



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

(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), 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 Prioritised List of Hazards in Feed, in Appendix 1, **by 15 October 2011**.

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

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INTRODUCTION

1. The purpose of this document is to provide descriptive guidance for feed safety bodies in member countries and regional authorities who need to prioritise hazards which may be present in feed of food-producing animals. It is intended for use by governments, but other parties who need to conduct such prioritisation may also find them useful. The extent of occurrence of a given hazard in feed may depend on local production, processing and storage conditions, and may therefore best be estimated at the country or regional level. Feed hazard prioritisation may require specialized support and/or training, particularly in countries without dedicated risk analysis staff.

2. This document should be read in conjunction with:

- *Code of Practice for Source Directed Measures to reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001);
- *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004);
- *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 Safety¹ and of the OIE *Terrestrial Animal Health Code*², the OIE Guide to Good Farming Practices for Animal Production Food Safety³, and the FAO/OIE Good Practices For The Feed Industry⁴.

SCOPE

3. The scope of this document is to provide practical guidance on how to identify and prioritise biological and chemical hazards including radionuclides which may be present in feed of food-producing animals, and for which there is likely to be carry-over to edible products for human consumption in amounts which may adversely affect human health.

4. "Feed" refers to feed ingredients including feed additives and water as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004) and/or their combination whether processed, semi-processed or raw, which are intended to be fed directly to food-producing animals.

5. "Hazard" refers to any substance which can adversely affect 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. This document considers 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 (*Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004)).

7. Hazards in feed can be biological or chemical. Biological hazards comprise bacteria, endoparasites, viruses and prions. Chemical hazards comprise toxic elements (including radionuclides), organic chemicals including toxins, veterinary drugs and pesticides, dioxins and other chemicals. Physical feed contaminants

¹ 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>.

² OIE. Terrestrial Animal Health Code. <http://www.oie.int/en/international-standard-setting/terrestrial-code/access-online/>

³ 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.fao.org/docrep/012/i0482t/i0482t00.pdf>

⁴ FAO 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>

such as sharp objects, stones and animal fur are not considered in this document. The list of hazards presented here is intended to be extensive but not exhaustive.

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

As low as reasonably achievable (ALARA): Reduction of hazards to the lowest level possible using best practice such as Good Agricultural Practice (GAP) and Good Manufacturing Practice (GMP).⁶

Acute reference dose (ARfD): An estimate of the amount of a substance in food or drinking water, normally expressed on a body weight basis, that can be ingested in a period of 24 hours or less without appreciable health risks to the consumer on the basis of all known facts at the time of the evaluation.⁷

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

Codex maximum level (ML): The maximum concentration of a contaminant in a food or feed commodity recommended by the Codex Alimentarius Commission to be legally permitted in that commodity.⁸

Codex maximum residue limit (MRL): The maximum concentration of a pesticide or veterinary drug residue recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. Codex MRLs, which are primarily intended to apply in international trade, are derived from estimations made by JMPR or JECFA following: (a) toxicological assessment (b) review of residue data from supervised trials and supervised uses including those reflecting national good agricultural and good veterinary practices, which are considered to represent effective pest control practices. Consideration of the various dietary residue intake estimates and determinations both at the national and international level in comparison with the ADI should indicate that foods complying with Codex MRLs are safe for human consumption.⁸

Contaminant: Any 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.⁹

Control: The prevention, elimination, or reduction of hazards and/or minimization of risks to human health.¹⁰

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).¹¹

⁵ *Pesticide Residues in Food and Feed, Glossary of Terms.*

<http://www.codexalimentarius.net/pestres/data/reference/glossary.html>

⁶ *Codex General Standard For Contaminants And Toxins In Food And Feed.* Codex Stan 193-1995. http://www.codexalimentarius.net/download/standards/17/CXS_193e.pdf

⁷ Solecki R, Davies L, Dellarco V, Dewhurst I, Raaij M, Tritscher A; Pesticides and Biocides Division, Federal Institute for Risk Assessment, Berlin, Germany. Guidance on setting of acute reference dose (ARfD) for pesticides. *Food Chem Toxicol.* 2005 Nov;43(11):1569-93

