CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

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PROPOSED DRAFT GUIDELINES ON APPLICATION OF RISK ASSESSMENT FOR FEED

(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 October 2011.**

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. The purpose of Codex work on animal feeding is to minimise food safety risk at the consumer level by covering the entire food chain, including primary production. Undesirable substances present in feed which are ingested by food-producing animals and carried over to edible products may pose a risk to human health.

2. In accordance with Codex principles, risk analysis is an essential tool in assessing the risk to human health from feed and food hazards and determining appropriate risk management strategies to control those risks. WHO/FAO and OIE guidelines on feed safety provide broad, structured approaches to address the human health impact of feed hazards of animal/crop origin via food[1,2]. However, a consolidated framework specific to feed risk analysis was considered necessary, due to the multidisciplinary aspects of feed hazards and their passage to food, and the need to identify appropriate risk assessment approaches.

3. At the 33rd plenary meeting of the Codex Alimentarius Commission, it was agreed to establish a Codex *ad hoc* Intergovernmental Codex Task Force on Animal Feeding with the following Terms of Reference referring to feed risk assessment (ALINORM 10/33/REP, Appendix VIII):

> *"Develop guidelines, intended for governments, on how to apply the existing Codex risk assessment methodologies to the various types of hazards related to contaminants/residues in feed ingredients, including feed additives used in feedingstuffs for food-producing animals. The guideline should include specific science-based risk assessment criteria to apply to feed contaminants/residues. These criteria should be consistent with existing Codex methodologies.*

[1] FAO/WHO 2006. Food safety risk analysis: A guide for national safety authorities. (FAO Food and Nutrition Paper 87). *ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf*.

[2] OIE. *Terrestrial Animal Health Code*. *http://www.oie.int/eng/normes/mcode/en_sommaire.htm*

The guidelines should also consider the need to address the establishment of rates of transfer and accumulation from feed to edible tissues in animal-derived products according to the characteristics of the hazard.

The guidelines should be drawn up in such a way as to enable countries to prioritise and assess risks based upon local conditions, use, exposure of animals and the impact, if any, on human health."

REQUEST FOR COMMENTS

4. Comments at Step 3 are requested on the attached proposed draft Guidelines on Application of Risk Assessment for Feed, in Appendix 1, **by 15 October 2011**.

Appendix I

PROPOSED DRAFT GUIDELINES ON APPLICATION OF RISK ASSESSMENT FOR FEED

(at Step 3 of the Procedure)

Table of Contents

INTRODUCTION

1. These guidelines provide a structured framework based on existing Codex risk assessment methods to address the risks to human health associated with the presence in animal feed, and the transmission through animal feed to food, of hazardous biological and chemical agents.

2. The purpose of these guidelines is to provide practical guidance on how to assess risks associated with feed hazards, to facilitate international comparability of feed risk assessments. They are intended for use by governments, but other parties who need to conduct such assessments may also find them useful. Their use may require specialized support and/or training, particularly in countries without dedicated risk analysis staff.

3. These guidelines should be read in conjunction with:

- *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (Codex Procedural Manual);
- *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 Assessment* (CAC/GL 30- 1999);
- *Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007);*
- *Risk Analysis Principles Applied by the Codex Committee on Food Additives (CCFA) and the Codex Committee on Contaminants in Foods (CCCF);*
- *Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues (CCPR);*
- *Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods (CCVDF)*; and
- *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004).

as well as the WHO/FAO risk analysis guidelines[1] and relevant sections of the FAO/WHO Expert Meeting report on Animal Feed Impact on Food Safety[2] and of the OIE *Terrestrial Animal Health Code*[3], and of the FAO Good Practices for the Feed Industry[4].

SCOPE

4. The scope of these guidelines is to provide guidance on risk assessment methods for government bodies (member countries and regional authorities) that need to conduct risk assessments for feed ingredients including feed additives and water as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 54/2004).

5. These guidelines are applicable to all hazards in the feed of food-producing animals. "Hazard" refers to any undesirable substance which adversely affects human health; effects on animal health which have no impact on food safety are not considered as they do not fall under the scope of Codex Alimentarius.

6. These guidelines consider exposure of food-producing animals only via feed, i.e. by the oral route. Dermal and inhalation exposure to hazards such as environmental contaminants, topical veterinary drugs and pesticides is not considered. Direct human exposure to feed hazards, for example in workers during feed production and processing, is also not considered. Such unintentional environmental and human exposure may be minimized by appropriate hygiene measures[4].

