribute to intake of a given hazard;
 - (b) Determination of the concentration of the hazard in feed;
 - (c) Calculation of hazard intake by the food-producing animal from relevant feed sources, based on information on feeding practices (quantity, frequency and duration of feed intake) as appropriate.
 - (d) Identification, and if possible quantification, of other sources of the hazard which may contribute to exposure to the hazard in the food-producing animal (e.g. bedding materials, soil, water, air or others).
- 35. Animal exposure will differ as a result of the formulation of the feed, the use patterns for the animal, and the exposure scenarios.

Second Step: Transfer

- 36. Modelling and measurements are used to calculate transfer through the food-producing animal and the resulting hazard level and/or prevalence in edible product.
- 37. Transfer of a hazard from feed to edible product depends on its kinetics in the food-producing animal, including absorption, biotransformation, distribution, excretion, and the potential for accumulation or proliferation in tissues.
- 38. The kinetics may be influenced, in particular, by:
 - Biological or chemical properties of the hazard;

- Species, breed, gender, life stage, and health status of the food-producing animal;
- Frequency and duration of feed intake;
- Formulation of the feed and potential interaction between the hazard and feed components.
- 39. Published, peer-reviewed, toxicokinetic or other models that can predict the transfer of hazard from feed to edible products, may be used or adapted for a given exposure assessment. Sources of information should be documented.
- 40. The feed exposure assessment should result in the determination of the predicted level or prevalence of a hazard in edible product. This result is then incorporated as a starting point in the human exposure assessment for food. The evaluation of the human exposure to the hazard should be done using relevant foods and food groups and/or specific human populations to account for feed as a source of exposure, (e.g. by modelling).

Risk characterization

- 41. Risk characterization, in a feed risk assessment, considers the outcomes from the hazard characterization and the exposure assessment to derive a risk estimate for food safety.
- 42. A first risk estimate may be performed by a comparison of the predicted levels of the hazard in edible product with existing national or international maximum levels for food commodities.
- 43. If a more extensive risk assessment is required, a risk estimate could be, for example: (a) an estimate of the probability that a given concentration of hazard in feed may result in a concentration in edible product, the human consumption of which may lead to exceeding a national or international health based guidance value (e.g. ADI, TDI); or (b) an estimate of the probability that an infectious agent in feed could lead to an infection in an animal, which may result in an unacceptable contamination of edible product.
- 44. When the hazard is also present in environmental sources such as water and air, or in foods of non-animal origin, other exposure assessments on these sources should be taken into consideration for the risk characterization and subsequent risk management options.
- 45. Additional outputs of a risk assessment, which would have been defined in the initiation of the risk assessment, can include evaluation of the effect of different risk management options on the estimated health risk.

REPORTING

- 46. The risk assessment should be fully and systematically documented and communicated to the risk manager.
- 47. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessor.
- 48. The conclusions of the risk assessment should be presented in a readily understandable and useful form to the risk manager and made available to other risk assessors and interested parties so that they can review the assessment.

ANNEX I

WHO Human Health Risk Assessment Toolkit: Chemical Hazards. IPCS Harmonization Project Document No. 8. WHO, Geneva, 2010. ISBN 978 92 4 154807 6.

(http://www.who.int/entity/ipcs/publications/methods/harmonization/toolkit.pdf)

FAO/WHO Expert Meeting report on Animal Feed Impact on Food Safety. FAO/WHO, Rome, 2008. ISBN 978-92-5-105902-9. (ftp://ftp.fao.org/docrep/fao/010/a1507e/a1507e00.pdf)

FAO/WHO Microbiological risk assessment publications

(http://www.who.int/foodsafety/publications/micro/en/) including Hazard Characterization for Pathogens in Food and Water (MRA Series 3); Exposure Assessment of Microbiological Hazards in Food (MRA Series 7); Risk Characterization of Microbiological Hazards in Food (MRA Series 17).