⁸ *Codex Alimentarius Commission: Procedural Manual*

⁹ adapted from *Codex Alimentarius Commission: Procedural Manual*

¹⁰ *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* CAC/GL-30-1999).

http://www.codexalimentarius.net/download/standards/357/CXG_030f.pdf

¹¹ 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

Edible product: All edible products intended for human consumption derived from food-producing animals, including for example meat, eggs and milk.⁹

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.).¹²

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.¹³

Feed: Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food producing animals.¹²

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.⁸

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

Medicated feed: Any feed which contains veterinary drugs as defined in the Codex Alimentarius Commission Procedural Manual.¹²

Risk assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.⁸

Undesirable substances: Contaminants and intentionally added substances which are present in and/or on feed and feed ingredients and which may constitute a risk to human health via food.¹²

CRITERIA FOR PRIORITISING HAZARD

9. At the FAO/WHO 2007 Expert Meeting on Animal Feed Impact on Food Safety¹, the proposed criteria for identifying important hazards in feed were

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

Relevance to human health

10. The human health relevance of a given hazard can be assessed by reference to Codex Official Standards¹⁴. These standards propose maximum limits for specific residues and contaminants in food. It is important to note that these limits are based on estimated human adverse effects (in terms of Acceptable Daily Intake (ADI), Acute Reference Dose (ARfD), etc.), but are also adjusted to take account of Good Manufacturing Practice (GMP), Good Agricultural Practice (GAP) and Good Veterinary Practice (GVP), and to keep levels of contaminants as low as reasonably achievable (ALARA). Codex maximum levels (MLs) and maximum residue limits (MRLs) should therefore not be taken as direct quantitative estimates of risk to human health. An example of such maximum levels and their derivation is given in the *Codex General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995). This standard lists the maximum levels of contaminants and natural toxicants in feed which are recommended by the CAC to be applied to commodities moving in international trade. Feed contaminants are included only in cases where these are transferred to food of animal origin and are relevant for human health, i.e. when a given hazard is present in food in amounts that are significant for the total exposure of the consumer, taking into

¹² *Code of Practice on Good Animal Feeding*. CAC/RCP 054/2004.

www.codexalimentarius.net/download/standards/10080/CXP_054e.pdf

¹³ adapted from *Code of Practice on Good Animal Feeding*. CAC/RCP 054/2004.

www.codexalimentarius.net/download/standards/10080/CXP_054e.pdf

¹⁴ <http://www.codexalimentarius.net>

consideration the Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (Codex *Procedural Manual*).

11. Normally, identification and characterization of a given hazard with respect to human health is done as part of risk assessment for Codex by independent scientific expert bodies, in particular the Joint FAO/WHO Expert Committee on Food Additives (JECFA), Joint FAO/WHO Meeting on Pesticide Residues (JMPR), and Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA), and other ad hoc meetings, as described in the FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition¹⁵ and the Codex *Procedural Manual*. The evaluation of new suspected hazards should generally be referred to such a body via the Codex Alimentarius Commission.

Extent of occurrence

12. Figure 1 in this document provides a schematic flowchart outlines the conditions under which the major feed hazards may be expected to occur. More detailed information on these hazards and the factors affecting their occurrence are given in Tables 1-3.

13. 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.

14. Major sources of hazards in feed and food, and how to reduce them, are described in the following documents:

- *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)

15. Contaminants in animal feeds are also summarized in the WHO/FAO documents on Animal Feed Impact on Food Safety¹, Good Practices for the Feed Industry⁴, radionuclide contamination¹⁶, Good Aquaculture Feed Manufacturing Practice¹⁷, and on the relevant FAO and WHO websites¹⁸. Information on the control of hazards of animal and human health importance in animal feed is included in the OIE

¹⁵ <ftp://ftp.fao.org/docrep/fao/010/a1296e/a1296e00.pdf>

¹⁶ Radionuclide contamination of foods: FAO recommended limits.
<http://www.fao.org/docrep/u5900t/u5900t08.htm>.

¹⁷ 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>

¹⁸ <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

Terrestrial Animal Health Code² and the OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety³.

Impact on international trade

16. Trade in primary feed ingredients and additives intended for food-producing animals is of worldwide economic importance. Animal feed is crucially important in the safety of food of animal origin. This document is intended to facilitate international comparability of feed hazard prioritisation, thus promoting fair practices in international feed and food trade.

