



**Food and Agriculture  
Organization of  
the United Nations**



**World Health  
Organization**

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**Agenda Item 5**

**CX/AF 12/6/5 Add. 2**

**November 2011**

## 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 PRIORITISED LIST OF HAZARDS IN 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 Prioritised List of Hazards in Feed 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](mailto: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](mailto: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 Prioritised List of Hazards in Feed (CX/AF 12/6/5), which was circulated for comments at Step 3 in July 2011 with a deadline of 15 October 2011 for submission of comments.
2. Comments were received from eleven Codex members: Australia, Brazil, Canada, Colombia, Costa Rica, European Union, Iran, Japan, New Zealand, Philippines and United States of America and from two Codex observers: International Feed Industry Federation (IFIF) and International Poultry Council (IPC)<sup>1</sup>.
3. The comments received provided extremely valuable input to Switzerland for the preparation of a further version of the proposed draft Prioritised List (*see* Appendix 1).
4. Main changes in the further proposed draft include:
  - in Background paragraph 3, the cited Terms of Reference has been corrected from risk assessment to hazard prioritization;
  - the definitions have been rewritten and now conform to Codex Procedural Manual or other cited documents;
  - physical hazards have been included, in accordance with the Codex Procedural Manual definition;
  - the term "carry-over" (to edible products) has been corrected to "transfer" (and definition added);
  - a section on the Codex risk analysis framework has been added to clarify the context of and rationale for prioritizing hazards, with the appropriate references;

<sup>1</sup> Comments submitted on the first version of proposed draft Prioritised List of Hazards in Feed (CX/AF 12/6/5) are compiled in CX/AF 12/6/5 Add.1 (in original language only)

- the section on criteria for prioritizing hazard has been expanded to describe in more detail how to assess relevance to human health, extent of occurrence in feed and food, and potential impact on international trade in feed and food. In particular, relevant information from the Codex Procedural Manual is included wherever possible. Relevance of other cited sources has been checked, including references to Codex general standards and Codes of Practice, other Codex documents, and non-Codex data sources (e.g. WHO/FAO programs and publications);
  - the section on specific hazards has been updated, taking into account specific detailed comments and corrections made by many members;
  - many members commented that the flowchart (original Figure 1) was not helpful. The flowchart is removed;
  - a new Figure 1 has been added, summarising the factors and criteria to consider when prioritizing hazards in feed, making reference to the updated tables;
  - the three tables appended to the document have been extensively revised in the light of extensive comments. There are now only two tables, summarizing factors, which may affect the occurrence of hazards in food and feed ingredients (Table 1) and in edible products (Table 2).
5. The following suggestions were not considered:
- addition of environmental and/or animal health impact. Both aspects are outside the scope of Codex Alimentarius;
  - addition of "inorganic chemicals", since these hazards seem to be covered by "toxic elements";
  - addition specific further potential sources of hazard, for example prions in fish meal. This may need to be discussed in the context of the scope and form of the document;
  - modification of the title of this document that does not precisely reflect the content, i.e. a prioritized list of hazards versus guidance on how to prioritize.
6. General comments were made on the form of the document, i.e. should it be a working document rather than a Codex guideline, and who should be responsible for updating it as necessary.

### **REQUEST FOR COMMENTS**

7. Comments at Step 3 are requested on the attached further version of proposed draft Prioritised List of Hazards in Feed, in Appendix 1, **by 15 January 2012**.

**Appendix I**

**PROPOSED DRAFT PRIORITISED LIST OF HAZARDS IN FEED  
(at Step 3 of the Procedure)**

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## **INTRODUCTION**

1. This guideline provides general principles and guidance for prioritization of hazards in feed by governments in accordance with Codex principles. It addresses the hazards in the feed of food-producing animals which may be transferred to edible products and thereby pose a risk to human health.
2. This guideline should facilitate prioritisation of hazards in feed based upon local conditions, considering the potential impact, if any, on human health. It should also enable international comparability of prioritization of hazards in feed, 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:

*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);

*Code of Practice for Source Directed Measures to reduce Contamination of Food with Chemicals*  
 (CAC/RCP 49-2001);

*Code of Hygienic Practice for Meat* (CAC/RCP 58-2005);

*Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004);

*Code of Hygienic Practice for Eggs and Eggs Products* (CAC/RCP 15-1976);

as well as relevant sections of

the FAO/WHO Expert Meeting report on Animal Feed Impact on Food Safety (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>);

the OIE Guide to Good Farming Practices for Animal Production Food Safety (FAO/OIE 2009; [http://www.oie.int/fileadmin/Home/eng/Food\\_Safety/docs/pdf/GGFP.pdf](http://www.oie.int/fileadmin/Home/eng/Food_Safety/docs/pdf/GGFP.pdf), <http://www.fao.org/docrep/012/i0482t/i0482t00.pdf>), and

the FAO/IFIF Good Practices For The Feed Industry (FAO and IFIF. 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. FAO 2010; <http://www.fao.org/docrep/012/i1379e/i1379e00.htm>).