7. As the risks to human health associated with hazards in food are already covered by existing Codex Standards (*Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*) and other internationally recognized guidelines, these feed risk assessment guidelines focus on estimating the risk that a given human health hazard will be transferred from feed to food.

DEFINITIONS

8. The following definitions are included to establish a common understanding of the terms used in this document. The definitions presented in the Codex Procedural Manual and the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004) are applicable to this document.

Acceptable daily intake (ADI): Estimate of the amount of a substance in food, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable health risk to the consumer on the basis of all the known facts at the time of the evaluation.[5]

Animal Food: see Feed.

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

Contaminant: Aany substance not intentionally added to feed or food, which is present in such feed or 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 feed or food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.[6]

Control: The prevention, elimination, or reduction of hazards and/or minimization of risks.[7]

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[1] FAO/WHO 2006. Food safety risk analysis: A guide for national safety authorities. (FAO Food and Nutrition Paper 87). *ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf*.

[2] FAO/WHO 2008. Animal Feed Impact on Food Safety. Report of the FAO/WHO Expert Meeting FAO Headquarters, Rome 8-12 October 2007. *ftp://ftp.fao.org/docrep/fao/010/a1507e/a1507e00.pdf*.

[3] OIE. *Terrestrial Animal Health Code*. *http://www.oie.int/eng/normes/mcode/en_sommaire.htm*

[4] FAO 2010. Good Practices for the Feed Industry. Implementing the Codex Alimentarius Code of Practice on Good Animal Feeding. FAO Animal Production and Health Manual No. 9. http://www.fao.org/docrep/012/i1379e/i1379e00.htm

[5] *Pesticide Residues in Food and Feed, Glossary of Terms*. http://www.codexalimentarius.net/pestres/data/reference/glossary.html

[6] adapted from *Codex Alimentarius Commission: Procedural Manual*

[7] *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999). http://www.codexalimentarius.net/download/standards/357/CXG_030f.pdf

Dose-response assessment: The determination of the relationship between the magnitude of exposure (dose) to a biological or chemical agent and the severity and/or frequency of associated adverse human health effects (response).[8]

Edible product: All edible products intended for human consumption derived from food-producing animals, including for example meat, eggs and milk.[6]

Exposure assessment: In human risk assessment, the qualitative and/or quantitative evaluation of the likely human intake of biological or chemical agent via food as well as exposures from other sources if relevant. In feed risk assessment, may also refer to evaluation of the likely amount of a biological or chemical agent in an edible product, given its presence in a feed ingredient.[9]

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. (Microorganisms, 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.)[10].

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.[10]

Feed: Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food producing animals.[10]

Feedingstuff: see Feed.

Hazard characterization: The qualitative and/or quantitative evaluation of the nature of the adverse human health effects associated with a given hazard.[9]

Hazard: A biological or chemical agent in, or condition of, feed or food with the potential to cause an adverse human health effect.[9]

Quantitative risk assessment: A risk assessment that provides numerical expressions of risk and indication of the attendant uncertainties.[7]

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food (proc).[8]

Risk analysis: A process consisting of three components: risk assessment, risk management and risk communication.[9]

Risk assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.[9]

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.[9]

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.[9]

Risk estimate: Output of risk characterization.[7]

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

[8] adapted from *Working Principles For Risk Analysis For Food Safety For Application By Governments* CAC/GL 62-2007. http://www.codexalimentarius.net/download/standards/10751/CXG_062e.pdf
[9] *Codex Alimentarius Commission: Procedural Manual*
[10] *Code of Practice on Good Animal Feeding.* CAC/RCP 054-2004. www.codexalimentarius.net/download/standards/10080/CXP_054e.pdf