Relevant sections of: OIE Terrestrial Animal Health Code

(http://www.oie.int/en/international-standard-setting/terrestrial-code/)

OIE Aquatic Animal Health Code

(http://www.oie.int/en/international-standard-setting/aquatic-code/)

FAO Good Practices for the Feed Industry. FAO Animal Production and Health Manual No. 9. FAO/IFIF, Rome, 2010. ISBN 978-92-5-106487-0. (http://www.fao.org/docrep/012/i1379e/i1379e00.htm)

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

(http://www.who.int/foodsafety/chem/jecfa/publications/en/ and

http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/

Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

(http://www.who.int/foodsafety/chem/jmpr/en/ and

http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/en/)

Joint FAO/WHO expert meetings on microbiological risk assessment (JEMRA)

(http://www.who.int/foodsafety/micro/jemra/en/ and

http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/

WHO International Programme on Chemical Safety (IPCS)

(http://www.inchem.org/)

WHO Concise International Chemical Assessment Documents (CICAD)

(http://www.who.int/ipcs/publications/cicad/)

The Gateway to Animal Feeding provides additional references and documents relevant to risk assessment of animal feed (http://www.fao.org/animalfeeding).

Appendix III

PROPOSED DRAFT GUIDANCE FOR GOVERNMENTS ON PRIORITIZING HAZARDS IN FEED (at Step 5/8 of the Procedure)

INTRODUCTION

- 1. Hazard prioritization is part of the risk management process within the risk analysis framework.
- 2. The purpose of prioritizing hazards in feed as described in this document is to contribute to the safety of edible products by optimizing allocation of the resources required for risk assessment and risk management.

SCOPE

- 3. This document provides guidance to governments on prioritizing hazards in feed and feed ingredients using the multi-criteria analysis approach. However, it is recognized that other approaches to prioritize hazards might be used.
- 4. This guidance is applicable to all hazards in the feed of food-producing animals which may adversely affect human health. Agents which may adversely affect animal health but which have no impact on food safety are not considered in this guidance, as they are not within the scope of the Codex Alimentarius.
- 5. Direct human exposure to hazards in feed, for example occupational exposure during feed production and processing, is not considered, as it is not within the scope of the Codex Alimentarius.

DEFINITIONS

6. The following definitions are included to establish a common understanding of the terms used in this guidance.

Biotransformation product: Product resulting from the transformation of a chemical or biological agent in the body of the food-producing animal (e.g. via metabolic processes).

Contaminant: 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.²

Cross-contamination: Contamination of a material or product with another material or product, including contamination originating from the previous use of equipment.

Edible product: Any tissue or product from a food-producing animal which is intended for human consumption, including for example meat, fish, eggs and milk.

Feed (Feedingstuff): Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food-producing animals.³

Feed additive: Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, that affects the characteristics of feed or animal products. Micro- organisms, enzymes, acidity regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration.²

Feed ingredient: A component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant, animal or aquatic origin, or other organic or inorganic substances.²

Food: means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which have been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs.²

¹ Throughout this document the term "feed" refers to both feed and feed ingredients, unless otherwise stated

² Codex Alimentarius Commission: Procedural Manual

³ Code of Practice on Good Animal Feeding (CAC/RCP 54-2004)

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.² In this guidance, it refers to an agent in feed which has the potential to cause an adverse human health effect after transfer into an edible product.

Medicated feed: Any feed which contains veterinary drugs as defined in the Codex Alimentarius Commission Procedural Manual.³

Processing Aid: Any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, food or food ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.² (In this guidance this definition applies to feed and feed ingredients).

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.² In this guidance, it may also refer to the probability that a hazard in feed eaten by a food-producing animal will transfer to an edible product at a level which may cause an adverse health effect in humans.

Risk analysis: A process consisting of three components: risk assessment, risk management and risk communication.²

Risk assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.²

Risk characterization: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.³

Risk communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.²

Risk management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.²

Transfer: Passing of a chemical or biological hazard (including hazardous biotransformation products) from feed of a food-producing animal to an edible product of the animal.

