CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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REP12/AF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty fifth Session
Rome, Italy, 2-7 July 2012

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

Berne, Switzerland
20-24 February 2012

NOTE: This report contains Codex Circular Letter CL 2012/3-AF

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CL 2012/03-AF
February 2012

To: Codex Contact Points
Interested International Organizations

From: Secretariat,
Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
00153 Rome, Italy

Subject: **Distribution of the Report of the Sixth Session of the *Ad Hoc* Intergovernmental Codex Task Force on Animal Feeding (REP12/AF)**

The report of the Sixth Session of the *Ad Hoc* Intergovernmental Codex Task Force on Animal Feeding will be considered by the 35th Session of the Codex Alimentarius Commission (Rome, Italy, 2-7 July 2012)

MATTERS FOR ADOPTION BY THE 35TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Proposed Draft Standards and Related Texts at Step 5 of the Procedure

Proposed draft Guidelines on Application of Risk Assessment for Feed at Step 5 (para. 47 and Appendix II).

Governments and international organizations wishing to submit comment on the above texts should do so in writing, ***preferably by e-mail***, 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, fax : +39 06 57054593) **before 30 April 2012.**

Content

SUMMARY AND CONCLUSIONS

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

Matters for the 35th Session of the Codex Alimentarius Commission

Matters for adoption

Proposed draft Standards and Related Texts at Step 5 of the Procedure

The Task Force agreed to forward the proposed draft "Guidelines on application of risk assessment for feed" to the Commission for adoption at Step 5 (*see* para. 47 and Appendix II).

Matters of interest

The Task Force agreed that the document on prioritised list of hazards in feed would only focus on the criteria for prioritization of hazards in feed and on guidance on how governments could use these criteria. The Task Force agreed to return the renamed proposed draft "Guidance for use by governments in prioritizing their national feed hazards" to Step 2 for redrafting by an electronic working group, for circulation for comments at Step 3 and further consideration at its next session (*see* paras 77-83).

LIST OF ABBREVIATIONS USED IN THIS REPORT

ADI	Acceptable Daily Intake
CAC/GL	Codex Alimentarius Commission / Guidelines
CAC/RCP	Codex Alimentarius Commission / Recommended Code of Practice
CCCF	Codex Committee on Contaminants in Foods
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CL	Circular Letter
CRD	Conference Room Document
FAO	Food and Agriculture Organization of the United Nations
FOAG	(Swiss) Federal Office for Agriculture
GAP	Good Agricultural Practice
GEMS/Food	WHO Global Environment Monitoring System
IFIF	International Feed Industry Federation
INFOSAN	International Food Safety Authorities Network
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
JEMRA	Joint FAO/WHO expert meetings on microbiological risk assessment Joint
ML	Maximum Level
MRL	Maximum Residue Limits
TFAF	*Ad hoc* Intergovernmental Codex Task Force on Animal Feeding
OIE	World Organisation for Animal Health
WHO	World Health Organization
WTO	World Trade Organization

INTRODUCTION

1. The *ad hoc* Intergovernmental Codex Task Force on Animal Feeding (TFAF) held its Sixth Session in Berne, Switzerland, from 20 to 24 February 2012, 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 139 delegates from 43 Member countries and one Member organization, 11 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 Prof Bernard Lehmann, Director-General of the Swiss Federal Office for Agriculture. In his keynote address, Prof Lehmann provided information on the status of Swiss agriculture and highlighted the importance of the food chain approach and of animal feed to ensure the production of food to respond to consumer demand for safe food. He emphasized that, while it was important to have a science-based approach to food safety, it was also important to consider consumers' concerns. In closing, Prof Lehmann wished the Task Force every success in its work.

Division of Competence[1]

3. 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]

4. 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]

5. The Task Force noted relevant decisions of the 33rd Session of the Codex Alimentarius Commission regarding the recommendations of the electronic working group established by the 32nd Session of the Commission on future work on animal feeding, as presented in CX/AF 12/6/2. The Task Force also noted the status of the discussion in various Committees on the proposed revision of their texts on risk analysis as to their applicability to feed and looked forward to being informed on further progress at its next session.

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

FAO and WHO

6. The Task Force noted the information provided by FAO and WHO on activities relevant to its work, as presented in CX/AF 12/6/3.

7. The FAO Representative informed the Task Force that for several years the FAO Programme of Work and Budget had included activities addressing capacity development for animal feeding and feed safety. In particular: the FAO/WHO Expert Meeting on "Animal feed impact on food safety" organized in 2007 that provided scientific advice; the FAO/IFIF Manual on Good Practices for the Feed Industry, which offered practical guidance on compliance with the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004); and activities that enhance dialogue and collaboration between the private and public sectors, such as the International Feed Regulator Meetings, organized annually and jointly with the International Feed Industry Federation (IFIF).

8. The Task Force noted that FAO was also addressing potential food safety hazards entering aquaculture through fish feed and the measures to minimize these hazards, for example through the FAO Technical

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1 CRD 1 (Annotated Agenda – Division of competence between the European Union and its Member States)
2 CX/AF 12/6/1
3 CX/AF 12/6/2; CRD 2 (Comments of Mali and Kenya)
4 CX/AF 12/6/3; CX/AF 12/6/3 Add.1; CRD 2 (Comments of Mali and Kenya)

Guidelines for Aquaculture Certification and the Supplement No 5 to the Technical Guidelines for Responsible Fisheries: Aquaculture Development.