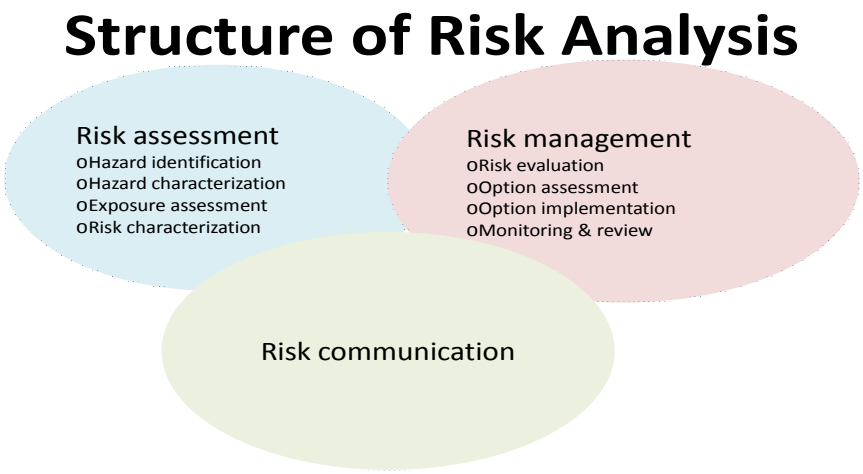
health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.[9]

Semi-quantitative risk assessment: A risk assessment based on data which, while forming an inadequate basis for numerical risk estimates, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties, permits risk ranking or separation into descriptive categories of risk.[11]

Undesirable substances: Contaminants and intentionally added substances which are present in and/or on feed and feed ingredients and which constitute a risk to human health via food.[10]

PRINCIPLES OF RISK ASSESSMENT

9. Risk assessment is one of three components in risk analysis. Its purpose is to protect human health. Risk assessment considers hazard type and exposure; it forms a solid basis for adequate risk management and communication to reduce, eliminate or prevent risks, and enhance consumer protection.



10. Risk assessment is initiated within a risk analysis framework. Good communication among risk assessors, managers and interested parties is essential for a transparent and informed risk analysis.

11. General guidance on conducting risk assessments is given in *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* and also in the *Codex General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) (procedure for risk assessment in relation to (proposed) MLs). More specific procedures for food risk assessment are described in the *Policy of the Codex Committee on Contaminants in Foods for exposure assessment of contaminants and toxins in foods or food groups.*

12. At the beginning of the work, the risk assessor should consider the information documented during commissioning the risk assessment and the risk assessment policy in accordance with national laws and regulations. In addition, risk assessors may require a preliminary investigation phase to define and map the work to be undertaken within the framework of the risk assessment.

13. Risk assessment comprises hazard identification, hazard characterization, exposure assessment, and risk characterization. The selection of a qualitative, semi-quantitative or quantitative approach should be made based on the purpose or the type of questions to be answered and data availability for a specific risk assessment. In accordance with the *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007), quantitative data should be used to the greatest extent possible without discounting the utility of available qualitative information.

[11] Referred to as Qualitative Risk Assessment in: *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* CAC/GL-30 (1999). http://www.codexalimentarius.net/download/standards/357/CXG_030f.pdf

Food risk assessment procedure

14. Food risk assessments are conducted for 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 joint expert consultations to assess risk associated with microbiological contamination of foods (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. The procedures are described in general in:

- Codex Procedural Manual *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius;*
- *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 Assessment (CAC/GL 30-1999)*;
- *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007);
- *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*,

as well as in the FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition[12], WHO/FAO risk analysis guidelines[1], and on the relevant FAO and WHO websites[13]. 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[14], which is primarily intended to guide JECFA and JMPR risk assessments of chemicals in food for Codex, but is also intended to be informative for users in other risk assessment bodies in Codex member countries and regional authorities.

Feed risk assessment procedure

15. Feed risk assessment comprises identification and characterisation of hazard and exposure assessment. The purpose of feed hazard identification is to describe the hazard of concern. Risk assessors should review literature and information from surveillance programmes to identify the physical, chemical and biological properties of a feed hazard. As hazards may enter feed by a variety of routes in different agricultural sectors and at different stages of production, knowledge of behaviour of a given hazard in different environments (e.g. interactions in the pre- and post-harvest environment and in feed mixtures during storage and processing) is useful. Science-based opinions on hazard identification can be sought from relevant experts.

16. As there are existing Codex standards or internationally recognized guidelines which consider human exposure to a given hazard in food, consideration of human exposure is not emphasised in the present document. Instead, exposure assessment and risk characterization in this feed risk assessment guidance focuses on the estimated amount of a given human health hazard which will be present in edible products from food-producing animals. Information on carry-over transfer rates from feed to food is particularly important.

