CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.net

Agenda Item 4 **CX/AF 12/6/4 Add.2**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

***AD-HOC* INTERGOVERNMENTAL CODEX TASK FORCE ON ANIMAL FEEDING**

Sixth Session
Berne, Switzerland, 20-24 February 2012

PROPOSED DRAFT GUIDELINES ON APPLICATION OF RISK ASSESSMENT FOR FEED

(Revised version)

(at Step 3 of the Procedure)

Prepared by Switzerland

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Guidelines at Step 3 (*see* Appendix I) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) **to** the: Federal Office for Agriculture, Mattenhofstrasse 5, 3003 Bern, Switzerland (Telefax:+ 41(0) 31 322 26 34, Email: secretariatTFAF@blw.admin.ch), with a copy **to**: The Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 15 January 2012.**

Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in the Annex to this document.

BACKGROUND

1. Switzerland, as host country of the *ad hoc* Task Force, prepared a first version of the proposed draft Guidelines on Application of Risk Assessment for Feed (CX/AF 12/6/4), which were circulated for comments at Step 3 in July 2011 with a deadline of 15 October 2011 for submission of comments.

2. Comments at Step 3 were received from eleven Codex members: Australia, Brazil, Canada, Colombia, Costa Rica, European Union, Iran, Japan, New Zealand, Philippines and the United States of America and from one Codex observers: International Feed Industry Federation (IFIF)[1].

3. The comments received provided extremely valuable input to Switzerland for the preparation of a further version of the proposed draft Guidelines (*see* Appendix 1).

4. Main changes in the further proposed draft Guidelines, in addition to many individual changes, include the following:

- the definitions have been rewritten and now conform to the Codex Procedural Manual or other cited documents. References to websites have been kept to a minimum;
- the term "carry-over" (to edible products) has been corrected to "transfer" (and definition added);
- the section on risk analysis has added text to show the context of risk assessment in the Codex risk analysis framework, with the appropriate references;

[1] Comments submitted on the first version of the proposed draft Guidelines on Application of Risk Assessment to Feed (CX/AF 12/6/4) will be compiled in CX/AF 12/6/4 Add.1 (in original language only)

- the section on risk assessment is split into hazard identification, hazard characterization, exposure assessment and risk characterization, in accordance with the Codex procedural manual definitions, and appropriate references have been added (including WHO EHC 240);
- the section on qualitative/semi-quantitative risk assessment has been deleted, as according to existing Codex guidance it is not the preferred risk assessment procedure. Furthermore, the revised draft refrains from the definition of a specific output in risk assessment, as the output is defined by the risk manager, in accordance with the Codex risk analysis framework;
- the factors to consider in a feed risk assessment compared to a food risk assessment are more clearly explained.

5. Several comments proposing the inclusion of environmental and/or animal health impact were not considered because these issues are outside the scope of Codex Alimentarius. Moreover, the proposal to classify "toxins" as biological hazards rather than chemical hazards was not retained as Switzerland considers "biological hazard" to be capable of reproduction (e.g. bacteria, prions).

REQUEST FOR COMMENTS

6. Comments at Step 3 are requested on the attached proposed draft Guidelines on Application of Risk Assessment for Feed, in Appendix 1, **by 15 January 2012**.

Appendix I

PROPOSED DRAFT GUIDELINES ON APPLICATION OF RISK ASSESSMENT FOR FEED

(at Step 3 of the Procedure)

Table of Contents

INTRODUCTION

1. This guideline provides general principles and guidance for feed risk assessment by governments in accordance with Codex principles. It addresses the potential risks to human health associated with the presence of hazards in the feed of food-producing animals, and the transfer of hazard to edible products.

2. This guideline should enable risk assessment of hazards in feed based upon local conditions, considering the impact, if any, on human health. It should also enable international comparability of feed risk assessments, thereby promoting fair practices in food trade.

3. Implementation of this guideline requires specialised support and/or training with animal feeding and risk analysis specialists.

4. This guideline should be read in conjunction with the:

- *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004).
- *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; and
  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); and
- *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30- 1999);

as well as

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

- the 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/);
- the 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),

and relevant sections of

- the 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),
- the OIE Terrestrial Animal Health Code (http://www.oie.int/eng/normes/mcode/en_sommaire.htm), and
- the 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).

SCOPE

5. This guideline provides guidance on risk assessment for feed and feed ingredients including feed additives and water, as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 54/2004).

6. This guideline is applicable to all hazards in feed. "Hazard" refers to any agent which may adversely affect human health.

7. Agents which may adversely affect animal health but which have no impact on food safety are not considered in this guideline as they are not within the scope of Codex Alimentarius.