17. Trade considerations are not relevant to the assessment of hazard within a risk analysis, but may be very relevant to the management of risk and where a country needs to prioritise risk management actions (*Working Principles for Risk Analysis for Food Safety for Application by Governments*; CAC/GL 62-2007).

FEED HAZARD LIST

18. 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 but is not exhaustive.

19. Factors which can markedly influence the occurrence of a given hazard in specific feed components and which may be country-specific include conditions during growth, harvesting, processing, storage and transport.

20. Prioritisation, in terms of effects on human health, depends crucially on rates of transfer from feed to food ("carry-over", typically expressed as a transfer coefficient). It is therefore essential to have some estimate of the transfer of contaminants/residues in feed to edible animal products (e.g. meat, fish meat, milk, and eggs). 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.

Biological hazards

Bacteria

21. The primary microbiological hazards in feed that may be transmitted to food and pose a hazard (health risk) to humans are organisms such as *Salmonella* and *Brucella* which contaminate animal and vegetable protein meals fed directly to animals. They may be introduced into feed from contaminated pasture land and/or forages and during processing, transport, and storage.

22. *Salmonella* is a worldwide human health concern. Infection in food-producing animals can be transmitted to humans via food. Contaminated feed may represent an important route of exposure of food-producing animals to *Salmonella*, but the correlation between contaminated feed and infection of livestock by the same *Salmonella* strains and the contamination of meat, milk and eggs produced from these animals needs to be established on a case-by-case basis. Adequate strain typing is necessary, because rates of transmission to food and human pathogenicity are typically strain-specific.

23. *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. If such contaminated forage is fed to milking animals, the microorganisms may be excreted in their milk. If this milk is not pasteurized prior to consumption by humans, it may be a human health risk.

24. Other: Some silage-related bacteria may contaminate milk via fecal contamination and present a human health risk. Spore-forming bacteria belonging to aerobic or facultatively anaerobic *Bacillus* spp. and anaerobic *Clostridium* spp., and the non-sporogenic *Listeria monocytogenes* are the most important organisms. Spores ingested in silage are unaffected by passage through the gastrointestinal tract of the cow and are excreted in the feces; they may be transferred to milk mainly via fecal contamination of the udder or milking equipment. Spores present in raw milk may survive during processing and after germination and outgrowth to high levels may cause spoilage and human disease. Some serotypes of *Escherichia coli*, for example *E. coli* O157, have been associated with human illness, and may contaminate animal feed and/or edible products via fecal contamination. The risk of such contamination can be minimised by adhering to good hygienic practice; 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).

25. Suggested control measures for microbial contamination are given in the WHO/FAO documents on Animal Feed Impact on Food Safety¹ and Good Practices for the Feed Industry⁴.

26. Bacterial toxins, such as *Botulinum* toxin and *Staphylococcus* enterotoxin, are listed under chemical hazards.

Endoparasites

27. Some animal endoparasites, such as *Trichinella*, *Echinococcus*, *Toxoplasma gondii*, and *Cisticercus*, are human health hazards. Various life stages of these organisms may contaminate pasture, forages and derived compound feed. Ingestion of contaminated feed by food-producing animals can result in the presence of infective cysts in edible products (e.g. meat). Particularly if such edible products are not adequately heat-treated, their ingestion may pose a risk to human health. Methods for on-farm prevention of such infection are given in the OIE Terrestrial Animal Health Code². Useful information on preventing contamination of edible products is given in the *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005).

Viruses

28. Some viruses such as hepatitis E may be pathogenic to both food-producing animals and humans¹⁹. 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, which is outside the terms of reference of the present document. The possibility of such contamination can be minimized by practicing good food hygienic, including food heating.

Prions

29. Prions are infectious agents composed of protein in a misfolded form which induces existing, properly-folded prion protein (PrP^c, a constituent of normal mammalian cells) to convert into the disease-associated, prion form (PrP^{Sc}). 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. Carry-over from prion-contaminated feed to edible products has been demonstrated.

