GUIDELINES ON THE APPLICATION OF RISK ASSESSMENT FOR FEED

CAC/GL 80-2013

INTRODUCTION

1. These guidelines provide guidance for feed and feed ingredients risk assessment by governments in accordance with Codex principles for risk analysis.[1] They address the potential risks to human health associated with the presence of hazards in the feed of food-producing animals and the subsequent transfer of hazards to edible products.

2. These guidelines should enable risk assessment of hazards in feed based upon local conditions considering the impact on food safety and human health. The application of these guidelines should also enable international comparability of feed risk assessments and thereby promote fair practices in food and feed trade.

3. Implementation of these guidelines requires specialised support and training of experts on animal feeding and risk analysis.

4. These guidelines should be read in conjunction with the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004).

5. Codex guidance on risk assessment of food additives, food contaminants, natural toxicants, residues of pesticides and veterinary drugs, and microbiological hazards is also provided in:

   - Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[2].
   - Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods[2].
   - Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues[2].
   - Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods[2].
   - *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007).
   - *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007).
   - *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011).
   - *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30- 1999).

6. Further information is provided in the WHO Principles and Methods for the Risk Assessment of Chemicals in Food[3] and the FAO/WHO Microbiological Risk Assessment Series (MRA)[4].

7. Annex 1 lists other references that have been used when developing this document.

SCOPE

8. These guidelines are applicable to all hazards in the feed of food-producing animals, which may adversely affect human health. Agents which may adversely affect animal health but which have no impact on food safety are not considered in these guidelines, as they are not within the scope of the Codex Alimentarius.

9. Direct human exposure to hazards in feed, for example occupational exposure during feed production and processing, is not considered as it is not within the scope of the Codex Alimentarius.

DEFINITIONS

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

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

Contaminant: Any substance not intentionally added to food or feed for food producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.[2]

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

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[1] Throughout the text the term “feed” refers to both feed and feed ingredients, unless otherwise stated
[2] Codex Alimentarius Commission: Procedural Manual
[3] http://www.who.int/foodsafety/chem/principles/en/index1.html
[4] http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Undesirable substances: Contaminants and other substances, which are present in and/or on feed and feed ingredients and which constitute a risk to consumers' health, including food safety related animal health issues.[5]

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

RISK ASSESSMENT IN THE CODEX RISK ANALYSIS FRAMEWORK

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

Figure 1. Risk analysis framework

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

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

RISK ASSESSMENT PROCEDURE

14. The scope and purpose of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined.

15. Experts involved in risk assessment should be objective in their scientific work and selected in a transparent manner on the basis of their expertise.

16. Risk assessment is a science based process and should follow a structured approach incorporating the following four steps: hazard identification, hazard characterization, exposure assessment and risk characterization.

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

18. Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

HAZARD IDENTIFICATION

19. Hazards in feed can include biological and chemical agents (such as "heavy metals", dioxins, excessive levels of pesticides, veterinary drugs and additives), radionuclides and other undesirable substances. Biotransformation products present in edible products also need to be considered.

20. Feed additives, veterinary drugs and pesticides used in feed, which have been assessed for safety and which have been used under stated conditions of use as pre- approved by the competent authorities, should not be *prima facie* considered as hazards.

21. Physical agents in feed are not known to be hazards reasonably likely to cause food safety risks, but rather may cause a risk to animal health, which is outside the scope of these guidelines.

22. Factors to be considered include those which can markedly influence the occurrence of a given hazard in feed and which may be specific to a locale, country, or region, include environmental conditions and interactions with other materials during growth, harvesting, drying, processing, storage, handling and transport.

23. Useful information on the presence of the hazard in feed may be obtained from regulatory surveillance samples and investigative work, published data from government agencies and scientific peer-reviewed publications, and from international programs such as the WHO Global Environment Monitoring System (GEMS/Food), the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN), and other reliable rapid alert systems, and industry self-monitoring programmes.

24. In order to evaluate which feed ingredients may contain a given hazard, consideration should be given to the source of feed ingredients and environmental conditions and interactions, and the potential for introduction of hazards during their manufacture, preparation, transportation, handling, storage and use. Many feed ingredients are produced as co-products or by-products from other production processes, including industrial processes, and an evaluation may need to be made of these processes and their potential for introducing hazards in feed.

HAZARD CHARACTERIZATION

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

26. Information on characterization of specific hazards may be obtained in international reports and monographs from risk assessment bodies and/or in peer-reviewed scientific literature. Sources of information should be documented.

27. For the hazard characterization of chemicals the relevant reference value especially for an oral route of exposure is identified, e.g. Acceptable Daily Intake (ADI), Tolerable Daily Intake (TDI), Acute Reference Dose (ARfD). For biological hazards, a dose-response relationship is established if possible.

28. If available scientific data are inadequate to characterize a hazard, it may be necessary to consider generating such data. The risk manager may request action to resolve the data gaps. Any generation of new data should be based on relevant scientific principles and procedures.