Undesirable substances: Contaminants and other substances, which are present in and/or on feed and feed ingredients and which constitute a risk to consumers' health, including food safety related animal health issues.³

PRIORITIZATION OF HAZARDS IN THE FRAMEWORK OF CODEX RISK ANALYSIS

- 7. Risk analysis comprises three distinct but closely linked components: risk assessment, risk management, and risk communication.²
- 8. Risk management comprises preliminary risk management activities (including: identification of a food safety problem arising from feed; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; determination of a risk assessment policy for the conduct of the risk assessment; definition of the output form of the risk assessment; commissioning of the risk assessment; and consideration of the possible results of the risk assessment), evaluation of risk management options, implementation of risk management options, monitoring and review⁴. Prioritization of hazards in feed is part of preliminary risk management activities but can also be undertaken at any point of the risk analysis process.
- 9. Annex 3 lists references that have been used when developing this document.

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Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)

10. Details of the steps are described below. An example of the prioritization process based on these steps is given in Annex 1 for illustrative purposes only.

PRIORITIZATION PROCESS

- 11. The prioritization process provides ranking for different combinations of hazard, feed and edible product in a risk analysis framework. A defined prioritization process ensures transparency and repeatability, and facilitates re-evaluation when new data are available without repeating all steps.
- 12. The prioritization process in this guidance comprises the following steps:
 - Step 1. Identification of the hazard, the feed and the edible product potentially associated with food safety problems.
 - Step 2. Identification and definition of the criteria by which each selected hazard/feed/edible product combination will be quantified.
 - Step 3. Assignment of criterion-based values to the hazard/feed/edible product combinations.
 - Step 4. Normalization of these values to make them comparable between criteria.
 - Step 5. Weighting of the criteria to reflect their relative importance.
 - Step 6. Combining the weighted normalized values for each hazard/feed/edible product combination to produce a score, and ranking of the scores to obtain the order of priority.
 - Step 7. Reporting of the process, methods and results.

Step 1. Identification of the hazard, the feed and the edible product potentially associated with food safety problems

- 13. In this initial screening step, the risk manager identifies hazard/feed/edible product combinations which are potentially associated with food safety problems, and which may need to be prioritized for risk assessment and risk management. Further guidance on risk assessment of feed is provided in the Guidelines on Application of Risk Assessment for Feed.
- 14. Useful information on the presence of the hazard in feed and/or edible product may be obtained from existing risk profiles and risk assessments, and from regulatory surveillance programs/data, published data from government agencies and scientific peer-reviewed publications, and from international programs such as the WHO Global Environment Monitoring System (GEMS/Food); the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN) (references in Annex 3); and other reliable rapid alert systems, and industry self-monitoring programs.
- 15. Information which may be useful includes:
 - Descriptions of the hazard, the feed and edible product;
 - Description of the food safety problem potentially associated with the hazard/feed/edible product combination;
 - Chemical or biological characteristics and toxicology profile of the hazard;
 - Levels of hazard in feed and edible products;
 - Possible sources of hazard during production, processing, packing, packaging, transport, storage and use;
 - Relevant legislation;
 - Information on economic impact;
 - Information on knowledge gaps.
- 16. If the data obtained in this step indicate that the association of a specific hazard/feed/edible product combination with a food safety problem is negligible, it may be decided to exclude that combination from further steps. Such screening should use defined exclusion/inclusion decision rules (for example, no occurrence in the area under consideration during a given time-frame).
- 17. Examples of hazards with potential relevance for human health are given in Annex 2.

Step 2. Identification and definition of the criteria by which each selected hazard/feed/edible product combination will be quantified

- 18. The criteria to be used to prioritize the hazard/feed/edible product combinations should be relevant and reflect the purpose of the prioritization.
- 19. Criteria which could be considered include those related to the extent of occurrence of a hazard in feed and edible product, effects on human health, and other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.
- 20. Each criterion should be defined so that there is no ambiguity in interpretation and so that it can be described quantitatively (e.g. number of illnesses, concentration of a hazard). Semi-quantitative descriptions (e.g. low, medium, high) should be clearly explained.
- Identification and definition of the criteria should be done with the assistance of experts.

