CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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

Agenda Item 5 **CX/AF 13/7/5**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Seventh Session
Berne, Switzerland, 4-8 February 2013

PROPOSED DRAFT GUIDANCE FOR USE BY GOVERNMENTS IN PRIORITIZING THEIR NATIONAL FEED HAZARDS

(prepared by an electronic Working Group led by Switzerland)

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Guidance for Use by Governments in Prioritizing the National Feed Hazards at Step 3 (*see* Appendix I) and should do so in writing in conformity with the Uniform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 (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 **by 15 November 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 Appendix III to this document.

REPORT FROM THE CODEX EWG FOR THE TASK FORCE ON ANIMAL FEEDING (TFAF) TO ELABORATE A NEW DRAFT FOR THE "GUIDANCE FOR GOVERNMENTS ON PRIORITIZING HAZARDS IN FEED"

INTRODUCTION

1. The 6th Session of the *ad hoc* Intergovernmental Task Force on Animal Feeding (TFAF) held in Bern, Switzerland from 20 to 24 February 2012, had two Terms of Reference documents (TORs) on the agenda. TOR1, "PROPOSED DRAFT GUIDELINES ON APPLICATION OF RISK ASSESSMENT FOR FEED" was progressed to Step 5 for presentation at the next CAC meeting, while for TOR2 "PROPOSED DRAFT PRIORITISED LIST OF HAZARDS IN FEED" it was agreed that further work was needed.

2. After discussion, the TFAF agreed to rename TOR2 to "Draft Guidance for use by governments in prioritizing their national feed hazards" and to return the renamed proposal for redrafting by an electronic Working Group (eWG) on the basis of the discussions and decisions taken at the session (Ref. REP12/AF, paragraphs 48-83).

3. The eWG, open to all Members and Observers, was hosted by Switzerland and worked in English only.

BACKGROUND

4. The TFAF noted that work needed to be undertaken on TOR2 by the eWG:

(i) on the description of the three criteria for identifying relevant hazards in feed;

(ii) on more detailed guidance on the application of the criteria by governments;

(iii) on preparing a list of "potential feed hazards" relevant for food safety in a separate Annex;

(iv) on a second Annex with examples for illustrative purposes on the application of the criteria for the prioritization of hazards in feed.

Procedure

5. The invitation to participate in the EWG was distributed to all Codex members on 16 March 2012. In addition to Switzerland, representatives from 32 countries, the EU, and 9 NGOs registered to join the group.

6. A complete list of participants is included in Appendix II.

Circulation of the first draft guidance document

7. The first draft guidance document (draft 1) was produced by the eWG host on the basis of the accepted outcomes of the TFAF, with proposals for the parts which needed more detailed texts.

8. Draft 1 was sent on 20 April 2012 with a deadline for comments of 01 June 2012. Comments came from 10 countries in addition to Switzerland - Argentina, Australia, Brazil, Canada, Chile, Israel, Japan, Nigeria, Poland and USA, from the EU, and from 3 NGOs - IDF, IFIF, and the International Egg Commission. These comments were the basis for draft 2.

Circulation of the second draft guidance document

9. Draft 2 was sent to all participants of the eWG on 04 July 2012 with a deadline for comments of 10 August 2012. Comments came from 9 countries in addition to Switzerland - Argentina, Australia, Brazil, Canada, Japan, Netherlands, Nigeria, Norway and USA, the EU and 3 NGOs - IDF, IFIF and IFAH. These comments were the basis for draft 3.

RESULT OF THE EWG: FINAL DRAFT AT STEP 3

10. The comments on draft 1 and 2 included many alternative detailed suggestions concerning identification of potential hazards and quantification of the criteria for prioritization. However several participants noted that the procedure for prioritization was not clear and needed to be defined. Therefore, for the final draft 3, a globally applicable step-by-step guidance for prioritization is presented, consistent with existing Codex guidance and with the terms of reference for this document, without describing the criteria in detail. This enables national risk managers to prioritize feed hazards in a multitude of situations. Details must be established on a case-by-case basis in consultation with experts. Examples of feed hazards potentially relevant to food safety are given in Annex 1 of the final draft. The prioritization example (now Annex 2 of the draft) is only partially complete, because the method details must be established on a case-by-case basis in consultation with experts.