30. 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

31. The *Codex General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) provides useful guidance on maximum levels in food of toxic elements, toxins, and organic and other chemicals. These maximum levels may be used as a guide to prioritising such hazards, i.e. to establish their relative importance.

Elements

32. A number of elements may present a toxic 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.

33. Radionuclides including caesium-134, caesium-137, strontium-90 and iodine-131 are relevant human hazards if present in animal feed and forages. They may arise from wind-borne environmental contamination. Carry-over of radioiodines to milk, radiostrontium to bone, and radiocaesium to milk, eggs and meat has been demonstrated.

34. Arsenic (inorganic) is found in sea plants, fish products and supplemental minerals. 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 contaminated soil, lead paints, water from lead-containing plumbing systems, and also as a contaminant in mineral supplements.

¹⁹ WHO. Hepatitis E. Fact sheet N°280. Revised January 2005.
<http://www.who.int/mediacentre/factsheets/fs280/en/>

Mercury (and/or methylmercury) levels in terrestrial animals and plants are usually very low; the use of fish meal as animal feed can however also lead to higher (methyl)mercury levels in edible products.

Toxins

35. Toxins are naturally occurring biogenic toxicants that are not intentionally added to feed, including
- mycotoxins, e.g. aflatoxin, ochratoxin, zearalenone
 - bacterial toxins, e.g. botulinum toxin and staphylococcus enterotoxin
 - terrestrial plant toxins, e.g. solanine in potatoes, gossypol in cottonseed
 - marine toxins: toxins from certain algae (particularly marine dinoflagellates)

Mycotoxins

36. Mycotoxins can pass from feed into edible products at levels that may represent a concern for human health.
37. Mycotoxins are produced by fungi which catabolise carbohydrates, and are therefore found in cereals (especially maize), cottonseed, peanut, and copra.
38. Mycotoxin contamination 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).
39. Transfer from feed to food of animal origin has been demonstrated for various mycotoxins including aflatoxin, ochratoxin and zearalenone, of which aflatoxin is the most frequently reported hazard. The significance depends on the rate of transfer.
40. There is some evidence that mycotoxins in grain which is fermented for ethanol production may concentrate in Distiller's Dried Grains with Solubles (DDGS)⁴.
41. Relevant guidance on the prevention and reduction of contamination by mycotoxins in feed and food components includes
- *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

42. Toxins produced by bacteria such as *Clostridium botulinum*, *C. tetani* and *C. perfringens*, *Vibrio cholerae*, *Staphylococcus aureus*, *Yersinia enterocolitica*, and *Shigella dysenteriae* are usually acutely toxic to food-producing animals when ingested with feed, and are therefore less likely to pass into edible products.
43. Some bacterial toxins, such as that produced by *Escherichia coli* O157:H7, do not cause disease in ruminants because they lack a receptor for the toxin. Such bacteria may occur as gut commensals in cattle and therefore be more difficult to detect. Reference is made to the *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005).

Terrestrial plant toxins

44. Toxin-producing plants may occur as botanical impurities of forages in grasslands around the world. Toxins can include alkaloids (e.g. atropine, caffeine, cocaine, ephedrine, morphine, nicotine, solanine), pyrrolizidine alkaloids (e.g. *Jacoline* from *Senecio jacobaea*), terpenes (e.g. camphor, menthol, pinene), THC, gossypol, isoflavones, and glycosides (e.g. cyanogenic glycosides, digitalis). Carry-over of some of these toxins to edible products such as milk and meat has been demonstrated.

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

Marine toxins

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

47. 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 shellfish²⁰. Excretion in human milk after maternal poisoning has been reported, so carry-over from feed to animal edible products, specifically milk, is a possibility which may need to be quantified on a case by case basis.

Organic chemicals

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

49. Dioxins, dibenzofurans and dioxin-like polychlorinated biphenyls (PCBs) are related groups of compounds and congeners which are more or less toxic to mammals including humans. Dioxins in feed can be formed during heat processing (e.g. lime in citrus pulp, directly dried bakery waste), or may arise by contamination, for example from dioxin-containing preservatives in wood used in animal production, from grass dried directly with exhaust gases from heating equipment, or from pasture near combustion sources (e.g. waste incineration plants, fossil fuel power stations, bush fires). Dioxins may be present as contaminants in feed 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.