## SCOPE

5. This guideline provides guidance on prioritization of hazards in 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 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, unless otherwise noted.

- Carry-over:** Contamination of a material or product with another material or product that originates from previous use of equipment (FAO and IFIF. 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. FAO 2010).
- 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 guidance, "food" should be read as "feed or food".
- Control:** The prevention, elimination, or reduction of hazards and/or minimization of risks to human health (*Principles and Guidelines for the Conduct of Microbiological Risk Assessment CAC/GL-30-1999*).
- Cross-contamination:** Contamination of a material or product with another material or product (FAO and IFIF. 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. FAO 2010).
- 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.
- 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, that 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) (*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 or animal origin, or organic or inorganic substances (*Code of Practice on Good Animal Feeding. CAC/RCP 54/2004*).
- Feedingstuffs:** see 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 guidance, it refers to an agent in feed which has the potential to cause an adverse human health effect after transfer into an edible product.
- 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*).

**Medicated feed:** Any feed which contains veterinary drugs as defined in the Codex Alimentarius Commission Procedural Manual (*Code of Practice on Good Animal Feeding*. CAC/RCP 054/2004).

**Processing Aid:** Means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product (*Codex Alimentarius Commission: Procedural Manual*).

**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 guidance, it may also refer to the probability that a hazard in feed eaten by a food-producing animal will transfer to an edible product at a level which may cause an adverse health effect in humans.

**Risk 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 analysis:** A process consisting of three components: risk assessment, risk management and risk communication (*Codex Alimentarius Commission: Procedural Manual*).

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

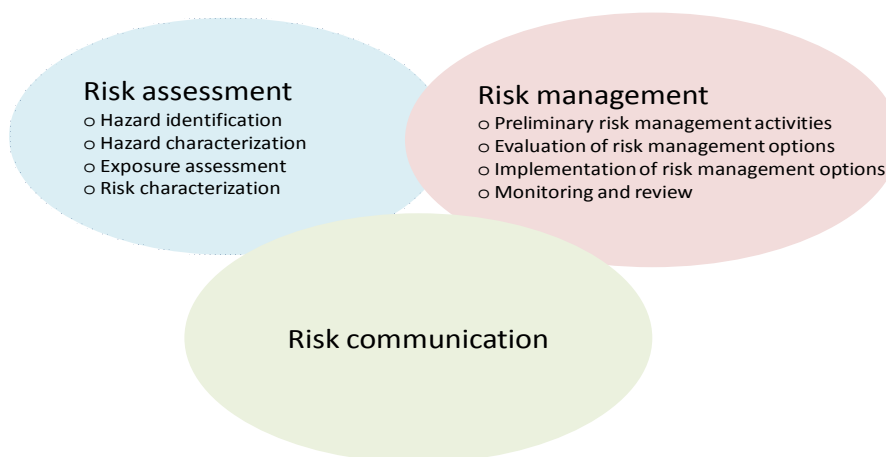
## PRIORITIZATION OF HAZARDS IN THE FRAMEWORK OF CODEX RISK ANALYSIS

10. Reference is made to the following Codex guidance on risk analysis:

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

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

**Figure 1. Risk analysis framework**



12. Preliminary risk management activities conducted by the risk manager prior to commissioning a risk assessment include identification of a feed or food safety problem; establishment of a risk profile; and ranking of the hazard for risk assessment and risk management priority. Reference is made to the draft *Guidelines on Application of Risk Assessment for Feed* (ad hoc Intergovernmental Task Force on Animal Feeding).

13. Prioritization of hazards as a risk management activity is included in the terms of reference of Codex Committees (*Codex Alimentarius Commission Procedural Manual*), specifically:

- the Codex Committee on Contaminants in Foods ("prepare priority lists of contaminants and naturally occurring toxicants for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives"),
- the Codex Committee on Food Additives ("prepare priority lists of food additives for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives"),
- the Codex Committee on Food Hygiene ("suggest and prioritize areas where there is a need for microbiological risk assessment at the international level...")
- the Codex Committee on Pesticide Residues ("prepare priority lists of pesticides for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR)"), and
- the Codex Committee on Residues of Veterinary Drugs in Foods ("determine priorities for the consideration of residues of veterinary drugs in foods").

#### **CRITERIA FOR PRIORITISING HAZARD**

14. Reference is made to the Codex Criteria for the Establishment of Work Priorities and the Guideline on the Application of the Criteria for the Establishment of Work Priorities (*Codex Alimentarius Commission Procedural Manual*), and to FAO/WHO 2008; *Animal Feed Impact on Food Safety*. Report of the FAO/WHO Expert Meeting FAO Headquarters, Rome 8-12 October 2007.