Step 3. Assignment of criterion-based values to the hazard/feed/edible product combinations

22. For each of the criteria, a value is assigned by experts to the hazard/feed/edible product combinations. Depending on the hazard/feed/edible product combinations and the criteria, different specialized experts may be needed.

Step 4. Normalization of these values to make them comparable between criteria

- 23. To permit comparison of values between criteria, they need to be normalized to a common scale with defined levels.
- 24. The method used for normalizing should be developed by experts and fully documented.

Step 5. Weighting of the criteria to reflect their relative importance

- 25. Criterion weighting is done independently from the previous steps, typically by risk managers with the support of experts, when required.
- 26. Each criterion is assigned a weighting which reflects its relative importance. The sum of the weightings is 100%.

Step 6. Combining the weighted normalized values for each hazard/feed/edible product combination to produce a score, and ranking of the scores to obtain the order of priority

- 27. For each hazard/feed/edible product combination, the weighted normalized values are combined to obtain a score, e.g. (C1*W1)+(C2*W2)+...(Cn*Wn), where C are the normalized criteria values and W are the criteria weights.
- 28. Ranking of the scores of each of the hazard/feed/edible product combinations yields the prioritized list, which reflects both the normalized criteria values and the weighting of the criteria.
- 29. It is important to demonstrate the influence of any assumptions used in the ranking process. This could be done for example by using sensitivity analyses (e.g. weighting all criteria equally or weighting which reflects the relative importance of each criterion).

Step 7. Reporting of the process, methods and results

- 30. The prioritization process, methods and results should be documented and reported fully, systematically and transparently. This should include:
 - The rationale for the choice of hazard/feed/edible product combinations;
 - The rationale for the criteria;
 - The rationale for the normalization method;
 - The rationale for the weightings;
 - An estimate of the sensitivity of the ranking to the normalization method and the weightings, if conducted;
 - Identification of all data gaps, assumptions and uncertainties.

ANNEX 1

EXAMPLE OF THE PRIORITIZATION PROCESS

The following is a fictitious example, which is intended only to illustrate the steps in the prioritization process. This example uses applicable but not exhaustive criteria and the values used are illustrative. In a real-life situation, details of the procedure, particularly the criteria definitions, quantification, normalization of the values and weighting of the criteria, must be developed on a case-by-case basis in consultation with experts.

<u>Step 1. Identification of the hazard, the feed and the edible product potentially associated with food</u> safety problems

For simplicity, this example uses only three hazard/feed/edible product combinations ("combinations 1, 2 and 3") to demonstrate the prioritization procedure. The process is however primarily intended to be used with a larger number of combinations.

<u>Step 2. Identification and definition of the criteria by which each selected hazard/feed/edible product combination will be quantified</u>

This example uses four criteria (C1-C4). The descriptions/definitions of these criteria are briefly summarized in Table 1.

Table 1: Criteria chosen for this example

| Criterion | Description/definition |
|---|--|
| C1. Occurrence level in feed | % of feed samples exceeding a defined level for the hazard |
| C2. Transfer from feed to edible product | %, based on measurement or modeling |
| C3(a) Toxicity of chemical hazard or | (a) Health-based guidance value (e.g. ADI ⁵ or TDI ⁶) |
| C3(b) Health effects of biological hazard | (b) Number of hazard-related illnesses |
| C4. Impact on feed availability | Replacement feed available (easy, difficult, impossible) |

Step 3. Assignment of criterion-based values to the hazard/feed/edible product combinations

For each of the criteria C1 to C4, a value is assigned to each hazard/feed/edible product combination, and categorized as shown in Table 2.