8. This guideline considers only exposure of food-producing animals to hazards in feed. Direct human exposure to hazards in feed, for example occupational exposure during feed production and processing, is not considered.

DEFINITIONS

9. 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 this 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*).

Codex 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 this guideline, "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 this guideline, 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). In this guideline, includes water.

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 054-2004).

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 054-2004).

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 this guideline, 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*).

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 this guideline, 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*).

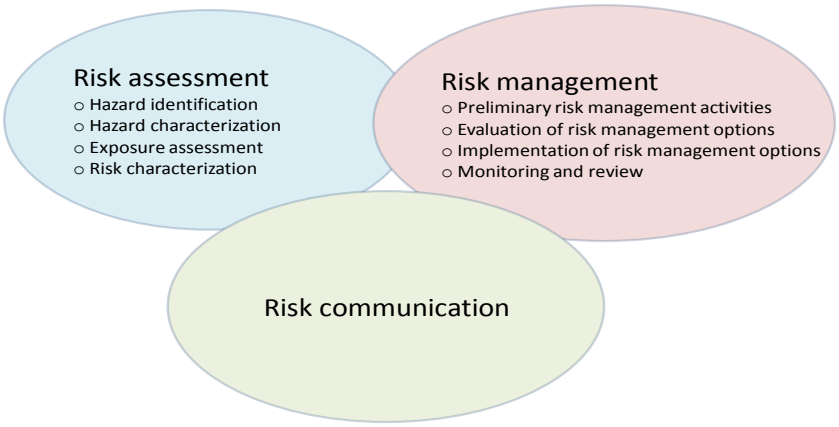
Transfer: Transfer of a hazard from feed of a food-producing animal to an edible product of the animal (usually expressed quantitatively as a transfer coefficient or transfer rate).

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).

RISK ASSESSMENT IN THE CODEX RISK ANALYSIS FRAMEWORK

10. Risk analysis comprises three distinct but closely linked components: risk assessment, risk management and risk communication.

Figure 1. Risk analysis framework



11. Guidance on risk analysis is given in the:

- *Codex Alimentarius Commission Procedural Manual:*
  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; and
  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); and
- *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011)

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

12. A risk assessment is commissioned by the risk manager. Preliminary risk management activities include identification of a safety problem in food or 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).

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, unbiased and transparent. The mandate given by risk managers to risk assessors should be as clear as possible.

RISK ASSESSMENT GUIDANCE

14. As described in the FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition (World Health Organization, Rome, 2007. ISBN 978-92-5-105807-7; ftp://ftp.fao.org/docrep/fao/010/a1296e/a1296e00.pdf), food risk assessments are conducted for use by Codex, governments and industry by the Joint FAO/WHO Expert Committee on Food Additives, Contaminants and Veterinary Drugs (JECFA), the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), and the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA). These expert groups assess hazard and exposure to establish the amount of a given hazard which may safely be present in a given food.

15. 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 (WHO IPCS Environmental Health Criteria 240. WHO, Geneva, 2009. ISBN 978 92 4 157240 8; http://whqlibdoc.who.int/ehc/). These principles and methods are primarily intended to guide JECFA and JMPR risk assessments of chemicals in food for Codex, but are also intended to be informative for users in other risk assessment bodies in Codex member countries and regional authorities. Practical guidance for human risk assessment is provided in the WHO Human Health Risk Assessment Toolkit (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). Guidance on microbiological risk assessment is given in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999).

RISK ASSESSMENT PROCEDURE

16. Reference is made to the *Codex Alimentarius Commission Procedural Manual: Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

17. 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.

18. 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 including a public declaration of any potential conflict of interest. This declaration should also identify and detail their individual expertise, experience and independence. Expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from developing countries.

19. Risk assessment should be conducted in accordance with the *Codex Alimentarius Commission Procedural Manual: Statements of Principle Relating to the Role of Food Safety Risk Assessment* and should incorporate the four steps of the risk assessment, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.

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

21. 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

22. Hazards in feed can include biological agents (viruses, bacteria, endoparasites, and prions), toxic elements such as radionuclides and "heavy metals", and organic chemicals including toxins, chemical contaminants such as dioxins, excessive levels of pesticides, veterinary drugs and additives (and certain of their residues).

23. 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 this guideline.

24. Useful information on hazard identification 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; http://www.who.int/foodsafety/chem/gems/en/), and the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN; http://www.who.int/foodsafety/fs_management/infosan/en/).

25. It should be ensured that feed sampling protocols use scientifically recognized principles and procedures in accordance with the *Principles for the Establishment or Selection of Codex Sampling Procedures* (Codex Procedural Manual). The sampling plan for hazard identification should take into consideration possible inhomogeneous distribution of the hazard, based on all relevant factors.