15. The proposed criteria for identifying relevant hazards in feed are

- relevance to human health,
- extent of occurrence in feed and food, and
- potential impact on international trade in feed and food.

#### **Relevance to human health**

16. 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, and excessive levels of pesticides, veterinary drugs and additives (and certain of their residues).

17. Physical agents in feed are not known to be hazards 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.

18. 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) (WHO Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food), <http://www.who.int/foodsafety/chem/gems/en/>), and the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN) (WHO International Food Safety Authorities Network (INFOSAN); [http://www.who.int/foodsafety/fs\\_management/infosan/en/](http://www.who.int/foodsafety/fs_management/infosan/en/)).

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

20. The *Codex General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) provides maximum levels for specific toxic elements, toxins, and organic and other chemicals in food and feed. This information may also be helpful in prioritising hazards.

21. If inadequate data are available to characterise 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.

22. To establish potential relevance to human health, it is essential to have some estimate of the transfer of hazard in feed to edible product. Factors which will influence the transfer rate 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.

23. Information on transfer rates for a given hazard may be available in national or Codex standards such as the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) or in international reports and monographs from bodies including JECFA, JMPR, JEMRA, WHO IPCS, WHO CICAD, and/or in the scientific literature.

24. 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.

#### **Extent of occurrence**

25. It should be ensured that sampling protocols for feed and edible products 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*. 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*.

29. The extent of occurrence of a given hazard may depend on local production and storage conditions, and therefore best be estimated at the country or regional level. Some of the factors which may affect the extent of occurrence of a given hazard are noted below and in the appended tabulated summaries.

30. Some major hazards in feed and food and their sources are described in the following documents:

*Codex General Standard for Contaminants and Toxins in Food and Feed*, CODEX STAN 193-1995

*Code of Practice on Good Animal Feeding* (CAC/RCP 054/2004)



*Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001)

*Recommended International Code of Hygienic Practice for Egg Products* (CAC/RCP 15-1976)

*Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003)

*Code of Hygienic Practice For Milk And Milk Products* (CAC/RCP 57-2004)

*Code of Hygienic Practice for Meat* (CAC/RCP 58-2005)

*Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003)

*Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997)

*Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, including annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes* (CAC/RCP 51-2003)

*Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk-Producing Animals* (CAC/RCP45)

*Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts* (CAC/RCP 59-2005)

*Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds* (CAC/RCP 62-2006)

31. Further useful information on the extent of occurrence of potential hazards in feed may be obtained from

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

Good Practices for the Feed Industry (FAO and IFIF. 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. FAO 2010;  
<http://www.fao.org/docrep/012/i1379e/i1379e00.htm>)

Radionuclide contamination of foods: FAO recommended limits;  
<http://www.fao.org/docrep/u5900t/u5900t08.htm>),

Good Aquaculture Feed Manufacturing Practice (FAO Technical guidelines for responsible fisheries 5  
Suppl. 1. Aquaculture Development. 1. Good Aquaculture Feed Manufacturing Practice. ISSN 1020-  
5292. FAO, Rome 2001; <ftp://ftp.fao.org/docrep/fao/005/y1453e/y1453e00.pdf>).

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

OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety (Guide to Good  
Farming Practices for Animal Production Food Safety. FAO/OIE 2009.  
[http://www.oie.int/fileadmin/Home/eng/Food\\_Safety/docs/pdf/GGFP.pdf](http://www.oie.int/fileadmin/Home/eng/Food_Safety/docs/pdf/GGFP.pdf),  
<http://www.fao.org/docrep/012/i0482t/i0482t00.pdf>).

and in reports and monographs from international bodies including JECFA, JMPR, JEMRA, IPCS,  
CICAD, and/or in the scientific literature.

### **Impact on international trade**

32. Factors to consider in evaluating the potential impact on international trade include:

- Number of feeds and edible products potentially affected by a given hazard.
- Volume of production and consumption of potentially affected feed and related edible products in individual countries and volume and pattern of trade between countries.
- International or regional market potential.

## POTENTIAL FEED HAZARDS

33. The following list of human health hazards associated with animal feed is intended to describe the major categories of hazards, which may be present in feed. The list is not exhaustive.

### Biological hazards

#### *Bacteria*

34. The primary microbiological hazards in feed that transfers to edible products of food-producing animals are zoonotic microorganisms which contaminate animal and vegetable protein meals fed to animals. They may be introduced into feed crops, forages and water from contaminated pasture land, may be present in animal materials which are used for feed, and/or may be introduced to feed by cross-contamination or carry-over during processing, transport, and storage.