9. Additional information was also provided on the work on criteria for the global identification and notification of emergency situations affecting animal feed and the fact that FAO was currently considering existing FAO and WHO mechanisms to verify whether they could adequately address such situations.

10. The Representative of WHO informed the Task Force that the human health impact from animal feeding, where relevant, was being addressed in the scientific advice activities and food risk assessments done by FAO and WHO expert bodies such as JECFA, JMPR and JEMRA or *ad hoc* expert meetings. To illustrate this, the Representative provided the following examples: (i) the consideration of antimicrobial resistance by WHO jointly with FAO and OIE which addressed the use of antimicrobial agents such as feed additives; and (ii) the *ad hoc* expert meeting on melamine, held by WHO in collaboration with FAO, which also considered the public health impact of melamine in and carried-over from animal feed.

11. The Representative indicated that the outcome of these scientific advice activities was taken into consideration by the relevant Codex subsidiary bodies and facilitated the development of the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011) and the Maximum Levels for melamine in food and in feed in the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995), respectively.

World Organisation for Animal Health (OIE)

12. The Observer from OIE, referring to CX/AF 12/6/3 Add.1, provided a brief update on relevant OIE activities and noted that since 2001, at the request of OIE members, the OIE mandate had included setting standards for animal production food safety, i.e. the management of risks arising at the level of the farm through to primary processing. 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.

13. The Observer from OIE noted that the OIE would continue to address food safety related issues as a high priority in its standard setting work and would continue working closely with the Codex Alimentarius Commission and its subsidiary bodies.

Conclusion

14. 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)[5]

15. The Task Force recalled that Switzerland had prepared a first version of the proposed draft Guidelines (CX/AF 12/6/4) that was circulated for comments at Step 3 and that a second version ("revised version") of these Guidelines (CX/AF 12/6/4 Add.2) had been prepared based on the comments submitted. The "revised version" was also circulated for comments at Step 3 and would be considered at the present session.

16. The Delegation of Switzerland introduced the "revised version" of the Guidelines and explained that they had tried to address the mandate given in the first term of reference of the Task Force (*see* Procedural Manual). The Delegation briefly described the various sections, which illustrate the four components of risk assessment, namely: hazard identification, hazard characterization, exposure assessment and risk characterization.

17. The Delegation highlighted that the Guidelines addressed only hazards in animal feed that enter the food chain via dietary exposure of food-producing animals and transfer into their edible products.

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[5] CX/AF 12/6/4; CX/AF 12/6/4 Add. 1 (Comments at Step 3 of Australia, Brazil, Canada, Colombia, Costa Rica, European Union, Iran, Japan, New Zealand, Philippines, United States of America and IFIF); CX/AF 12/6/4 Add. 2 (Proposed draft Guidelines on application of risk assessment for feed – revised version); CX/AF 12/6/4 Add. 3 (Comments at Step 3 of Argentina, Canada, Chile, Iran, Japan, Norway, Thailand, United States of America, FAO, IDF, IFIF and OIE); CX/AF 12/6/4 Add. 4 (Comments of Australia, European Union, Indonesia, Mali and Philippines); CRD 3 (comments of Ghana); CRD 4 (Proposed revision of selected sections of the proposed draft Guidelines); CRD 5 (Proposed revision of "Exposure assessment" section)

General discussion

18. The Task Force had a general discussion on the proposed draft guidelines. Delegations were of the opinion that the document was a good basis for further elaboration and that there was a need: to focus on scientific aspects associated with hazards in feed; to improve the readability of the document and make it more consistent with other related Codex texts; to better clarify the scope and to whom the Guidelines were addressed; to clarify that the Guidelines address feed for all food-producing animals, including those from aquaculture; to discuss whether biological hazards were to be addressed, as the terms of reference refer to "hazards related to contaminants/residues"; and to discuss whether feed additives could be included.

19. With regard to the scope of the Guidelines, the Codex Secretariat reminded the Task Force that the Guidelines were intended for governments on how "to apply risk assessment methodologies" and not to replace the work on the development of Maximum Residue Limits (MRLs) for veterinary drugs and pesticides and Maximum Levels (MLs) for contaminants by the Committees on Residues of Veterinary Drugs in Foods (CCRVDF), on Pesticide Residues (CCPR) and on Contaminants in Foods (CCCF), respectively.

20. The Task Force agreed that the Guidelines, when finalised, would provide a useful tool to countries for addressing hazards in feed and thereby contributing to food safety. It was further agreed that aspects related to animal health and welfare were outside the scope of the work of Codex and, therefore, should not be considered in the Guidelines.

21. The Task Force considered the document section by section and, in addition to editorial amendments for the purpose of clarity, made the following comments and changes.

Specific comments[6]

Introduction

22. The Task Force considered that the contents of the Introduction were sufficient for its purpose and that there was no need to include additional information. Paragraph 2 was amended to clarify that risk assessment of hazard in feed impacted on food safety and human health and that the application of the guidelines would allow international comparability of risk assessments and, thereby, promote fair practices in the food and feed trade.

23. In paragraph 4, the Task Force agreed to refer only to the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004) and to transfer all other references to an Annex. It was agreed to decide at a later stage whether to retain the Annex and, if so, its structure, content and where to refer to this Annex in the main text. The Task Force noted that the references to the OIE documents needed to be updated and completed. In this regard, it was noted that references in Codex texts should be limited to the extent possible and used only when necessary, due to the practical difficulties to regularly update such references.