Step 4. Normalization of these values to make them comparable between criteria

An example of normalization is summarized in Table 2. In this example, each criterion value is assigned to one of a range of levels chosen for this example and then normalized to a scale of 0, 0.5, 1.0.

Table 2: Normalization of values

| Normalized value | 0 | 0.5 | 1.0 |
|--|--------------------|--------------------------|------------------------|
| | Low | Medium | High |
| C1. Occurrence level in feed (% of feed samples exceeding a defined level for the hazard) | <10% | 10–25% | >25% |
| C2. Transfer from feed to edible product (based on measurement or modeling) | <5% | 5-50% | >50% |
| C3(a). Toxicity of chemical hazard (health-based guidance value (e.g. ADI ⁵ or TDI ⁶) | >1 mg/kg bw/day | 1 μg-1 mg/kg bw/day | <1 μg/kg bw/day |
| C3(b). Health effects of biological hazard (number of hazard-related illnesses per 100'000 of population) | <0.1 | 0.1-1 | >1 |
| C4. Impact on feed availability (replacement feed available) | Replacement easy | Replacement difficult | Replacement impossible |

⁵ Acceptable Daily Intake (ADI)

⁶ Tolerable Dietary Intake (TDI)

Step 5. Weighting of the criteria to reflect their relative importance

The weightings chosen for the criteria C1 to C4 in this example are summarized in Table 3.

Table 3: Criterion weighting chosen for this example

| Criterion | Weighting code | Average weighting decided by experts |
|--|----------------|--------------------------------------|
| C1. Occurrence level in feed | W1 | 15% |
| C2. Transfer from feed to edible product | W2 | 40% |
| C3. Health hazard ((a) or (b), depending on the hazard*) | W3 | 30% |
| C4. Impact on feed availability | W4 | 15% |
| Sum | | 100% |

^{*} C3(a) for chemical hazards, C3(b) for biological hazards

Table 3 shows that the criterion related to transfer from feed to edible product in this example is assigned the greatest weight (40%), followed by health hazard, occurrence level, and impact on feed availability.

Step 6. Combining the weighted normalized values for each hazard/feed/edible product combination to produce a score, and ranking of the scores to obtain the order of priority

The score for each hazard/feed/edible product combination in this example is calculated using the following equation:

Score = C1*W1 + C2*W2 + C3(a or b)*W3 + C4*W4

where C are the combination-specific normalized values and W are the criteria weightings.

An example of the calculation of the score for one hazard/feed/edible product combination is shown in Table 4.

Table 4: Example of scoring of a hazard/feed/edible product combination for Combination 1 (for a chemical hazard)

| Criterion | Value | Normalized value (C) | Criterion Weight (W) | C *W |
|--|---------------------|----------------------|----------------------|------|
| C1. Occurrence level in feed | <10% | 0 | 15% | 0 |
| C2. Transfer from feed to edible product | 5-50% | 0.5 | 40% | 0.2 |
| C3(a). Health hazard | <1 µg/kg bw /day | 1.0 | 30% | 0.3 |
| C4. Impact on feed availability | Low | 0 | 15% | 0 |
| Score | | | | 0.5 |

This scoring is performed for each hazard/feed/edible product combination to be prioritized.

Scores and the resulting ranking/prioritization of Combination 1 with two other hypothetical hazard/feed/edible product combinations are summarized in Table 5.

Table 5: Prioritization of three hazard/feed/edible product combinations based on ranked scores

| Hazard/feed/edible product combination | Score | Ranking / priority |
|--|-------|--------------------|
| Combination 1 | 0.5 | 2 |
| Combination 2 | 0.475 | 3 |
| Combination 3 | 0.75 | 1 |

Step 7. Reporting of the process, methods and results

The report should include full documentation as described in paragraph 30 of the Guidance.