EXPOSURE ASSESSMENT

29. Human exposure assessment is the qualitative and/or quantitative evaluation of the likely intake of the hazard(s) via food. The aim of the exposure assessment in feed risk assessment is to estimate the level or prevalence of hazard(s) in edible product(s) after transfer from feed. Subsequently, these estimated levels of hazard in edible product arising from feed are used as input for human exposure assessment.

30. The final edible product(s) in the exposure assessment should be defined as precisely as necessary.

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

32. Data obtained from sampling and testing of feed and edible product may be useful for quantifying the exposure. Sampling plans for feed and edible products should use scientifically recognized principles and procedures in accordance with the *General Guidelines on Sampling* (CAC/GL 50-2004). The sampling plan should take into consideration possible non-homogeneous distribution of the hazard. Analytical laboratory methods should be validated using scientifically recognized principles and procedures in accordance with the *General Criteria for the Selection of Methods of Analysis Using the Criteria Approach*[1].

33. Exposure assessment for a hazard in feed is a two-step process. The first step concerns the exposure of the food-producing animal to hazard(s) through feed. If such exposure is present, the second step is to evaluate the transfer of hazard(s) to edible product(s) of the food-producing animal.

First Step: *Animal exposure assessment*

34. The first step involves:

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

(b) Determination of the concentration of the hazard in feed;

(c) Calculation of hazard intake by the food-producing animal from relevant feed sources, based on information on feeding practices (quantity, frequency and duration of feed intake) as appropriate.

(d) Identification, and if possible quantification, of other sources of the hazard which may contribute to exposure to the hazard in the food-producing animal (e.g. bedding materials, soil, water, air or others).

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

Second Step: *Transfer*

36. Modelling and measurements are used to calculate transfer through the food-producing animal and the resulting hazard level and/or prevalence in edible product.

37. Transfer of a hazard from feed to edible product depends on its kinetics in the food-producing animal, including absorption, biotransformation, distribution, excretion, and the potential for accumulation or proliferation in tissues.

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

- Biological or chemical properties of the hazard;
- Species, breed, gender, life stage**,** and health status of the food-producing animal;
- Frequency and duration of feed intake;
- Formulation of the feed and potential interaction between the hazard and feed components.

39. Published, peer-reviewed, toxicokinetic or other models that can predict the transfer of hazard from feed to edible products, may be used or adapted for a given exposure assessment. Sources of information should be documented.

40. The feed exposure assessment should result in the determination of the predicted level or prevalence of a hazard in edible product. This result is then incorporated as a starting point in the human exposure assessment for food. The evaluation of the human exposure to the hazard should be done using relevant foods and food groups and/or specific human populations to account for feed as a source of exposure, (e.g. by modelling).

RISK CHARACTERIZATION

41. Risk characterization, in a feed risk assessment, considers the outcomes from the hazard characterization and the exposure assessment to derive a risk estimate for food safety.

42. A first risk estimate may be performed by a comparison of the predicted levels of the hazard in edible product with existing national or international maximum levels for food commodities.

43. If a more extensive risk assessment is required, a risk estimate could be, for example: (a) an estimate of the probability that a given concentration of hazard in feed may result in a concentration in edible product, the human consumption of which may lead to exceeding a national or international health based guidance value (e.g. ADI, TDI); or (b) an estimate of the probability that an infectious agent in feed could lead to an infection in an animal, which may result in an unacceptable contamination of edible product.

44. When the hazard is also present in environmental sources such as water and air, or in foods of non-animal origin, other exposure assessments on these sources should be taken into consideration for the risk characterization and subsequent risk management options.

45. Additional outputs of a risk assessment, which would have been defined in the initiation of the risk assessment, can include evaluation of the effect of different risk management options on the estimated health risk.

REPORTING

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

47. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessor.

48. The conclusions of the risk assessment should be presented in a readily understandable and useful form to the risk manager and made available to other risk assessors and interested parties so that they can review the assessment.

ANNEX I

WHO Human Health Risk Assessment Toolkit: Chemical Hazards. IPCS Harmonization Project Document No. 8. WHO, Geneva, 2010. ISBN 978 92 4 154807 6. (http://www.who.int/entity/ipcs/publications/methods/harmonization/toolkit.pdf)

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

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

Relevant sections of: OIE Terrestrial Animal Health Code
(http://www.oie.int/en/international-standard-setting/terrestrial-code/)
OIE Aquatic Animal Health Code
(http://www.oie.int/en/international-standard-setting/aquatic-code/)

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

Joint FAO/WHO Expert Committee on Food Additives (JECFA) (http://www.who.int/foodsafety/chem/jecfa/publications/en/ and http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/

Joint FAO/WHO Meeting on Pesticide Residues (JMPR)
(http://www.who.int/foodsafety/chem/jmpr/en/ and
http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/en/)

Joint FAO/WHO expert meetings on microbiological risk assessment (JEMRA) (http://www.who.int/foodsafety/micro/jemra/en/ and
http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/

WHO International Programme on Chemical Safety (IPCS)
(http://www.inchem.org/)

WHO Concise International Chemical Assessment Documents (CICAD)
(http://www.who.int/ipcs/publications/cicad/)

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