Scope

24. The Task Force generally agreed with the content of the section. After a long discussion on the need to have specific references to biological hazards and to radionuclides, it was agreed that, based on the Codex definition for hazard, the Guidelines should cover all hazards in feed that impacted on human health.

25. The Task Force clarified the section to make it more explicit that the Guidelines were aimed at governments; that they only apply to food-producing animals; that they apply to all hazards; and that they do not cover agents that might adversely affect animal health.

Definitions

26. The Task Force agreed to consider the definitions in detail when the document is in a more advanced form. It was further agreed to make maximum use of the relevant Codex definitions (i.e. *Definitions for the Purpose of the Codex Alimentarius* and *Definitions of Risk Analysis Terms related to Food Safety*) and of the definitions in the *Code of Practice on Good Animal Feeding*, for reason of consistency.

[6] Paragraph numbers correspond to the paragraph numbers of document CX/AF 12/6/4 Add.2; when paragraph number in the Appendix II are different from paragraph number of document CX/AF 12/6/4 Add.2, these are presented in *italic font in parenthesis*

27. The Task Force agreed that the addition of a reference to "water" in the definition of "feed" was not necessary and that specific references to water for drinking could be made as such in the document wherever it was relevant. It was further agreed to add the Codex definitions for "Hazard identification" and "Risk profile".

Risk Assessment in the Codex Risk Analysis Framework

28. The Task Force agreed to amend paragraph 10 to more clearly illustrate that risk assessment was one of the three components of risk analysis.

29. The Task Force agreed to move all references in paragraphs 11, 14 and 15 to the Annex (*see* para. 23) but to place in paragraph 11, the references to risk assessment guidance from WHO and FAO, as these documents contain relevant detailed guidance. The heading "Risk Assessment Guidance" was therefore deleted.

30. It was agreed to amend: paragraph 12, to explain the link between a food safety problem and feed; and paragraph 13, to indicate that the risk assessment policy also aims to ensure that risk assessment should be documented.

31. In paragraph 12, the Task Force agreed to put in square brackets the reference to the document on the prioritised list of hazards (*see* Agenda Item 5) for further discussion on the relationship between the two documents at its next session.

Risk Assessment Procedure

32. The Task Force deleted paragraph 16, as not applicable, and amended paragraph 18 (*paragraph 15*) to make it less prescriptive regarding the declaration of potential conflicts of interest; the reference to the geographical representation of experts was deleted as not relevant to national situations.

Hazard identification

33. The Task Force improved paragraph 22 (*paragraph 19*) to better describe the hazards in feed; deleted the specific examples of biological hazards, as not all were necessarily applicable to feed; and included "undesirable substances". In view of the latter decision, the definition for "undesirable substances" of the *Code of Practice for Good Animal Feeding* was added to the "Definitions" section.

34. Paragraph 22 (*paragraph 19*) was further amended to address the issue of metabolite hazards by indicating that products of bio-transformation should also be considered. The Task Force agreed to place "bio-" in square brackets as it was not clear whether bio-transformation was also applicable to biological hazards.

35. It was agreed to add a new paragraph to clarify that pre-approved substances, such as feed additives, veterinary drugs and pesticides, previously assessed for safety and used according to their intended use should not necessarily be considered as risks. The Task Force agreed to place pesticides in square brackets, since an agreement on whether they were relevant in this context could not be reached.

36. The Task Force agreed: to amend paragraph 24 (*paragraph 22*) to better clarify that information on the presence of a hazard could be obtained from several sources; to move paragraphs 25 and 26 (*paragraphs 32 and 33*) to the section on exposure assessment for further discussion, while noting that sampling could also be useful in hazard identification; and to place paragraph 27 (*paragraph 23*) in square brackets for further discussion on its relevance to the section.

37. Paragraph 28 (*paragraph 24*) was amended to clarify that hazards might also be introduced into feed ingredients during preparation and storage. The paragraph was further amended to indicate that feed ingredients could also be obtained from agricultural processes.

Hazard characterization

38. This section was rewritten to provide better guidance on how to undertake hazard characterization. In particular, the Task Force added an introductory paragraph to explain the intention of hazard characterization and an explanation on where information on characterization of specific hazards could be obtained. A new paragraph was added to better explain what was identified or characterized during chemical and microbiological hazard characterization; and the last paragraph was amended to clarify what actions needed to be taken when available data were inadequate.

Exposure assessment[7]

39. The Task Force considered a proposal, prepared by an informal working group, for the revision of the "Exposure assessment" section, as presented in CRD 5. The informal working group had revised and reordered the paragraphs of the entire section, including the two paragraphs that were moved from the "Hazard identification" section. The informal working group had: (i) added a new introductory paragraph to explain the intention of exposure assessment and another new paragraph on the preferable use of quantitative data; and (ii) revised the section to more clearly describe the two-step process of exposure assessment of a hazard arising from feed, i.e. the exposure of a food-producing animal to a hazard through feed; and transfer/transmission of a hazard to edible product through food-producing animals.

40. The Task Force considered the proposal in detail and, in addition to some editorial changes to improve the readability and clarity and to align the section with the other parts of the Guidelines, agreed to the following changes.