ANNEX 2

EXAMPLES OF HAZARDS IN FEED WITH POTENTIAL RELEVANCE FOR HUMAN HEALTH

- 1. This Annex is not a comprehensive description of the different situations related to feed and food safety. The information included in this Annex may need to be updated as more scientific knowledge becomes available on these issues. By illustrating hazards which may occur in different parts of the world, this Annex is intended to provide additional information on how to use the prioritization procedure in practice as described in the guidance. Therefore, this Annex should not be taken as a risk assessment of the cases mentioned.
- 2. This Annex should be considered in conjunction with the report of the FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety (FAO/WHO, Rome, 2008) when making the initial step of the prioritization process.
- 3. The examples may not be relevant everywhere or at all times; they simply illustrate the range of hazards, feeds and edible products which may need to be considered in a given location at a given time. In addition, rare and emerging hazards are not covered.
- 4. The following examples are listed according to the types of hazards.

Biological hazards

Bacteria

- 5. The primary microbiological hazards in feed that can transfer to edible products of food-producing animals are zoonotic microorganisms contaminating feeds. These microorganisms may be introduced into feed by, for example, crops, forages and water from contaminated pasture land or cross-contamination from infected animals (including carcasses) during feed production, processing, transport, storage and use.
- 6. <u>Salmonella</u> is a worldwide human health concern. Contaminated feed can represent a route of exposure of food-producing animals to *Salmonella*. Edible products affected can include eggs, meat and meat products. However, the correlation between contaminated feed and infection by a given *Salmonella* strain and the contamination of edible products from these animals needs to be established on a case-by-case basis. Adequate strain typing is necessary to establish such correlations. Strain typing is also important to identify strain types that are more commonly associated with human pathogenicity. In the absence of the establishment of such correlation or of strain typing, any contamination of feed with *Salmonella* could be considered as a hazard, particularly if not adequately heat-treated prior to its use.
- 7. <u>Brucella</u>: In countries where <u>Brucella</u> is endemic, pasture may be contaminated by ruminants which deliver or abort offspring there, because the placentas of infected animals contain high levels of these microorganisms. Milk-producing animals may become infected by eating forage from contaminated pastures and excrete the microorganisms in their milk. This milk may be a risk to human health if not pasteurized prior to use.

Endoparasites

8. Some animal endoparasites, such as *Toxoplasma* and *Taenia* spp., are human health hazards. Various life stages of these organisms may contaminate pasture and forages and the derived feed via infected animals. Ingestion of contaminated feed by food-producing animals can result in the presence of infective cysts in edible products (e.g. meat), which may pose a risk to human health, particularly if not adequately heat treated prior to consumption.

Prions

9. Prions are infectious agents composed of protein in a misfolded form which induces existing, properly-folded prion protein (PrPc, a constituent of normal mammalian cells) to convert into the disease-associated, prion form (PrPsc). Prions are responsible for the transmissible spongiform encephalopathies in a variety of mammals, including bovine spongiform encephalopathy in cattle and variant Creutzfeldt–Jakob disease in humans. Prions are extremely resistant to denaturation by chemical and physical agents including heat. Exposure of food-producing animals can occur via feed contaminated with material from prion-infected carcasses. Transfer from prion-contaminated feed to edible products has been demonstrated.

Chemical hazards

Elements

10. A number of elements may present a hazard to humans. This includes radionuclides and elements commonly referred to as "heavy metals", such as arsenic, cadmium, lead and mercury.

- 11. Radionuclides including caesium-134, caesium-137, strontium-90 and iodine-131 present in animal feed and forages may transfer to edible products. Major sources are contaminated soil, water and forage. Transfer of radioiodine to milk, radiostrontium to bone, and radiocesium to milk, eggs and meat has been demonstrated.
- 12. The following are non-exhaustive examples of "heavy metals":
 - <u>Arsenic</u> is a naturally-occurring contaminant found in minerals and (mainly in the less toxic organic form) in marine plants, fish and shellfish and other farmed aquatic animals.
 - <u>Cadmium</u> is a naturally-occurring contaminant in soil minerals (such as phosphate and zinc sources), and in forages and cereals grown near smelting and mining areas, or where the soil has been treated with contaminated manure, sewage, sludge or phosphate fertilizers; edible products affected include shellfish, oysters, salmon, also kidney and liver.
 - <u>Lead</u> contamination may occur naturally or from industrial waste in, for example, feed minerals (e.g. copper sulphate, zinc sulphate, zinc oxide) and in forages and cereal via air, soil or water contamination; it is found in edible products such as fish, milk, bone, brain and kidney.
 - Mercury from industrial sources, which contaminates soil and water can produce secondary contamination of forages, crops and aquatic organisms; edible products affected have included liver, kidney, fish, and other aquatic animals.