11. The new final draft for consideration at the final session of this TFAF in February 2013 is included in Appendix I to this document.

Appendix I

PROPOSED DRAFT **GUIDANCE FOR GOVERNMENTS ON PRIORITIZING HAZARDS IN FEED**

(at Step 3)

Table of Contents

INTRODUCTION

1. Hazard prioritization is a preliminary risk management activity within the risk analysis framework (*Working Principles for Risk Analysis for Food Safety for Application by Governments* CAC/GL 62-2007).

2. The purpose of prioritizing hazards in feed as described in this document is to ensure the safety of foods of animal origin by optimizing allocation of the resources required for risk management activities.

SCOPE

3. In this document, "feed" refers to both feed ingredients and feed.

4. "Hazard" refers to any agent in feed which may adversely affect human health after transfer into an edible product.

5. Agents which may adversely affect animal health, but which have no impact on food safety, are not considered.

6. Direct human exposure to hazards in feed, for example occupational exposure during feed production and processing, is not considered.

DEFINITIONS

7. 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).

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

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

Feed (Feedingstuff): 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 54/2004).

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 54/2004).

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).

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.

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 54/2004).

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)*. In this guidance, the word "food" should be read as "feed".

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

Risk assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization (*Codex Alimentarius Commission: Procedural Manual)*.

Risk communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, and the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions. *Codex Alimentarius Commission: Procedure Manual).*

Risk management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options (*Codex Alimentarius Commission: Procedural Manual)*.

Risk profile: The description of the food safety problem and its context (*Codex Alimentarius Commission: Procedural Manual).*

Transfer: In this document, refers to transfer of a chemical or biological hazard, present in animal feed, to an edible product of a food-producing animal.

PRIORITIZATION OF HAZARDS IN THE FRAMEWORK OF CODEX RISK ANALYSIS

8. Risk analysis comprises three distinct but closely linked components: risk management, risk assessment and risk communication (*Codex Alimentarius Commission Procedural Manual*).

9. Risk management comprises preliminary risk management activities (identification of feed-related food safety problems, risk profiling, and prioritization), evaluation of risk management options (for example commissioning of risk assessments, risk communication), implementation of risk management options, monitoring and review.

10. Hazard prioritization is a preliminary risk management activity within the risk analysis framework; it includes identification of feed-related food safety problems, risk profiling, and prioritization (*Working Principles for Risk Analysis for Food Safety for Application by Governments* CAC/GL 62-2007).

PRIORITIZATION PROCESS

11. In this guidance, the process for prioritizing hazards in feed involves the following steps: (1) identification of hazard/feed/edible product combinations potentially associated with food safety problems, (2) risk profiling for selected hazard/feed/edible product combinations, (3) establishment of the criteria to be used for prioritization, (4) prioritization by multi-criteria decision analysis, and (5) reporting of the process, methods and results.

12. It is important to note that this is an iterative process, i.e. new data may require returning to a previous step for re-evaluation.

Step 1. Identification of potential hazard/feed/edible product combinations

13. Based on reports of occurrence of hazards in feed or edible products, this initial step identifies hazard/feed/edible product combinations which are potentially associated with food safety problems, and which may need to be prioritized for further risk management activities.

14. Examples of potentially relevant hazard/feed/edible product combinations are given in Annex 1.

15. Sources of information on occurrence of hazard in feed and edible products include, for example, feed and edible product inspections and monitoring programmes, animal and human surveillance data, environmental monitoring, feed- and food-borne disease outbreak investigations, national and international alert systems, international programmes such as the WHO Global Environment Monitoring System (GEMS/Food) and the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN) (references in Annex 3), and scientific peer-reviewed publications.