- in paragraph 1 (*paragraph 29*), agreed to refer to "hazard" and not to "biological, chemical and physical agents" for purposes of consistency with its previous decision. In paragraph 3, a new sentence was added regarding the use of a semi-quantitative or qualitative risk assessment approach when quantitative data were not available.
- in paragraph 4 (*paragraph 32*), agreed to replace the reference to the *Principles for the Establishment or the Selection of Codex Sampling Procedures* (Procedural Manual of the Codex Alimentarius Commission) with the *General Guidelines for Sampling* (CAC/GL 50-2004) as the latter is a text intended for governments. The Task Force further agreed to consider at its next session replacing the reference to the *General Criteria for the Selection of Method of Analysis Using the Criteria Approach*, in paragraph 5 (*paragraph 33*), with a corresponding text intended for governments.
- in paragraph 7 (*paragraph 36*), agreed to a new point on the "determination of concentration of hazard in feed" to more clearly describe the animal exposure step.

41. The Task Force further agreed to consider at its next session, the need to add a closing paragraph to the section.

Risk characterization

42. The Task Force revised the introductory paragraph (*paragraph 42*) of the "Risk characterization" section to be more consistent with the Codex definition for risk characterization. In the following paragraph, it was clarified that the risk manager defines the format of the output of the feed risk characterization when determining the risk assessment policy. The Task Force further agreed to place in square brackets a proposal, presented in CRD 5, regarding human exposure assessment for further discussion at its next session.

43. In paragraph 40 (*paragraph 44*), a biological example of a risk estimate was added. The Task Force further agreed to generally refer to acceptable maximum levels in accordance with national and international standards not to imply any obligation for governments to estimate risk based on Codex standards only. A final sentence was added to provide guidance for those situations where there is no international or national standard.

Conclusion

44. The Task Force acknowledged that good progress had been made on the document and noted that some work was still necessary on the section on definitions, i.e. to identify the definitions to be included and those that still needed to be revised and/or developed. It was further noted that some texts were left in square brackets for further discussion at the next session and that discussion was still needed on the use of the Annex on references and on the relationship of the Guidelines with the document on the prioritised list of hazards (*see* Agenda Item 5).

45. In view of the considerable progress made on the revision of the document and agreement on its structure and on the "Introduction", "Scope" and main sections of the various components of risk assessment, the Task Force agreed that the document could progress in the Step procedure and to focus the

[7] In this section, paragraph numbers correspond to the paragraph numbers of document CRD 5; corresponding paragraph number of Appendix II are presented in *italic font in parenthesis*

discussion at its next session on the remaining outstanding issues and on improving the flow and the consistent use of terms throughout the Guidelines.

46. In order to facilitate the finalisation of the proposed draft Guidelines at its next session and thus comply with the timeframe given by the Codex Alimentarius Commission to complete its mandate, the Task Force further agreed to establish a physical working group, which would meet immediately prior to its seventh Session, chaired by Switzerland and working in English only, to review comments submitted and prepare recommendations for the plenary. The Task Force noted that Switzerland would explore all possibilities to provide the physical working group with interpretation in French and Spanish.

Status of the proposed draft Guidelines on application of risk assessment for feed

47. The Task Force agreed to forward the proposed draft Guidelines to the 35th Session of the Commission for adoption at Step 5 (*see* Appendix II).

PROPOSED DRAFT PRIORITISED LIST OF HAZARDS IN FEED (Agenda Item 5)[8]

48. The Task Force recalled that Switzerland had prepared a first version of the proposed draft Prioritised List (CX/AF 12/6/5) that was circulated for comments at Step 3 and that a second version ("revised version") of the document (CX/AF 12/6/5 Add.2) had been prepared based on the comments submitted. The "revised version" was also circulated for comments at Step 3 and would be considered at the present session.

49. The Delegation of Switzerland introduced the "revised version" of the prioritised list and explained that they had tried to address the mandate given in the second term of reference of the Task Force (*see* Procedural Manual). The Delegation briefly described the various sections, which illustrated the three criteria for prioritization of hazards in feed, namely: "relevance to human health"; "extent of occurrence in feed and food"; and "potential trade impact on the feed and food".

General discussion

50. The Task Force generally agreed that the document was a good attempt to fulfil the mandate, i.e. the second term of reference, received from the Commission and to provide guidance to governments on how they could prioritise hazards in feed.

51. The Task Force focused its discussion on: the intent of the document; the appropriateness of a list of prioritised hazards in feed; the maintenance of such a list; and the use of such a list by governments.

52. Delegations were of the opinion that the document should only provide governments with guidance for the prioritization of hazards in feed and the criteria that governments could use when prioritising these hazards. Other delegations considered it also useful to provide governments with information on hazards in feed.

53. Some delegations felt that the development of a list of common hazards in feed was not useful for use at national level; that it was difficult to scientifically justify the importance of the all hazards listed in the document; that the list should only include hazards that have been evaluated by FAO/WHO; that the development of a list was not a correct approach in Codex and could be perceived and used by countries for the development of measures/limits, not based on science, which could become barriers in international trade.

54. Some delegations also recognised that it would not be possible to develop a complete list of hazards in feed, that a list could only be indicative and that it would be difficult to keep the list updated. In this regard other delegations questioned the need to keep the list updated. It was also noted that it would not be possible to establish a prioritised list relevant to all countries, as prioritization of hazards depend also on local and regional conditions.