Hazard identification

17. Identification of human hazards in feed should be based on Codex standards, and as necessary scientific literature and on published data from government agencies, the feed and food industries, and relevant international organizations such as FAO[2,4].

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[12] ftp://ftp.fao.org/docrep/fao/010/a1296e/a1296e00.pdf

[13] http://www.fao.org/es/esn/jecfa/jecfa.htm; http://www.fao.org/ag/agp/agpp/pesticid/jmpr/pm_jmpr.htm, http://www.fao.org/es/esn/food/risk_mra_jemra_en.stm

[14] WHO 2009. IPCS International Program on Chemical Safety, Environmental Health Criteria series: EHC 240 Principles and Methods for the Risk Assessment of Chemicals in Food. WHO 2009. http://www.who.int/ipcs/food/principles/en/index.html.

18. Hazards in feed include biological agents (viruses, bacteria, endoparasites, prions) and chemicals (toxins, toxic elements such as radionuclides and "heavy metals", and organic chemicals such as dioxins and organochlorine pesticides and also excessive levels of veterinary drugs, pesticides and additives).

19. Useful information for feed hazard identification may include data from official inspections, quality control data, analysis results by internal and external laboratories of feed production facilities, and investigative work.

20. Factors should be considered which can markedly influence the occurrence of a given hazard in specific feed components and which may be specific to a locale, country, or region, such as conditions during growth, harvesting, drying, storage, handling and transport.

Hazard characterization

21. Hazard characterization in human risk assessment provides a description of the severity and duration of adverse effects in humans that may result from the ingestion of a contaminant in food, ideally establishing a dose-response relationship. Feed risk assessment considers the same hazards as human risk assessment.

22. The soundness and validity of a given hazard characterization and the resultant modelling are heavily dependent upon the extent to which adequate scientific information about the contaminant exists.

23. Information on characterization of specific hazards is included in Codex Standards[15] and in the *Codex General Standard for Contaminants and Toxins in Food and Feed*, CODEX STAN 193-1995). If inadequate data are available to characterize a hazard in feed, it may be necessary to launch such activities at Codex level. A Member State can request action at Codex level and suggest feed-specific hazard data to be considered, usually compiling scientific data for consideration by the relevant scientific body such as JECFA. According to the Procedural Manual, the decision to undertake new work or revision of individual maximum residue limits for pesticides or veterinary drugs, or the maintenance of the *General Standard on Food Additives*, and the *General Standard on Contaminants and Toxins in Food and Feed* follows the procedures established by the relevant Committees and endorsed by the Commission.

24. It may also be helpful to refer to chemical hazard classification data established by an internationally recognised standard, such as the UN Globally Harmonized System of Classification and Labelling of Chemicals[16], or the WHO International Programme on Chemical Safety[17].

Exposure assessment

25. The fundamental activities in exposure assessment should include: (a) clear depiction or drawing of the exposure pathway; (b) detailing the necessary data requirements based on the pathway; (c) obtaining the necessary data, and (d) summarising the data. In feed risk assessment, this step focuses on estimating the concentration of a given hazard which is likely to appear in food after feeding it to food-producing animals. [Generally, the process of assessing exposure as part of a feed risk assessment is practically more achievable than a hazard assessment.]

26. Exposure assessment is best carried out using actual monitoring data of hazard levels in food. In the absence of this, estimates of food levels may be obtained from monitoring data on feed levels combined with carry-over models to enable estimates of corresponding food levels. Factors to be considered include:

- The concentration of the hazard present in the feed;
- The physico-chemical characteristics of the hazard, e.g. stability and solubility in water and fat;
- Increases or decreases in hazard concentration due to processing of feed;
- The frequency and amount of feed eaten by the food-producing animal. Feeding specialists should be consulted for this information. For substances with a long half-life (due to slow metabolism and/or excretion), cumulation may occur even if the hazard is only ingested at long intervals. (For this reason, human Provisional Maximum Tolerable Intake of hazards is given per day, per week or per month,

[15] http://www.codexalimentarius.net
[16] Globally Harmonized System of Classification and Labelling of Chemicals. Third revised edition. ST/SG/AC.I0/30/Rev.3. United Nations, New York and Geneva, 2009. http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html
[17] http://www.who.int/ipcs/publications/jecfa/en/

depending on the biological half-life of the hazard) (*General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995));

- Kinetics in the food-producing animal, including systemic absorption, metabolism including generation of more or less hazardous metabolites, and distribution/transfer into edible products;

27. According to the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995), criteria for establishing maximum levels in feed and food may include toxicokinetic and toxicodynamic data including information on possible carry-over of the undesirable substance from feed to edible product. If there is no Codex information on carry-over for a given hazard, published data from the scientific literature may also provide directly relevant information. However, if such data are inadequate or not available, data modelling or feed to food carry-over studies may be necessary on a case-by-case basis.