35. *Salmonella* is a worldwide human health concern. Salmonella in infected food-producing animals can be transmitted to humans via food. Contaminated feed can represent a route of exposure of food-producing animals to *Salmonella*. However, the correlation between contaminated feed and infection of livestock by a given *Salmonella* strain and the contamination of edible products from these animals needs to be established on a case-by-case basis. Adequate strain typing is necessary, because rates of transmission to edible products and human pathogenicity are typically strain-specific; only a limited number of serotypes adversely affect human health.

36. *Brucella*: In countries where *Brucella* is endemic, pasture may be contaminated by ruminants which deliver or abort offspring there, because the placentas of infected animals contain high levels of these microorganisms. Milk-producing animals may become infected by eating forage from contaminated pastures and excrete the microorganisms in their milk. This milk may be a risk to human health if not pasteurised prior to consumption.

37. Spore-forming bacteria belonging to aerobic or facultatively anaerobic *Bacillus spp.*, *anaerobic Clostridium spp.* and the non-sporogenic *Listeria monocytogenes* are human health hazards. Spores ingested in silage are unaffected by passage through the gastrointestinal tract of the ruminants and are excreted in the faeces; they may be transferred to milk mainly via faecal contamination of the udder or milking equipment. Spores present in raw milk may survive during processing and subsequently germinate and grow in the milk, so producing a potential risk to human health; reference is made to the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004) and the *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005).

38. Suggested control measures for microbial contamination are given in the WHO/FAO documents on Animal Feed Impact on Food Safety and Good Practices for the Feed Industry.

39. Bacterial toxins, such as *Botulinum* toxin and *Staphylococcus* enterotoxin, are listed under “Chemical hazards”.

#### *Endoparasites*

40. Some animal endoparasites, such as *Trichinella*, *Toxoplasma gondii*, and *Cysticercus*, are human health hazards. Various life stages of these organisms may contaminate pasture and forages and the derived feed. Ingestion of contaminated feed by food-producing animals can result in the presence of infective cysts in edible products (e.g. meat), which may pose a risk to human health, particularly if not adequately heat treated prior to consumption. Methods for on-farm prevention of such infection are given in the OIE Terrestrial Animal Health Code. Information on preventing contamination of edible products is given in the *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005).

#### *Viruses*

41. Some viruses such as hepatitis E are pathogenic to both food-producing animals and humans (Hepatitis E. WHO Fact sheet N°280. Revised January 2005; <http://www.who.int/mediacentre/factsheets/fs280/en/>). Viral contamination of feed is possible via body fluids of infected animals. The most likely route of contamination of edible products of food-producing animals is probably external, by contamination with virus-containing faeces. The risk of such contamination can be minimized by respecting good food hygiene practice.

**Prions**

42. Prions are infectious agents composed of protein in a misfolded form which induces existing, properly-folded prion protein (PrP<sup>c</sup>, a constituent of normal mammalian cells) to convert into the disease-associated, prion form (PrP<sup>Sc</sup>). Prions are responsible for the transmissible spongiform encephalopathies in a variety of mammals, including bovine spongiform encephalopathy in cattle and variant Creutzfeldt–Jakob disease in humans. Prions are extremely resistant to denaturation by chemical and physical agents including heat. Transfer from prion-contaminated feed to edible products has been demonstrated.

43. Reference is made to the Code of Hygienic Practice for Meat (CAC/RCP 58-2005), which recommends that animals should not be given feed and feed ingredients that are recognised as likely to introduce zoonotic agents (including transmissible spongiform encephalopathy agents) to the slaughter population.

**Chemical hazards****Elements**

44. A number of elements may present a hazard to humans, depending on their ionic form and ligands. This includes radionuclides and elements commonly referred to as "heavy metals", such as arsenic, cadmium, lead and mercury.

45. Radionuclides including caesium-134, caesium-137, strontium-90 and iodine-131 are human hazards when present in animal feed and forages as they may transfer to edible products. They may arise from water- or wind-borne environmental contamination. Transfer of radioiodine to milk, radiostrontium to bone, and radiocesium to milk, eggs and meat has been demonstrated.

46. The following are non-exhaustive examples: Arsenic is found in minerals and (mainly in the less toxic organic form) in marine plants, fish and shellfish. Cadmium is a contaminant in many feed and feed ingredients, in particular in minerals (such as phosphate and zinc sources), and in forages and grain grown near smelting and mining areas, or where the soil has been treated with contaminated manure, sewage, sludge or phosphate fertilizers. Lead may occur in grain or forage grown on contaminated soil, water from lead-containing plumbing systems, and also as a contaminant in minerals. Levels of (methyl)mercury in terrestrial animals and plants used for feed are usually very low, but the use of fish meal as animal feed can result in relevant (methyl)mercury levels in edible products.