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[8] CX/AF 12/6/5; CX/AF 12/6/5 Add. 1 (Comments at Step 3 of Australia, Brazil, Canada, Colombia, Costa Rica, European Union, Iran, Japan, New Zealand, Philippines, United States of America, IFIF and IPC); CX/AF 12/6/5 Add. 2 (Proposed draft Prioritised list of hazards in feed – revised version); CX/AF 12/6/4 Add. 3 (Comments at Step 3 of Argentina, Canada, Chile, Iran, Japan, New Zealand, Norway, USA, FAO, IDF, IFIF, OIE); CX/AF 12/6/5 Add. 4 (Comments of Australia, European Union, Kenya, Mali, Philippines, Thailand); CRD 3 (comments of Ghana)

55. Delegations were of the opinion that the document could provide examples on how governments could use the criteria for prioritising the hazards but should not attempt to develop a prioritised list as this could result in a barrier to international trade of feed.

56. Based on this discussion, the Task Force agreed that it was not possible to develop a prioritised list of hazards in feed and feed ingredients, as per its second term of reference, and that the document should focus on the criteria that governments could use to prioritise their hazards and could include examples of hazards in feed of international relevance for information to governments.

57. The Task Force considered the document in detail and made the following comments and decisions.

Specific comments[9]

Title

58. Based on the above discussion, the Task Force agreed to change the title to "*Guidance for use by governments in prioritizing their national feed hazards*"; this working title would better reflect the revised focus and purpose of the document.

Introduction

59. The Task Force agreed to revise the introduction to align it with the format and language of the "Introduction" section of the proposed draft Guidelines on application of risk assessment for feed (*see* Agenda Item 4). In this regard, it was recalled that the relationship between the two documents would be discussed at the next session.

60. In particular, the Task Force agreed:

- to delete paragraph 1, which repeated the first paragraph of the "Scope" section;
- to revise paragraph 2 to read "*These guidelines aim at facilitating prioritization of hazards in feed based upon regional or local scientific data, considering the impact on human health. The consistent application of these prioritization criteria should also enable international comparability of the output of prioritization of hazards in feed and thereby promote fair practice in food and feed trade*"; and
- to revise paragraphs 3 and 4 in accordance with the corresponding paragraphs of the proposed draft Guidelines on application of risk assessment to feed (consequentially all other references were to be included in an Annex for further consideration).

Scope

61. The Task Force agreed to revise paragraph 5 to reflect the revised scope of the document to read "*These guidelines aim at providing guidance to governments on criteria for prioritization of hazards in feed and feed ingredients and their application"* and to align paragraphs 6-8 with the corresponding paragraphs of the proposed draft Guidelines on application of risk assessment for feed.

Definitions

62. The Task Force agreed to consider the "Definitions" section at a later stage and to follow the same approach agreed to in Agenda Item 4.

Criteria for prioritizing hazard

63. The Task Force had a general discussion on whether the criteria were the appropriate criteria for prioritization. There was general agreement with the first two criteria, viz., "relevance to human health" and "extent of occurrence in feed and food".

64. The Task Force considered a proposal to include two additional criteria: (i) potential for control; and (ii) transfer rate or potential for amplification. It was agreed that:

- "potential for control" was not a criterion for prioritization but should be taken into account during the preliminary risk management activity; and
- "transfer rate or potential for amplification" was already covered by the "relevance to human health" criterion.

[9] Paragraph numbers correspond to the paragraph numbers of document CX/AF 12/6/5 Add.2

65. The Task Force agreed to specifically refer to food of animal origin in the second and third criteria and in the third criterion to delete "international" as the criterion could also apply to the national and regional level.

66. The Task Force, therefore, concluded that the three criteria for prioritizing hazards were the key criteria for prioritization.

67. The Task Force proceeded to discuss how to structure the sections on each criterion and considered whether there was a need for specific text to illustrate the criteria and their application, and whether this could also be illustrated through the use of examples.

68. In this regard, it was agreed that some text was necessary to explain what needed to be considered for each criterion; that examples could be considered to illustrate the application of the criteria; and that consideration could be given to using a format similar to the one of the Annex on Elements to Consider in an AMR Risk Profile of the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011) for listing the elements that should be considered.

Relevance to Human Health

69. The Task Force agreed that all information in this section was relevant, but that there was a need to align the section with similar relevant text of the proposed draft Guidelines on application of risk assessment for feed. It was also agreed that the section should capture the importance of a multidisciplinary approach to ensure that all aspects of human health and food and feed safety were covered; and to detail the factors to be considered.

Extent of occurrence

70. The Task Force agreed that paragraphs 27-29 already contained useful information and that the section should include both the extent of occurrence in feed and the occurrence in food and to clarify the relationship between the two. Consideration could also be given to the different occurrence of hazards at the national and international level.

Impact on trade

71. The Task Force had extensive discussion on how best to structure the section. Some delegations were of the opinion that impact on trade was not an applicable criterion in the national context, but only at the international level and that prioritization of a hazard based on impact on trade, if done arbitrarily, could lead to risk management decisions that could become barriers to trade. Other delegations were of the opinion that this criterion was useful and that it would allow governments to rank hazard based on whether they were importers, exporters or had no trade.

72. It was acknowledged that the impact on trade was important for a risk management decision and that the first version of the document (CX/AF 12/6/5) contained useful language in this regard. The Task Force concluded that this section should be restructured with emphasis that the criterion was important in this context but not relevant for risk assessment.

73. The Task Force further agreed that it would be useful to add a short chapter addressing the application of the three criteria.