28. The various potential sources of a given hazard in food should be considered.

29. The level of detail of the exposure assessment, and consequently the data and/or model used, need to be decided on a case by case basis. If a low tier conservative estimate results in 'no concern', then there is no need for a sophisticated approach. On the other hand, when exposure via various routes and various sources needs to be assessed, this might require high tier models and high quality data. In the ideal case, the high tier exposure assessment results in exposure values that are close to realistic levels.

Risk characterization

30. Risk characterization considers the key findings from the hazard identification, hazard characterization and exposure assessment to estimate the risk. The form that the risk characterization takes and the outputs it produces will vary from assessment to assessment as a function of the risk management request. This section provides examples of the general types of outputs that may be informative in risk characterization, but specific outputs may need to be established at the onset of the assessment process based on the risk question(s) and the risk manager's needs.

31. Additional outputs of risk characterization, which would have been defined in the purpose of a feed risk assessment, may include scientific evaluation of risk management options within the context of the risk assessment.

32. In a feed risk assessment, a plausible endpoint is the likelihood that a given hazard in feed will be transferred to food in a concentration which, for example, exceeds its Codex maximum level or maximum residue limit, since these levels and limits reflect, at least partly, human risk assessment data.

33. Feed risk estimates can be calculated, for example, with reference to a single or several foodstuffs, as a time-limited point estimate, or a longer-term estimate of contamination. The selection of the final risk estimate should generally have been defined during the commissioning of the feed risk assessment.

34. Other elements to consider in association with risk characterization, depending upon the purpose of the risk assessment and the details necessary to adequately characterize the risk, may be:

- Types of food which are particularly susceptible to contamination (e.g. milk or meat), and whether the estimated food concentrations are adequately characterized.
- Key scientific assumptions used and their impact on the assessment's validity.
- A description of the variability and uncertainty of the assessment, which determine the degree of confidence in the final estimation of risk. Risk assessors should ensure that risk managers understand the impact of these aspects on the risk characterization.
- Strengths and weaknesses/limitations of the risk assessment – what parts are more or less robust, for example, a small number of feed ingredient samples or limited carry-over data. Discussion of the robustness of data used, i.e. weight of evidence, will enhance confidence in and usefulness of the assessment.

35. The conclusions of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

36. The feed risk assessment may also identify areas of research needed to fill key gaps in scientific knowledge on a particular risk or risks associated with a given feed ingredient.

CONDUCT OF FEED RISK ASSESSMENT

37. There should be a clear statement on the purpose and scope of the risk assessment at the beginning of the work, and the type of result which is required should be well defined. For example, the desired output might be an estimate of the maximum amount of an undesirable substance in a specific feed ingredient which will not lead to exceeding a given threshold in a given edible product over a given time period, as a function of feed type, target food-producing species and feeding regimes.

38. As much high quality quantitative information as possible should be included to reduce uncertainty and increase the reliability of the risk estimate. In practice, scientific evidence may be limited, incomplete or conflicting. In such cases, transparently documented decisions have to be made on how to complete the risk assessment process with semi-quantitative data. The formal record of the risk assessment should include an evaluation of the impact of resource constraints on the reliability of the risk assessment.

39. In many cases, insufficient data will be available for quantitative risk assessment of feed or feed components. In these cases, a semi-quantitative approach may be the best option. This guidance presents an example of a semi-quantitative feed risk assessment. It is not intended to imply that this is the preferred approach but merely to illustrate ways in which semi-quantitative data can be handled if limited data are available.