50. Dioxins accumulate in fat to a high degree, so even extremely low levels of dioxin in feed can become significant if fed to food-producing animals over their lifetime, and can result in unacceptable residues in edible products such as meat, milk, and eggs. Implementing controls for dioxins in feed therefore represents an important step towards reducing dioxins in the food chain. Toxicokinetic models have been developed to estimate the transfer rates of dioxins from feed to animal tissues.

51. 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.

52. Some organic chemicals such as organochlorine pesticides (e.g. aldrin, dieldrin, DDT) are relatively persistent in the environment and the mammalian body, and are still in use in some countries. This can result in contaminated feed and thus accumulation in the fat tissues of food-producing animals.

53. Risks arising from the **intentional** addition of chemicals in the production, of or directly to feed of food-producing animals are addressed in Codex Standards¹⁴. 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 processing aids that are within the terms of reference of the Codex Committee on Food Additives (CCFA).

54. Information on pesticide MRLs and their derivation is given in *Pesticide Residues in Food and Feed; Codex Pesticides Residues in Food Online Database*

²⁰ Marine biotoxins - FAO Food and Nutrition Paper 80 (2004).
<http://www.fao.org/docrep/007/y5486e/y5486e00.htm>

(<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 relevant FAO manual²¹.

55. 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 World Organization for Animal Health²².

56. 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).

57. **Unintentional** exposure to pesticides residues in crops may result from the uptake of soil residues present as a result of treating a previous crop or from the off-target movement of pesticide applications (spray-drift, volatilisation) to adjacent or near-by crops. Veterinary drug residues may be present in feed ingredients sourced from terrestrial animals or aquaculture material, although this is not normally considered a major potential route of exposure. There is some evidence to suggest that antibiotics used to control microbiological contamination during grain fermentation for ethanol production may concentrate in Distiller's Dried Grains with Solubles (DDGS)⁴.

58. Veterinary drug and processing aid residues in feed may also result from carry-over contamination 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 feed².

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

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

Other chemicals

61. The following are examples only. Chemicals with relevance to human health are described as Codex standards.

Nitrites: A principal concern about nitrite in edible products, particularly meat, is the subsequent formation of carcinogenic nitrosamines in the human gut. The interconversion of nitrate to nitrite is a major contributor to nitrite exposure in food-producing animals. Carry-over of nitrite to edible products has been demonstrated but is not normally considered to raise any concern for human health.

Acrylamide: A toxic substance which can be formed in carbohydrate-rich substances at high temperature (usually in excess of 120°C) and low moisture. Carry-over from contaminated feed to eggs has been demonstrated.

PROCEDURE

Checklist

62. The following flowchart may be helpful as a preliminary aid in prioritising hazards. It is intended to be a graphic representation of the more detailed information provided in Tables 1 to 3. It is recommended that the flowchart be consulted in conjunction with these tables, which provide more detailed information on factors affecting the likelihood of occurrence of feed hazards, by feed component.