Toxins

- 13. Toxins are naturally occurring hazards that include:
 - Mycotoxins, e.g. aflatoxins, ochratoxins, zearalenone;
 - Bacterial toxins, e.g. botulinum toxin and staphylococcal enterotoxin;
 - Terrestrial plant toxins, e.g. solanine in potatoes, gossypol in cottonseed;
 - Marine toxins, e.g. toxins from certain algae, particularly dinoflagellates.

Mycotoxins

- 14. Mycotoxins are produced by fungi commonly found in cereals (especially wheat, sorghum and maize), oilseed meals and cakes, and silage.
- 15. Transfer from feed to edible products has been demonstrated for various mycotoxins including aflatoxins and ochratoxins.
- 16. Aflatoxins can occur in e.g. copra, peanut cake, sunflower cakes, corn, corn gluten, rice bran, cottonseed, palm kernel and soy beans. Aflatoxin B_1 is metabolized in some food-producing animals to aflatoxin M_1 which transfers to milk. Aflatoxin M_1 is a human carcinogen.
- 17. Ochratoxin A is most commonly found in cereals such as rye, barley, maize and wheat, and to a lesser extent in peanuts and soybeans. It transfers to edible products such as blood, liver and kidney and to a lesser extent meat, fat and milk. Ochratoxin A is nephrotoxic in humans.
- 18. Fumonisins, deoxynivalenol, T-2 and HT-2 toxin and zearalenone are rapidly metabolized and/or excreted by food-producing animals and are therefore not major contaminants of edible products.

Bacterial toxins

19. A limited number of toxins produced by bacteria such as *Clostridium botulinum*, *C. tetani* and *C. perfringens*, *Vibrio cholerae*, *Staphylococcus aureus*, *Yersinia enterocolitica*, and *Shigella dysenteriae* are acutely toxic to food-producing animals when ingested with feed but transfer of toxin to edible products is unlikely.

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Terrestrial plant toxins

20. Toxin-producing plants may occur in grasslands used for forage. Naturally occurring toxins can include pyrrolizidine alkaloids (e.g. jacoline from *Senecio jacobaea*) and other alkaloids (e.g. atropine, cocaine, ephedrine, morphine, nicotine, solanine), terpenes (e.g. camphor, pinene), tetrahydrocannabinol, gossypol, isoflavones, and glycosides (e.g. cyanogenic glycosides, digitalis). Transfer of some of these toxins to edible products such as milk and meat has been demonstrated.

Marine toxins

21. Dinoflagellates such as *Gambierdiscus toxicus* in tropical and subtropical waters produce marine toxins including heat-resistant ciguatoxin, maitotoxin, scaritoxin and palytoxin. Small filter-feeding fish which can accumulate such biotoxins and their predators may be harvested and used to make fish meal. Transfer of ciguatera toxin to human milk after maternal poisoning has been reported, so transfer from feed to milk of food-producing animals is a possibility.