Suggested procedure for semi-quantitative risk assessment

40. The suggested procedure in conducting a semi-quantitative risk assessment is:

a. Hazard characterization using ordinal scores (e.g. “negligible”, “moderate”, “severe”). These scores refer to hazard adverse effects in humans. Information on specific hazards is included in Codex Official Standards[15], and in the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995). For chemical hazards, if there is no Codex or national information available, internationally recognised sources such as the UN Globally Harmonized System of Classification and Labelling of Chemicals[16] or the WHO International Programme on Chemical Safety[14] may be useful.

b. Exposure assessment using ordinal scores (e.g. “negligible”, “moderate”, “high) for expected levels of undesirable substances in edible products of food-producing animals, based on the best available data on hazard concentration in feed, the amount of feed ingested, and rate of carry-over to edible products. For some hazards, quantitative carry-over data are available in the scientific literature (e.g. transfer of heavy metals, dioxins and aflatoxins into milk of dairy cattle). If such carry-over data are not available for a given hazard and edible product, it may be necessary to commission studies to generate such data. However, it is often not possible to conduct direct feeding studies to account for all situations (e.g. multiple species, life stages, and sexes). Therefore, toxicokinetic or other models that can predict the transfer of residues or pathogens from feed to foods may need to be used in consultation with appropriate experts.

c. Integration of hazard characterization and exposure assessment to yield an ordinal risk characterization. The method for deriving risk ratings from hazard and exposure estimates requires careful consideration, and will be guided by the required output of the risk assessment. For example, will the risk manager need to know if “moderate” exposure to a “moderate” hazard is worse than "high" exposure" to a "slight" hazard?

41. The following example illustrates a possible approach for semi-quantitative assessment; it should not be viewed as a recommended or accepted default method for adoption. There are no pre-defined categories for hazard characterization or exposure assessment, and no pre-defined method or categories for calculating risk by integration of hazard and exposure to calculate risk.

Example of hazard characterization scoring

Severe	Hazard produces irreversible adverse effects in humans (carcinogenicity, reproductive toxicity, or target organ toxicity).
Moderate	Hazard produces short-term and/or reversible adverse human health effects.
Negligible	Hazard produces no significant adverse human health effects.

Example of exposure assessment scoring with reference to a threshold level

High	Significant probability that concentration in food will exceed threshold level.
Moderate	Some probability that concentration in food will exceed threshold level.
Negligible	Virtually no probability that concentration of hazard in food will exceed threshold level.

42. The threshold level referred to in the exposure assessment example above should be explicitly defined and justified. It could be, for example, a Codex Standard guideline or maximum level, or a tolerable intake as set in an expert committee evaluation. Examples of such maximum levels and their derivation are given in the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995).

43. To set a threshold exposure level in the absence of Codex standards or relevant national standards or legislation, it may be necessary to consult other sources such as published scientific literature, on a case-by-case basis.

Example of risk characterization output

44. In risk characterization, the hazard characterization and exposure assessment are integrated to estimate the risk. By assigning a numerical score (e.g. 1, 2, 3) to each of the qualitative hazard and exposure categories (e.g. “high,” “medium,” etc.), risk scores can be derived in a transparent way by simply multiplying hazard and exposure scores. The resulting risk characterization score can then be translated into meaningful semi-quantitative risk categories. In the example shown here, the risk characterization scores, which are products of the hazard characterization and exposure assessment scores, are assigned to arbitrary categories:

Negligible risk:	1
Some risk:	2 to 3
High risk:	4 to 6
Very high risk:	9

45. The risk characterization output example is summarized in Table 1. This example provides a clear range of risk assessment results, from “negligible risk” to “very high risk”.

Table 1 Example of semi-quantitative assessment outcome[18]

		Exposure = Carry-over estimate		
		Negligible = 1	Moderate = 2	High = 3
Hazard characterization	Severe = 3	3	6	9
	Moderate = 2	2	4	6
	Negligible = 1	1	2	3

Numbers are arbitrary ordinal units of risk;
1 = Negligible risk, 2-3 = Some risk; 4-6 = High risk; 9 = Very high risk

46. Such feed risk scores permit simple prioritization of hazards for risk management and possible further risk analysis activities.

Documentation

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

48. A formal record, including a summary, should be prepared and made available to interested independent parties so that other risk assessors can critically review and if necessary repeat the assessment. The formal record and summary should indicate all constraints, uncertainties, and assumptions made, and their possible impact on the risk assessment.

Reassessment

49. If new relevant scientific information becomes available, for example from food contamination monitoring or human health surveillance programs, previously completed feed risk assessments may have to be checked and if necessary revised to incorporate new findings. This emphasizes the dynamic iterative nature of risk assessment.

[18] adapted from the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011).

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.