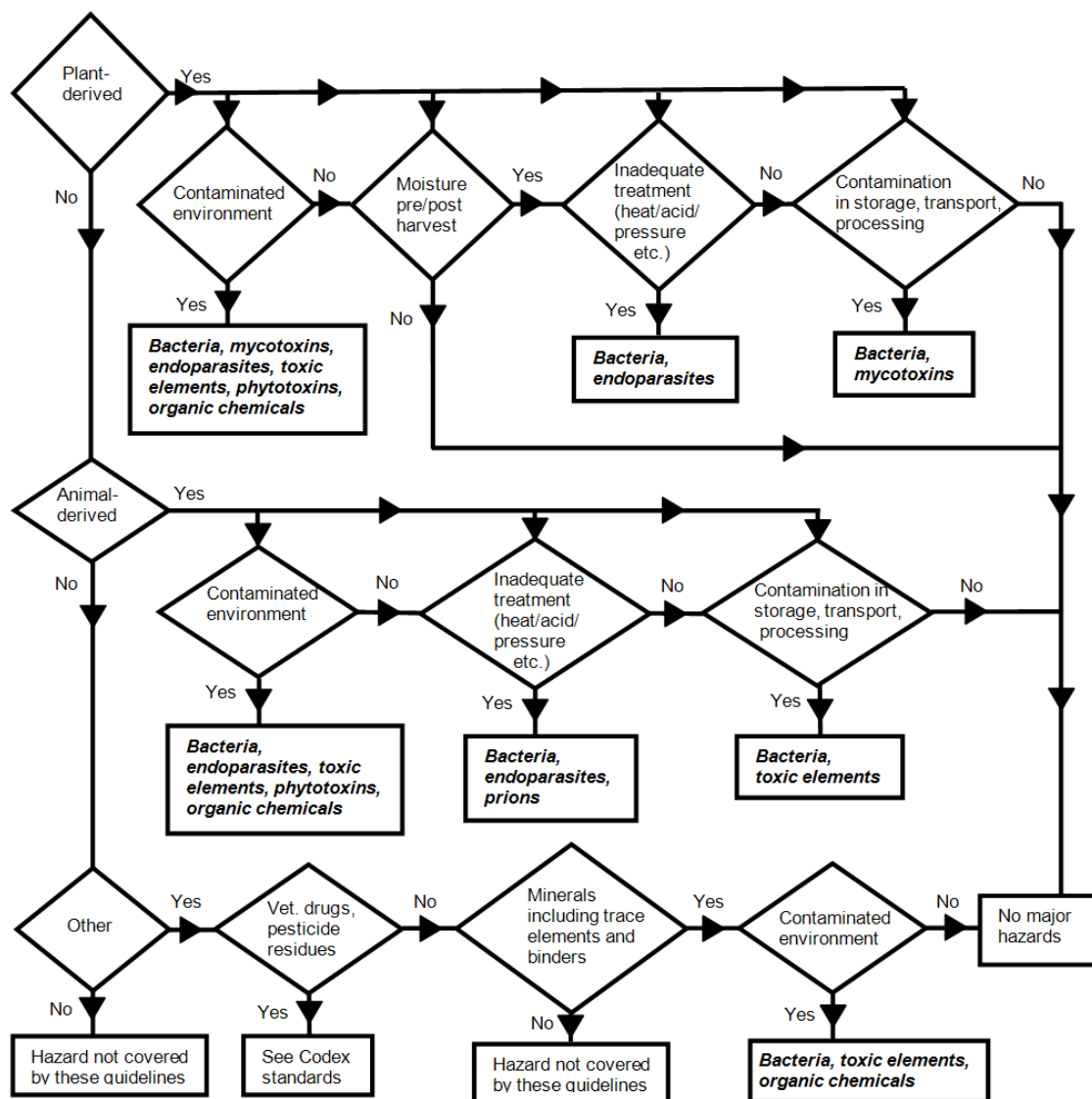
²¹ FAO Plant Protection Paper 197. Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. FAO Rome, 2009.

<http://www.fao.org/docrep/012/i1216e/i1216e.pdf>

²² 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

Figure 1 Flowchart for assessing the likelihood of occurrence of feed hazards



“Plant-derived”, “animal-derived” and “other” refer to sources of feed ingredients.

Detection

63. Reference is made to the Report of the FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety¹, which lists assay methods for microbial pathogens and for chemicals (mycotoxins, heavy metals, dioxins, organochlorine pesticides, veterinary drugs).

64. If a new assay is developed, the methods should comply with a specific set of criteria, such as accuracy, applicability (matrix and concentration range), limits of detection and determination, precision, repeatability and reproducibility.

Documentation

65. Hazard prioritisation should be fully and systematically documented. A formal record, including a summary, should be prepared and made available to interested independent parties so that other 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 hazard prioritisation.

Reassessment

66. If new potentially relevant scientific information becomes available, for example from food contamination monitoring or human health surveillance programs, previously completed feed hazard prioritisation may have to be reviewed and if necessary revised to incorporate new findings.