Organic chemicals

- 22. Of the many organic chemical contaminants that are present in the environment and therefore are potentially present in feed, it is the lipophilic compounds that have the greatest tendency to accumulate in edible products of food-producing animals.
- 23. Polychlorinated dibenzodioxins (PCDD) and polychlorinated dibenzofurans (PCDF) commonly known as dioxins, and organochlorine pesticides such as aldrin, dieldrin, and dichlorodiphenyltrichloroethane (DDT), are lipophilic and have long half-lives in the environment. Dioxins in feed may arise by contamination, for example from dioxin-containing preservatives in wood, or from combustion sources (e.g. waste incineration plants, fossil fuel power stations, bush fires, exhaust gases) or by chemical reactions during processing involving solvents containing chlorine. Dioxins may be present as contaminants in mineral sources, such as clays, recuperated copper sulphate, zinc oxide, and in food by-products, including fish by-products such as fish meal and fish oils. Dioxin contamination of edible products has been reported for fish, fat of meat, milk, and egg yolk.
- 24. Polychlorinated biphenyls (PCBs) have been widely used in a number of industrial and commercial applications. Although the manufacture, processing and distribution of PCBs have been prohibited in almost all industrial countries since the 1980s, their entry into the environment still occurs. Following exposure of farmed animals, including aquaculture, PCBs will accumulate in meat, liver and particularly in fat tissues. PCBs have been reported to be associated with an increased risk of cancer of the digestive system and possibly other sites.

Pesticides, veterinary drugs, feed additives and processing aids

- 25. Cross-contamination of feed by pesticides, veterinary drugs, medicated feed, feed additives and processing aids may occur during production, processing, transport or storage.
- 26. Unapproved use of pesticides, veterinary drugs, medicated feed, feed additives and processing aids, or the presence of undesirable substances, may lead to excessive levels in feed and edible products (e.g. clenbuterol in meat).

ANNEX 3

ADDITIONAL REFERENCES

Useful sources of information on potential hazard/feed/edible product combinations include:

WHO Global Environment Monitoring System (GEMS) (WHO Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food). (http://www.who.int/foodsafety/chem/gems/en/)

Joint FAO/WHO International Food Safety Authorities Network (INFOSAN) (WHO International Food Safety Authorities Network (INFOSAN); (http://www.who.int/foodsafety/fs_management/infosan/en/).

Notifications from the European Rapid Alert System for Food and Feed (EU RASFF); (https://webgate.ec.europa.eu/rasff-window/portal/index.cfm?event=notificationsLis t)

Some examples of prioritization frameworks, processes and methods are given in:

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FDA 2011. Multi-Criteria Decision Analysis Methodology Used to Prioritize Inspection of Subject: Egg Farms for Monitoring Compliance with the Egg Safety Rule. U.S. Food and Drug Administration, Department of Health and Human Services, Memorandum, August 9, 2011.

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Henson SJ, Caswell JA, Cranfield JAL, Fazil AF, Davidson VJ, Anders SM, Schmidt C (2007). A Multi-Factorial Risk Prioritisation Framework for Food-Borne Pathogens. University of Massachusetts, Amherst MA, Department of Resource Economics. Working Paper No. 2007-8, 21 May 2007. (http://people.umass.edu/resec/workingpapers/documents/ResEcWorkingPaper2007-8.pdf)

Humblet MF, Vandeputte S, Albert A, Gosset C, Kirschvink N, Haubruge E, Fecher-Bourgeois F, Pastoret PP, Saegerman C (2012). Multidisciplinary and evidence-based method for prioritizing diseases of food-producing animals and zoonoses. Emerg Infect Dis 18(4):e1. doi: 10.3201/eid1804.111151

Lake R, Hudson A, Cressey P, Nortje G (2000). Risk Profiles For The Foods New Zealanders Eat: Project F13ra3. Prepared as part of a Ministry of Health contract for scientific services by ESR Risk Profile Project Team, November 2000. (http://www.foodsafety.govt.nz/elibrary/industry/Risk Profiles-Science Research.pdf

New Zealand Ministry for Primary Industries, Food safety science group. Risk ranking. (http://www.foodsafety.govt.nz/science-risk/risk-assessment/risk-ranking.htm.)

Ng V, Sargeant JM (2010). A stakeholder-informed approach to the identification of criteria for the prioritization of zoonoses in Canada. PLoS One7(1):e29752. doi: 10.1371/journal.pone.0029752

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