Potential Feed Hazards

74. The Task Force noted that the useful information of the section could be moved to an Annex but that further work was needed to retain only the relevant information.

75. The Task Force considered two proposals on how to illustrate the application of the criteria. The European Union proposed using the format of Table. 1 "Factors affecting occurrence of hazards in feed and feed ingredients" and to include additional columns representing each of the three agreed criteria. This table would allow governments to rank their hazards based on information applicable to their situation. The Delegation of Switzerland proposed a table using a mathematical approach to rank hazards using only two of the three criteria: "relevance to human health" and "extent of occurrence".

76. The Task Force noted that both proposals had merit and that a combination of the two could be used. It agreed that it would be important to have an introductory paragraph to the examples clearly explaining that

they were for illustrative purposes only. It was also noted that it would be useful to provide examples for both chemical and biological hazards and that these examples could be included in an Annex.

Conclusion

77. The Task Force noted that progress had been made in the introduction and scope of the renamed document. It was further recalled that there was general agreement on the three criteria and that the document would only focus on the prioritization of hazard in feed and on guidance on how governments could use these criteria. The Task Force agreed to inform the Commission of the latter.

78. The Task Force noted that work was still needed on the description of the three criteria and how governments could apply them and agreed that the entire section on "Potential feed hazards" would be transferred to an Annex, which would require some work to ensure that the hazards listed are relevant to animal feed.

79. It was further agreed that the document would include another Annex with examples on the application of the criteria for prioritization of hazards in feed, covering a range hazards. The examples would be structured taking into account the proposals of the European Union and Switzerland (*see* above). The Annex would include a clear introduction explaining that the examples were intended for illustrative purposes only.

80. In view of the above and the considerable work still to be done, the Task Force agreed to establish an electronic working group, led by Switzerland, open to all Members and Observers and working in English only, to prepare a further proposed draft Guidance on the basis of the above discussion and decisions and the written comments submitted at the present session. The Task Force noted that the participation of FAO and WHO in the electronic working group was also necessary to ensure that updated and scientifically accurate information and references are taken into account, e.g. whether viruses are relevant hazards in feed.

81. It was also noted that the electronic working group, if a need were to be identified, could make recommendations to the Task Force to request FAO and WHO to update the current information on hazards in feed.

82. The Task Force further agreed to request the physical working group, to be convened immediately before its next session (*see* Agenda Item 4), to consider and prepare recommendations on the proposed draft guidance prepared by the electronic working group, if time allowed.

Status of the proposed draft prioritised list of hazards in feed

83. The Task Force agreed to return the renamed proposed draft Guidance for use by governments in prioritising their national feed hazards to Step 2 for redrafting by the aforementioned electronic working group for circulation for comments at Step 3 and consideration at its next session.

OTHER BUSINESS (Agenda Item 6)

84. The Task Force noted that no other business had been put forward.

DATE AND PLACE OF NEXT SESSION (Agenda Item 7)

85. The Task Force noted that its Seventh Session was tentatively scheduled in approximately one year in Switzerland, subject to further discussion between the Codex and Swiss Secretariats.

SUMMARY STATUS OF WORK

Subject Matter	**Step**	**Action by:**	**Document Reference (REP12/AF)**
Proposed draft Guidelines on application of risk assessment for feed	5	35th CAC	Para. 47 and Appendix II
Proposed draft Guidance for use by governments in prioritizing the national feed hazards (former Prioritised List of Hazard in Feed)	2/3	Electronic working group 7th TFAF	Para. 83

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Appendix II

PROPOSED DRAFT GUIDELINES ON APPLICATION OF RISK ASSESSMENT FOR FEED

(at Step 5 of the Procedure)

INTRODUCTION

1. These guidelines aim at providing guidance for feed risk assessment by governments in accordance with Codex principles. They address the potential risks to human health associated with the presence of hazards in the feed of food-producing animals, and the 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).

SCOPE

5. These guidelines aim at providing guidance to governments on risk assessment for feed and feed ingredients.

6. These guidelines are applicable to all hazards in feed for food-producing animals. "Hazard" refers to any agent, 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

7. Direct human exposure to hazards in feed, for example occupational exposure during feed production and processing, is not considered.

DEFINITIONS (*for further discussion*)

8. The following definitions are included to establish a common understanding of the terms used in this guideline. The definitions presented in the Codex Alimentarius Commission: Procedural Manual and in the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004) are applicable to these guideline, unless otherwise noted.

Codex Maximum Level for a Contaminant in a Food or Feed Commodity (ML) is the maximum concentration of that substance recommended by the Codex Alimentarius Commission to be legally permitted in that commodity (Codex Alimentarius Commission: Procedural Manual).

C**odex Maximum Limit for Pesticide Residues** (MRL) is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. MRLs are based on GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable (Codex Alimentarius Commission: Procedural Manual).

Codex Maximum Limit for Residues of Veterinary Drugs (MRL) is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food (Codex Alimentarius Commission: Procedural Manual).

Contaminant: Contaminant means any substance not intentionally added to food, which is present in such food 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 as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter (Codex Alimentarius Commission: Procedural Manual). In these guidelines, "food" should be read as "feed or food".

Control: The prevention, elimination, or reduction of hazards and/or minimization of risks (*Principles and Guidelines for the Conduct of Microbiological Risk Assessment*, CAC/GL 30-1999).