**Toxins**

47. Toxins are naturally occurring hazards that include

- mycotoxins, e.g. aflatoxins, ochratoxins, zearalenone
- bacterial toxins, e.g. botulinum toxin and staphylococcal enterotoxin
- terrestrial plant toxins, e.g. solanine in potatoes, gossypol in cottonseed
- marine toxins: toxins from certain algae (particularly marine dinoflagellates)

**Mycotoxins**

48. Mycotoxins are produced by fungi which catabolise carbohydrates, and are therefore found most commonly in cereals (especially wheat, sorghum and maize), but also in oilseed meals and cakes, and silage.

49. Mycotoxin contamination in feed is not homogeneous. Relevant information on sampling is provided in the Codex General Standard for Contaminants and Toxins in Food and Feed (Codex standard 193-1995).

50. There is some scientific evidence that mycotoxins in grain which is fermented for ethanol production may concentrate in Distiller's Dried Grains with Solubles (DDGS).

51. Transfer from feed to edible products has been demonstrated for various mycotoxins including aflatoxins, ochratoxins and zearalenone.

52. Relevant guidance on mycotoxins in feed and food is given in

*Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, including annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes (CAC/RCP 51-2003),*

*Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk-Producing Animals (CAC/RCP 45-1997),*

*Code Of Practice For the Prevention And Reduction of Aflatoxin Contamination In Peanuts (CAC/RCP 55-2004),*

*Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005).*

### **Bacterial toxins**

53. Toxins produced by bacteria such as *Clostridium botulinum*, *C. tetani* and *C. perfringens*, *Vibrio cholerae*, *Staphylococcus aureus*, *Yersinia enterocolitica*, and *Shigella dysenteriae* are acutely toxic to food-producing animals when ingested with feed. Transfer of toxin to edible products is therefore unlikely.

### **Terrestrial plant toxins**

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

55. The risk of botanical contamination of feed can be minimized by adherence to good agricultural practices, and by visual inspection at harvest or targeted chemical analysis.

### **Marine toxins**

56. Dinoflagellates such as *Gambierdiscus toxicus* in tropical and subtropical waters produce marine toxins including heat-resistant ciguatera toxin, maitotoxin, scaritoxin and palytoxin. Small filter-feeding fish which can accumulate such biotoxins and their predators may be harvested and used to make fish meal.

57. The Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003) refers to hazards in human food originating from tropical reef fish that accumulate ciguatera toxin. Reference is also made to FAO guidance on monitoring, sampling and analysis methods, and proposed maximum levels of marine toxins in shellfish (Marine biotoxins - FAO Food and Nutrition Paper 80 (2004); <http://www.fao.org/docrep/007/y5486e/y5486e00.htm>). Excretion in human milk after maternal poisoning has been reported, so transfer from feed to edible products, specifically milk, is a possibility.

### **Organic chemicals**

58. Of the many organic chemical contaminants that are present in the environment and therefore are potentially present in feed, it is the lipophilic compounds that have the greatest tendency to accumulate in edible products of food-producing animals.

59. Polychlorinated dibenzodioxins (PCDD), dibenzofurans (PCDF) and dioxin-like polychlorinated biphenyls (DL-PCBs), hereafter referred to as dioxins, are related groups of compounds and congeners which are hazardous. Dioxins in feed may arise by contamination, for example from dioxin-containing preservatives in wood, or from combustion sources (e.g. waste incineration plants, fossil fuel power stations, bush fires, exhaust gases). Dioxins may be present as contaminants in mineral sources, such as clays, recuperated copper sulphate, zinc oxide, and in food by-products, including fish by-products such as fish meal and fish oils.

60. Dioxins and some organic chemicals such as organochlorine pesticides (e.g. aldrin, dieldrin, DDT) can accumulate in the environment and in fat, so the duration of exposure is important.

61. The Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds (CAC/RCP 62-2006) provides guidance on the occurrence, reduction and prevention of dioxin contamination.

62. Risks arising from the intentional addition of chemicals to feed or feed ingredients are addressed in different Codex standards. These provide maximum levels for:

- Pesticide residues, as defined by the Codex definition, that are within the terms of reference of the Codex Committee on Pesticide Residues (CCPR).

- Residues of veterinary drugs, as defined by the Codex definition, that are within the terms of reference of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).
- Residues of feed additives and other residues of certain processing aids that are within the terms of reference of the Codex Committee on Food Additives (CCFA).

63. Information on pesticide MRLs and their derivation is given in Pesticide Residues in Food and Feed; Codex Pesticides Residues in Food Online Database (<http://www.codexalimentarius.net/pestres/data/index.html>), Recommended Methods of Sampling for Pesticide Residues for the Determination of Compliance with MRLs (CAC/GL 33-1999), Maximum Residue Limits for Veterinary Drugs in Food (CAC/MRL 2-2009), and in the related FAO manual (FAO Plant Protection Paper 197. Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. FAO Rome, 2009; <http://www.fao.org/docrep/012/i1216e/i1216e.pdf>).