26. Analytical laboratory methods should be validated using scientifically recognized principles and procedures in accordance with the *Codex Alimentarius Commission Procedural Manual: General Criteria for the Selection of Methods of Analysis Using the Criteria Approach*.

27. 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.

28. Consideration should be given to the source of feed ingredients, and the potential for introduction of hazards during their manufacture. Many feed ingredients are produced as by-products from other production processes, e.g., distillers grains from the production of biofuel, food processing wastes, minerals from industrial processes, etc. In accordance with the *Code Of Practice on Good Animal Feeding* (CAC/RCP 54-2004), 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

29. Information on characterization of specific hazards may be obtained in international reports and monographs from bodies including JECFA (Joint FAO/WHO Expert Committee on Food Additives; http://www.who.int/foodsafety/chem/jecfa/publications/en/), JMPR (Joint FAO/WHO Meeting on Pesticide Residues; http://www.who.int/foodsafety/chem/jmpr/en/), JEMRA (Joint FAO/WHO expert meetings on microbiological risk assessment; http://www.who.int/foodsafety/micro/jemra/en/), the 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/), and/or in the scientific literature.

30. If inadequate data are available to characterize a hazard in feed, it may be necessary to consider generating such data. The risk manager may request action at national level or at the appropriate Codex Committee.

Exposure assessment

31. Table 1 summarises exposure assessment methods in feed risk assessment.

Table 1: Exposure assessment in feed risk assessment

Hazard identification in:	Exposure assessment method	Endpoint of risk assessment
Feed of food-producing animal	Identify all feeds which may contribute to intake of a given hazard, based on hazard identification. Calculate hazard intake from all relevant feed sources, based on information from animal feeding specialists. Use toxicokinetic measurements/modelling of transfer rate to calculate relative hazard concentration in feed and edible product.	Hazard concentration in edible product (e.g. mg/kg product)

32. Human exposure assessment is done during risk assessment for foods. This requires modelling of dietary intake of relevant foods and food groups by specified human groups; see for example *Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups* (Codex Procedural Manual). The results of such assessments are considered in setting limits for hazards in food, such as national or Codex maximum limits or levels, e.g. the *Codex General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995). Details of the exposure assessments are given in published reports by the risk assessor (e.g. JECFA, http://www.who.int/foodsafety/chem/jecfa/publications/en/; JMPR, http://www.who.int/foodsafety/chem/jmpr/en/). Transfer rates from feed to edible products are considered in risk assessment by JECFA when evaluating veterinary drugs and by JMPR when evaluating pesticides used in food-producing animals.

33. Feed exposure assessment is best carried out using monitoring data of hazard levels in feed and edible product.

34. If the amount of a given hazard in feed and edible product is known, then it is possible to derive the transfer rate for the given hazard. In general, if any two of these three variables (hazard level in feed, transfer rate, and hazard level in edible product) is known, the third can be derived.

35. Factors which will influence the transfer rate from feed to edible product include:

- The physico-chemical characteristics of the hazard, e.g. pKa/pKb, log Kow, water solubility, and chemical and thermal stability.
- Kinetics of the hazard in the food-producing animal, including systemic absorption, metabolism (including generation of hazardous metabolites), distribution and accumulation potential of hazard in body compartments, and extent of transfer of hazard into edible products.

36. In some cases, published toxicokinetic or other models that can predict the transfer rate of hazard from feed to edible products, may be used or adapted for a given exposure assessment.

37. If animal feeding studies are considered necessary to establish transfer rates, careful consideration should be given to factors which may affect transfer in a given species of food-producing animal, including strain, sex, and life stage.

38. The edible product should be defined as exactly as necessary (e.g. for animal fats).

39. Sampling protocols for edible products should use scientifically recognized principles and procedures in accordance with the *Codex Alimentarius Commission Procedural Manual: Principles for the Establishment or Selection of Codex Sampling Procedures*. Analytical laboratory methods should be validated using scientifically recognized principles and procedures in accordance with the *Codex Alimentarius Commission Procedural Manual: General Criteria for the Selection of Methods of Analysis Using the Criteria Approach*.

Risk characterization

40. Risk characterization considers the key findings from hazard characterization and exposure assessment to estimate the risk.

41. The output of a feed risk characterization and, if appropriate a risk estimate, are defined by the risk manager.

42. A risk estimate could be, for example, an estimate of the probability that a given concentration of hazard in feed will result in a concentration in edible products which, for example, exceeds the Codex Maximum Level for a contaminant or a Codex Maximum Limit for residues of pesticides or veterinary drugs (MRL), or a similar national standard.

43. Additional outputs of risk characterization, 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

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

45. 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.

46. 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

GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

In order to facilitate the compilation and prepare a more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

(i) General Comments

(ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in underlined/bold font and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.