TABLE 1: RELEVANT HAZARDS IN FEED COMPONENTS

67.		Biological hazard			Chemical hazard						
68.	<i>Feed ingredient *</i>	Pathogenic bacteria	Viruses, endo-parasites	Prions	Mycotoxins	Plant toxins	Toxic elements		Organic chemicals		
69.							"Heavy metals"	Radio-nuclides	Dioxins, PCBs	Organo-chlorine pesticides	Residues of veterinary drugs, pesticides, processing aids
70.	<i>Cereal grains, legume seeds; tubers, roots, seeds and fruits</i>	(+)	-	-	+	+	+	(+)	+	+	
71.	<i>Forages and roughage</i>	+	+	-	+	+	+	(+)	+	(+)	(+)
72.	<i>Algae</i>	-	-	-	-	+	+	(+)	+	-	(+)
73.	<i>Milk products</i>	+	-	-	+	+	+	(+)	+	-	-
74.	<i>Land animal products</i>	+	+	+	-	(+)	+	(+)	+	-	+
75.	<i>Fish, other marine animals</i>	+	-	-	-	-	+	(+)	+	-	+
76.	<i>Minerals, trace elements, binders, feed additives and vitamins</i>	-	-	-	-	-	+	(+)	+	-	+
77.	<i>Fermentation by-products</i>	-	-	-	+	-	-	(+)		-	-
78.	<i>Fats and oils (animal and plant)</i>	-	-	(+)	-	-	-	(+)	+	(+)	+
79.	<i>Water (not drinking water quality)</i>	(+)	(+)	-	(+)	-	(+)	(+)	-	-	-

* This list of feed ingredients is intended to be extensive but not complete.

- unlikely

+ possible

(+) in special circumstances

TABLE 2: FACTORS AFFECTING PRESENCE OF HAZARDS IN FEED

80.	Feed ingredient source	Contaminated environment	Inadequate treatment (heat/acid/pressure etc.)	Moisture pre/post-harvest	Transport/storage contamination	Processing contamination
81.	Pasture	1cd, 2abcef	-	1c	-	-
82.	Conserved forages and roughage	1cd, 2abcef	2c	1c, 2b	1c, 2b	2e
83.	Cereal grains	1c, 2abef	-	2b	1c, 2b	1c, 2b
84.	Oil seeds and fruits	1c, 2abcef	2c	2b	1c, 2b	1c, 2b
85.	Legume seeds	1c, 2abcef	2c	2b	1c, 2b	
86.	Tubers, roots	1c, 2abef	2c	2b	1c, 2b	
87.	Other seeds and fruits	1c, 2abcef	2c	2b	1c, 2b	
88.	Other plants, algae	1c, 2acef	2c	1c, 2b	1c, 2b	
89.	Milk products	1c, 2bcdef	1ace, 2c	2b	1c, 2b	1ac, 2d
90.	Land animal products	1acd, 2acdef	1abce, 2c	-	1c, 2b	1abce, 2d
91.	Fish, other marine animals	1c, 2acdef	1c	-	1c, 2b	1ace, 2d
92.	Minerals, including trace elements and binders	2aef	-	-	-	2e
93.	Feed additives	2acef	-	-	-	2e
94.	Fermentation by-products	1c, 2abd	1c	-	1c	1c, 2bd
95.	Oil, fat	2e	-	-	-	2e
96.	Water	1acd, 2aef	1ace, 2bcd	-	1c	-
97.	Compound feed	-	1c	-	1c, 2b	2d

1 Biological (a viruses, b prions, c bacteria, d endoparasites)

2 Chemical (a "heavy metals"; b mycotoxin; c bacterial/plant/marine toxin; d veterinary drug; e organic chemicals; f radionuclides,