64. Concerning the use of veterinary drugs in food-producing animals, reference is made to the Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009). Reference is also made to guidance on the responsible and prudent use of antimicrobial agents in veterinary medicine by the OIE World Organization for Animal Health (World Organisation for Animal Health. Terrestrial Animal Health Code, volume 1, chapter 6.9: Responsible and prudent use of antimicrobial agents in veterinary medicine. [http://www.oie.int/fileadmin/Home/eng/Health\\_standards/tahc/2010/en\\_chapitre\\_1.6.9.pdf](http://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/2010/en_chapitre_1.6.9.pdf)).

65. Information on processing aids in food production which is also relevant to feed production is given in the *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010).

66. Non-intentional exposure to pesticide residues in crops may result from the uptake of residues present as a result of treating a previous crop with pesticides or from spray-drift, volatilisation, and/or runoff. Veterinary drug residues may be present in feed ingredients sourced from terrestrial or aquatic animals, although this is not normally considered to be a major route of exposure. There is some evidence that antibiotics used to control microbiological contamination may concentrate in yeast cultures used for ethanol production and sold as dehydrated protein source, and in Distiller's Dried Grains with Solubles (DDGS) after their use in fermentation for ethanol production (FAO/IFIF Good Practices For The Feed Industry (FAO and IFIF. 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. FAO 2010).

67. Veterinary drug, feed additive and processing aid contamination may arise during feed production. For veterinary drugs, reference is made to the recommendations of the OIE Terrestrial Health Code on precautions to be taken (flushing, sequencing, cleaning) after the production of a medicated feed (OIE Terrestrial Animal Health Code; <http://www.oie.int/en/international-standard-setting/terrestrial-code/access-online/>).

68. Unapproved use of drugs leading to excessive levels in feed ingredients may result in transfer of residues to meat, fish, milk or eggs (e.g. nitrofurans in shrimps, chloramphenicol in milk powder).

69. The possibility of intentional adulteration of feed should also be considered, for example by melamine or cyanuric acid.

#### ***Other chemicals***

70. The following are examples only.

Nitrites: The interconversion of nitrate to nitrite is a major contributor to nitrite exposure in food-producing animals. Nitrite in edible products, particularly meat, are metabolised to carcinogenic nitrosamines in the human gut. Transfer of nitrite from feed to edible products has been demonstrated but is not normally considered to be a relevant route of exposure.

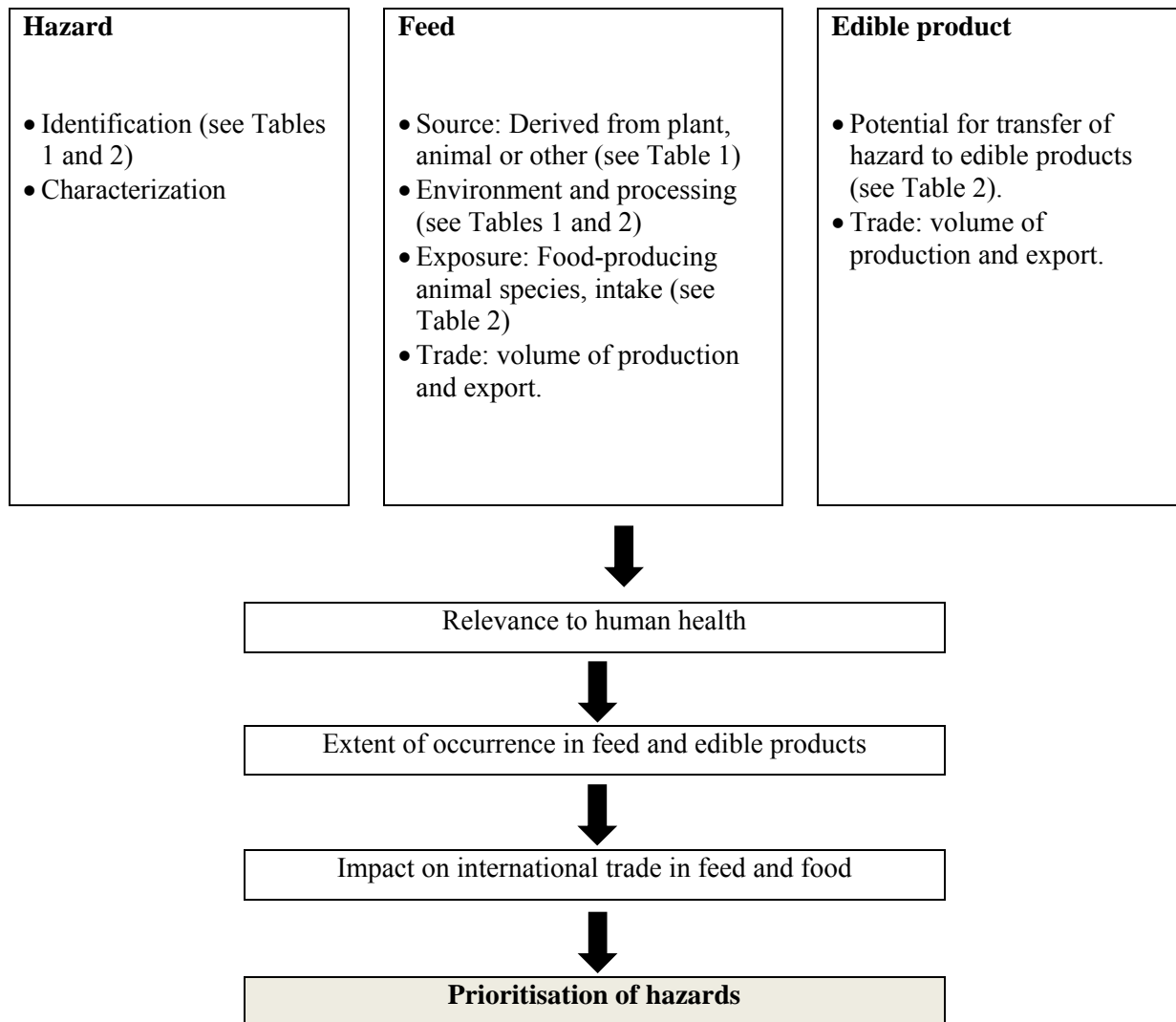
Acrylamide: is formed in carbohydrate-rich substances at high temperature (usually in excess of 120°C) and low moisture. Transfer from contaminated feed to eggs has been demonstrated but is not normally considered to be a relevant route of exposure.