Edible product: All edible tissues and products from food-producing animals which are 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 (Codex Alimentarius Commission: Procedural Manual). In these guidelines, it may also refer to evaluation of the likely amount of a biological or chemical agent in an edible product of animal origin, given the presence of that agent in feed.

Feed: Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food-producing animals (*Code of Practice on Good Animal Feeding*, CAC/RCP 054-2004).

Feed additive: Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which 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.) (*Code of Practice on Good Animal Feeding*, CAC/RCP 54-2004).

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

Feedingstuffs: In this guideline, means Feed.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (Codex Alimentarius Commission: Procedural Manual). 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 (Codex Alimentarius Commission: Procedural Manual).

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 (Codex Alimentarius Commission: Procedural Manual).

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

Quantitative risk assessment: A risk assessment that provides numerical expressions of risk and indication of the attendant uncertainties (*Principles and Guidelines for the Conduct of Microbiological Risk Assessment*, CAC/GL 30-1999).

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food (Codex Alimentarius Commission: Procedural Manual). 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 (Codex Alimentarius Commission: Procedural Manual).

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

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 (Codex Alimentarius Commission: Procedural Manual).

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 (Codex Alimentarius Commission: Procedural Manual).

Risk estimate: The quantitative estimation of risk resulting from risk characterization (Codex Alimentarius Commission: Procedural Manual).

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 (Codex Alimentarius Commission: Procedural Manual).

Risk profile: The description of the food safety problem and its context (Codex Alimentarius Commission: Procedural Manual).

Transfer: Transfer of a hazard from feed of a food-producing animal to an edible product of the animal (usually expressed quantitatively as a transfer coefficient or transfer rate).

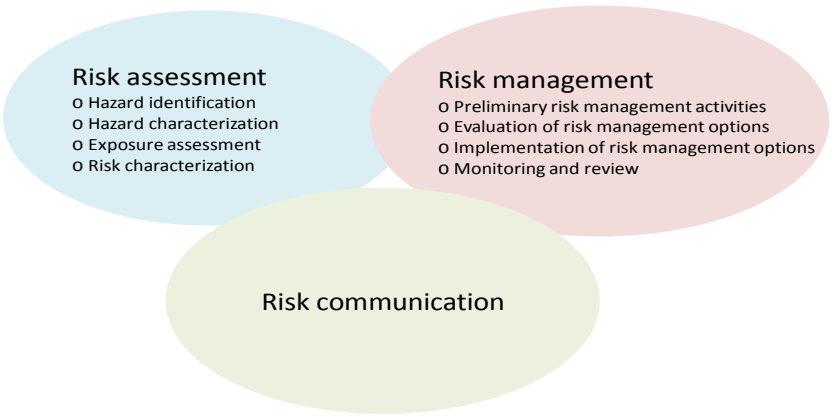
Transparent: Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgements, decisions, limitations and uncertainties of the expressed determination are fully and systematically stated, documented, and accessible for review (*Principles and Guidelines for the Conduct of Microbiological Risk Assessment*, CAC/GL 30-1999).

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

RISK ASSESSMENT IN THE CODEX RISK ANALYSIS FRAMEWORK

9. Risk assessment is one of the three components of the risk analysis framework together with risk management and risk communication.

Figure 1. Risk analysis framework



10. Detailed guidance on risk assessment of food additives, food contaminants, natural toxicants and residues of pesticides and veterinary drugs is provided in the WHO *Principles and Methods for the Risk Assessment of Chemicals in Food*[1]. Guidance on microbiological risk assessment is given in the FAO/WHO Microbiological Risk Assessment (MRA)[2]. Reference for additional guidance on risk assessment is given in the Annex I.

11. A risk assessment is commissioned by the risk manager. Preliminary risk management activities include 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; commissioning of the risk assessment; and consideration of the result of the risk assessment. **[** Reference is made to the Proposed draft prioritised list of hazards in feed (*ad hoc* Intergovernmental Task Force on Animal Feeding) **]**.

12. 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 risk managers to risk assessors should be as clear as possible.

RISK ASSESSMENT PROCEDURE

13. 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.

14. Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise, experience and their independence with regard to the interests involved. The procedures used to select these experts should be documented and may include a public declaration of any potential conflict of interest. This declaration could also identify and detail their individual expertise, experience and independence.

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[1] WHO IPCS Environmental Health Criteria 240. WHO, Geneva, 2009. ISBN 978 92 4 157240 8; http://whqlibdoc.who.int/ehc/

[2] Series: Hazard Characterization for Pathogens in Food and Water (MRA3); Exposure Assessment of Microbiological Hazards in Food (MRA7); Risk Characterization of Microbiological Hazards in Food (MRA 17)

15. 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.

16. Risk assessment should be based on all relevant available scientific data. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.

17. 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 and should be documented.

Hazard identification

18. Hazards in feed can include biological agents, chemical substances (such as "heavy metals", dioxins, excessive levels of pesticides, veterinary drugs and additives), radionuclides and other undesirable substances. Products of [bio-] transformation of the hazard present in edible products also need to be considered.

19. Feed additives and 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 a hazard.

20. Physical agents in feed are not known to be hazards reasonably likely to cause adverse health effects in humans; but rather may cause a risk to animal health, which is outside the scope of these guidelines.

21. 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 from international programs such as the WHO Global Environment Monitoring System (GEMS/Food)[3]; the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN)[4]; and other reliable rapid alert systems.