TABLE 3: SOURCES OF RELEVANT HAZARDS

98.	Hazard	Sources	How to reduce	Edible products
99.	<u>Biological</u>			
100.	Bacteria (e.g. Salmonella, Brucella, Listeria monocytogenes)	Contaminated pasture, forages and feed(especially Salmonella), animal and vegetable protein meals	Keep sick animals distant from feed production or storage. Hygiene during feed production (slaughter and processing of edible tissues)	Eggs, poultry products (Salmonella), milk and milk products (Brucella, Listeria monocytogenes)
101.	Endoparasites (e.g. Echinococcus, Toxoplasma gondii, Cisticercus, Trichinella)	Contaminated pasture, forages, compound feed	Remove animals from source, treat animals, heat treat feed components	Various tissues containing infective cysts
102.	Prions	Contaminated animal [ruminant] protein (containing misfolded prion protein)	Prevent cross-contamination of feeds for ruminants with ruminant protein	Nervous system tissue
103.	Viruses: hepatitis E, rotavirus	Feed contaminated by body fluids of infected animals	As for bacteria	Various tissues contaminated during preparation by virus-containing body fluids
104.				
105.	<u>Chemicals</u>			
106.	Radionuclides: ⁹⁰ Sr, ¹³¹ I, ¹³⁷ Cs	Contaminated animal feed and forages	Measure on suspicion	Milk (radioiodines, radiocesium), bone (radiostrontium), meat (radiocesium)
107.	"Heavy metals":			
108.	Arsenic (inorganic)	Sea plants, fish products and supplemental minerals.	Assay feed for content	Fish
109.	Cadmium	Mineral supplements (such as phosphate, zinc sources). Forage/grains (depending on geographical area). Manure, sewage, sludge or phosphate fertilizers can enrich soil.		Higher concentrations in shellfish, oysters, salmon, edible fungi, also kidney and liver. Lower concentrations in dairy products, meat, eggs, poultry.

98.	Hazard	Sources	How to reduce	Edible products
110.	Lead	Contaminated soil, lead paints and batteries, water from plumbing systems that contain lead. Mineral supplements (e.g. copper sulphate, zinc sulphate, zinc oxide).		Bone, brain and kidney
111.	Mercury/methyl mercury	Anthropogenic contamination, fish meal.		Liver, kidney, fish products
112.	Tin	Contaminated soil		
113.	<i>Mycotoxins:</i>	Produced by carbohydrate-eating fungi, therefore found in cereals (especially maize), cottonseed, peanut, copra		
114.	(from field fungi)	Produced by plant pathogenic (field) fungi from spores/conidia in soil, air/insect borne (secondary storage contamination also possible); mycotoxin accumulates in the inner parts of the kernel in humid conditions (e.g. deoxynivalenol, zearalenone, fumonisins, trichothecenes)	Caution if humidity high during growth and harvest; reduce fungal contamination in field by adhering to Good Agricultural Practices	Meat (DOM1, zearalenol)
115.	(from storage fungi)	Produced by saprophytic (storage) fungi from contaminated soil and storage areas which infect kernels from the outside, mycotoxin more concentrated on hull, tip cap and outer layers, so contamination depends on milling system (e.g. aflatoxins from <i>Aspergillus flavus</i> , ochratoxins from <i>A. ochraceus</i>)	Reduce humidity post-harvest. Separate hull, tip cap and outer layers before milling	Liver, milk, eggs (aflatoxins), meat (ochratoxin)
116.	<i>Plant toxins:</i>			
117.	Tremetone	Contaminated forage		Milk
118.	Alkaloids (e.g. atropine, caffeine, cocaine, ephedrine, morphine, nicotine, solanine)	Botanical impurities in forages	Avoid botanical contamination of fodders (by visual inspection or chemical analysis)	Milk, meat
119.	Pyrrizolidine alkaloids, terpenes, glycosides	botanical impurities in forages (e.g. <i>Senecio jacobaea</i>), endogenous toxin in plants (e.g. gossypol in cottonseed)	As for alkaloids	No data, or no carry-over demonstrated at sub-toxic concentrations
120.	<i>Organic chemicals:</i>			

98.	Hazard	Sources	How to reduce	Edible products
121.	Dioxins, PCBs	Soil contamination (e.g. clay minerals). Formation during heat processing (e.g. lime in citrus pulp, directly dried bakery waste); from biocide-treated wood used during feed ingredient production; from flue gases used directly during grass drying; from pasture contaminated by industrial combustion sources (e.g. fossil fuel power stations, refuse incineration plants). Oil in fish meal.	Lipophilic, so assay oil/fat feed components	Fat (in meat, milk, egg yolk)
122.	Organochlorine pesticides	Environmental contamination	Adhere to Good Agricultural Practices	Fat
123.	Veterinary drug, pesticide, processing aid residues	Milk of antibiotic-treated cows, nectar of antibiotic-treated fruit trees, meal from medicated fish and shrimps	Adhere to recommended doses and wait times	Veal, honey, pork meat

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.