#### **PROCEDURE**

71. Hazard prioritisation should be documented fully and systematically in a transparent manner.

72. Figure 2 summarises factors, which determine the occurrence of hazard in feed and food. The resulting occurrence should be considered in relation to the three criteria for hazard prioritisation, namely relevance to human health, extent of occurrence, and impact on international trade in feed and food. More detailed information is given in Tables 1 and 2.

**Figure 2. Factors and criteria to consider when prioritising hazards in feed**



**TABLE 1: FACTORS AFFECTING OCCURRENCE OF HAZARDS IN FEED AND FEED INGREDIENTS**

<b>Feed or feed ingredient</b>	<b>Risk factor</b>	<b>Hazard</b>
<u>Plant origin</u>		
Forages (pasture, hay, silage)	Botanical contamination, environment, field conditions, plant species	Bacteria, endo-parasites, mycotoxins, plant toxins, heavy metals, dioxin, organic chemicals, radionuclides
Plant feed or feed ingredient	Crop and harvest (environment, field conditions, plant species)	Residues, environment chemicals, heavy metal, plant toxins, mycotoxins, radionuclides, (pathogenic bacteria)
	Manufacturing (carry-over, cross-contamination), by-products from industrial food-production, processed feed ingredients, mixed feed	Residues of veterinary drugs, residues of feed additives and processing aids
	Treatment to eliminate toxins or for conservation (heat/acid/pressure etc.)	Plant toxins or bacteria
	Condition of storage, transport (moisture, temperature), manufacturing (cross-contamination)	Pathogenic bacteria, mycotoxins, toxic elements
Fat/oil	Origin, purity, blending	Dioxins, organochlorine pesticides
Algae	Environment, species	Plant toxins, heavy metals, dioxin, residues, (radionuclides)
<u>Terrestrial animal origin</u>		
Land animal and milk products	Livestock conditions (animal, environment)	Bacteria, viruses, endoparasites, prions
	Inadequate treatment (heat/acid/pressure etc.)	Bacteria, viruses, endoparasites or prions
	Condition of storage, transport (moisture, temperature), manufacturing (cross-contamination)	Bacteria, toxic elements
<u>Aquatic animal origin</u>		
Fish, other marine animals	Aquatic environment	Heavy metal, organic chemicals, bacteria, viruses, radionuclides
	Inadequate treatment (heat/acid/pressure etc.)	Bacteria
	Condition of storage, transport (moisture, temperature), manufacturing (cross-contamination)	Bacteria, toxic elements



<b>Feed or feed ingredient</b>	<b>Risk factor</b>	<b>Hazard</b>
<u>Mineral origin</u>		
Minerals, including additives (trace elements and binders)	Origin, purity, authorization (trace elements)	Heavy metal, dioxins
<u>Fermentation by-products</u>		
Protein concentrate from bacteria and yeasts	Processing, storage, transport	Bacteria, antibiotics