22. **[** Factors to be considered 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, storage, handling and transport. **]**

23. Consideration should be given to the source of feed ingredients, and the potential for introduction of hazards during their manufacture, preparation and storage. Many feed ingredients are produced as by-products from other production processes, including but not limited to distillers grains from the production of biofuel, agriculture and food processing minerals from industrial processes, etc. Feed ingredients should be obtained from safe sources and be subject to a risk analysis where the ingredients are derived from processes or technologies not hitherto evaluated from a food safety point of view. The procedure used should be consistent with the Codex Alimentarius Commission Procedural Manual: Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

Hazard characterization

24. Hazard characterization refers to the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with hazards, which may be present in edible products. For any hazard identified, including [bio-] transformation products in edible products, a hazard characterization should be conducted.

25. Information on characterization of specific hazards may be obtained in international reports and monographs from bodies and/or preferably in peer-reviewed scientific literature (relevant references are included in Annex 1).

26. For the hazard characterization of chemicals the relevant reference value especially for an oral route exposure are identified (e.g. LD50, ADI). For microbiological hazards, the nature and severity of the adverse health effects are characterized and where possible a dose-response relationship established.

[3] http://www.who.int/foodsafety/chem/gems/en/
[4] http://www.who.int/foodsafety/fs_management/infosan/en/

27. If available data are inadequate to characterize a hazard in feed, it may be necessary to consider generating such data. The risk manager may request action to resolve the data gaps.

Exposure assessment

28. Exposure assessment is the qualitative and/or quantitative evaluation of the likely intake of the hazard(s) via food.

29. The edible product in exposure assessment should be defined as precisely as necessary.

30. Exposure assessment should use quantitative data on the level of hazard(s) or prevalence in feed and/or edible product. If quantitative data are not available, a semi-quantitative or qualitative risk assessment approach may be useful in assessing the potential food safety risk.

31. 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.

32. 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* (Codex Alimentarius Commission, Procedural Manual) **]**.

33. Exposure assessment for a hazard arising from feed is a two-step process. The first step concerns the exposure of food-producing animal to hazard(s) through feed. The second step is to evaluate the transfer/transmission of hazard(s) to edible products through food-producing animals. The aim of exposure assessment in feed risk assessment is to estimate the level or prevalence of hazard(s) in edible product.

34. Human exposure is considered under Risk characterization.

Animal exposure assessment

35. The first step involves:

(a) Identification of feeds, which may contribute to intake of a given hazard;

(b) Determination of 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.

36. Animal exposure will differ as a result of the formulation of the feed, the use patterns for the animal, and the exposure scenarios.

Transfer/Transmission

37. The second step uses modelling and measurements to calculate transfer through food-producing animal and the resulting hazard level and/or prevalence in edible product.

38. Transfer of a hazard from feed to edible product depends on its kinetics in the food-producing animal, including absorption, hazard [bio-] transformation, distribution, and potential for accumulation or proliferation in tissues.

39. The kinetics may be influenced, in particular, by:

- biological or chemical properties of the hazard;

- species, strain, gender, and life stage of the food-producing animal;

- potential interaction between the hazard and feed components.

40. Published, preferably 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.

Risk characterization

41. Risk characterization considers the key findings from hazard characterization and exposure assessment to estimate the risk for a given population. Establishing the probability of occurrence and severity of an identified adverse effect is the expected result of risk characterization. **[** Feed exposure assessment considers hazards in edible products. Human exposure assessment is conducted during risk assessment for foods. This may require modelling of dietary intake of relevant foods and food groups in specified human groups. The results of such assessments are considered in setting limits for hazards in food, such as national or Codex maximum limits or levels.]

42. The format of the output of a feed risk characterization and, if appropriate a risk estimate, are defined by the risk manager in advance when establishing the risk assessment policy.

43. 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 products, exceeding an acceptable maximum level, according to national or international standards; or (b) a certain prevalence of a biological level in feed may result in an infected animal, which could then lead to a level of contamination of food of animal origin, exceeding acceptable levels, according to national or international standards. If there is no international or national standard for food relevant to a feed-derived hazard in edible product, consideration may be given to conducting a food risk assessment to determine the acceptability of the edible product for human consumption.

44. Additional outputs of risk assessment, which would have been defined in the initiation of the risk assessment, can include scientific evaluation of risk management options within the context of the risk assessment.

REPORTING

45. The risk assessment should be fully and systematically documented and communicated to the risk manager.

46. 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.

47. The conclusion of the risk assessment including a risk estimate, if appropriate, 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 (*for further discussion*)

Codex Alimentarius Commission: Procedural Manual, in particular :

Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius;

Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods;

Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues;

Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods

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)

FAO/WHO food safety risk analysis guide for national authorities (Food safety risk analysis: A guide for national safety authorities. FAO Food and Nutrition Paper 87. FAO/WHO, Rome 2006. ISBN 978-92-5-105604-2. ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf)

WHO Principles and Methods for the Risk Assessment of Chemicals in Food. WHO IPCS Environmental Health Criteria 240. WHO, Geneva, 2009. ISBN 978 92 4 157240 8. (http://whqlibdoc.who.int/ehc/)

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)

Relevant sections of:

OIE Terrestrial Animal Health Code (http://www.oie.int/en/international-standard-setting/terrestrial-code/access-online/)

OIE Aquatic Animal Health Code (http://www.oie.int/en/international-standard-setting/aquatic-code/access-online/)

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/pm/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/)