**TABLE 2: FACTORS AFFECTING OCCURRENCE OF HAZARDS IN EDIBLE PRODUCTS**

<b>Hazard</b>	<b>Feed sources and risk factors</b>	<b>Edible products</b>
<u>Biological</u>		
Bacteria (e.g. <i>Salmonella</i> , <i>Brucella</i> , <i>Listeria monocytogenes</i> )	Contaminated pasture, forages and feed (especially <i>Salmonella</i> ), animal and vegetable protein meals. Sick animals close to feed production or storage. Diseased animal cadavers in storage. Poor hygiene during feed production, slaughter and processing of edible tissues.	Eggs, meat and meat products ( <i>Salmonella</i> ), milk and milk products ( <i>Brucella</i> , <i>Listeria monocytogenes</i> )
Endoparasites (e.g. <i>Toxoplasma gondii</i> , <i>Cysticercus</i> , <i>Trichinella</i> )	Contaminated pasture, forages, compound feed. Inadequate environmental monitoring or not treated in feed or animal.	Various tissues containing infective cysts
Prions	Contaminated animal [ruminant] protein (containing misfolded prion protein). Cross-contamination of feeds for ruminants with ruminant protein.	Nervous system tissue
Viruses: hepatitis E, rotavirus	Feed contaminated by body fluids of infected animals. Sick animals close to feed production or storage. Poor hygiene during feed production (slaughter and processing of edible tissues).	Various tissues contaminated during preparation by virus-containing body fluids
<u>Chemicals</u>		
Radionuclides: <sup>90</sup> Sr, <sup>131</sup> I, <sup>134</sup> Cs, <sup>137</sup> Cs	Contaminated feed and forages. Inadequate environmental monitoring.	Milk (radioiodines, radiocesium), bone (radiostrontium), meat (radiocesium)
"Heavy metals"	Poor quality minerals, inadequate environmental monitoring.	
Arsenic (inorganic)	Sea plants, fish products and minerals.	Fish
Cadmium	Minerals (such as phosphate, zinc sources). Forage/grains (depending on geographical area). Soil contamination by manure, sewage, sludge or phosphate fertilizers.	Higher concentrations in shellfish, oysters, salmon, also kidney and liver. Lower concentrations in dairy products, meat, eggs, poultry.
Lead	Contaminated soil, lead paints and batteries, water from plumbing systems that contain lead. Minerals (e.g. copper sulphate, zinc sulphate, zinc oxide).	Bone, brain and kidney
Mercury/methyl mercury	Anthropogenic contamination, fish meal.	Liver, kidney, fish products

Hazard	Feed sources and risk factors	Edible products
Mycotoxins	Produced by carbohydrate-catabolising fungi, found in cereals (especially wheat, sorghum and maize), in oilseed meals and cakes, and silage (e.g. aflatoxins from <i>Aspergillus flavus</i> , ochratoxins from <i>A. ochraceus</i> , zearalenone, fumonisins, trichothecenes such as deoxynivalenol). High humidity during growth and harvest; non-adherence to good agricultural practices. High humidity post-harvest. Hull, tip cap and outer layers not separated before milling.	Meat (depoxy-deoxynivalenol, zearalenol, ochratoxins), liver, milk, eggs (aflatoxins)
Plant toxins	Non-adherence to good agricultural practices, inadequate visual inspection or chemical analysis.	
Tremetone	Contaminated forage.	Milk
Pyrrizolidine alkaloids, terpenes, glycosides	Botanical contamination in forages (e.g. <i>Senecio jacobaea</i> ), endogenous toxin in plants (e.g. gossypol in cottonseed).	Milk, meat
Other alkaloids (e.g. atropine, caffeine, cocaine, ephedrine, morphine, nicotine, solanine)	Botanical contamination in forages.	Milk, meat
Organic chemicals		
Dioxins (polychlorinated dibenzodioxins, dibenzofurans and dioxin-like polychlorinated biphenyls)	Soil contamination (e.g. clay minerals). From combustion sources (e.g. fossil fuel power stations, waste incineration plants, exhaust gases), from biocide-treated wood used during feed ingredient production. Contaminated mineral sources. Oil in fish meal. Non-adherence to good agricultural practices. Non-certified source of oil/fat feed components.	Fat (in meat, milk, egg yolk)
Organochlorine pesticides	Non-adherence to good agricultural practices. Environmental contamination. .	Fat
Veterinary drug, pesticide, processing aid residues	Milk of antibiotic-treated cows, nectar of antibiotic-treated fruit trees, cross-contamination of manufactured feed with veterinary drugs, meal from medicated fish and shrimps, fodder, grain and by-products (e.g. grape pomace) from crops treated with pesticides. Non-adherence to good agricultural practices. Non-adherence to recommended dose and drug withdrawal periods. Non-adherence to good manufacturing practices.	Meat, milk, eggs, honey.

## 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 ~~striketrough 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.