16. When knowledge gaps prevent identification of a clear association between a hazard/feed/edible product combination and a food safety problem, the risk manager may include the combination in the next step (risk profiling) to obtain additional information.

Step 2. Risk profiling

17. A risk profile is established for each potential hazard/feed/edible product combination identified in the previous step.

18. The risk profile collates all information which is relevant to risk management decisions.

19. It is important to note that risk profiling is a scoping exercise; it is not intended to be an abbreviated version of a risk assessment.

20. Examples of information which may be collated in a risk profile include: a description of the food safety problem potentially associated with the hazard/feed/edible product combination, descriptions of the feed and edible product, chemical or biological characteristics and toxicology profile of the hazard, levels of hazard in feed and edible products, possible sources of hazard during production, processing, transport and storage, relevant legislation, availability of risk assessments, availability of risk management options, information on economic consequences, and information on knowledge gaps.

21. If the information in a risk profile indicates that a specific combination is not associated with a food safety problem, it may be decided not to include that combination in further prioritization steps.

Step 3. Establishment of the criteria applicable to the hazard/feed/edible product combinations for prioritization

22. The criteria chosen for the evaluation of hazard/feed/edible product combinations to prioritize feed hazards must reflect the overall purpose of ensuring the safety of foods of animal origin.

23. The criteria need to reflect relevant local and regional conditions and practices concerning feed and food.

24. The chosen criteria must be objectively quantifiable to enable scoring. This should be established in consultation with scientific experts.

25. If data relevant to a given criterion are not provided in the risk profiles, then the risk profiles will have to be updated accordingly.

Step 4. Prioritization

26. Prioritization of selected hazard/feed/edible product combinations is based on the aggregation of the scores of the criteria defined in step 3.

27. Aggregation of the criteria scores of the selected hazard/feed/edible product combinations requires some form of multi-criteria decision analysis. Examples of such analysis methods and their application are available in the scientific literature and in reports from regulatory bodies (see references in Annex 3).

28. The aggregated scores of individual hazard/feed/edible product combinations determine the order of priority for the national risk management activities.

Step 5. Reporting

29. The prioritization process, methods and results should be documented and reported fully, systematically and transparently, including identification of all key data gaps, assumptions and uncertainties.

ANNEX 1: EXAMPLES OF HAZARD/FEED/EDIBLE PRODUCT COMBINATIONS WITH POTENTIAL RELEVANCE FOR HUMAN HEALTH

1. The following examples describe some hazard/feed/edible product combinations which may be associated with a food safety problem.

2. The examples may not be relevant everywhere or at all times; they simply illustrate the range of hazards, feeds and edible products which may need to be considered in a given location at a given time. In addition, rare and emerging hazards are not covered.

Biological hazards

Bacteria

3. The primary microbiological hazards in feed that transfer 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 may be introduced to feed by cross-contamination or carry-over during processing, transport, and storage.

4. *Salmonella* is a worldwide human health concern. 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 transfer to edible products and human pathogenicity are typically strain-specific.

5. *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 pasteurized prior to consumption.

Endoparasites

6. 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.

Viruses

7. Some viruses such as hepatitis E are pathogenic to both food-producing animals and humans (Hepatitis E. WHO Fact sheet N°280. Revised July 2012; 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, which is outside the scope of this guidance.

Prions

8. Prions are infectious agents composed of protein in a misfolded form which induces existing, properly-folded prion protein (PrPc, a constituent of normal mammalian cells) to convert into the disease-associated, prion form (PrPSc). 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.

Chemical hazards

Elements

9. 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.

10. Radionuclides including caesium-134, caesium-137, strontium-90 and iodine-131 present in animal feed and forages may transfer to edible products. Major sources are water- or wind-borne environmental contamination. Transfer of radioiodine to milk, radiostrontium to bone, and radiocesium to milk, eggs and meat has been demonstrated.

11. 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. Mercury levels (particularly methyl mercury, the more toxic organic form) are usually very low in terrestrial animals and plants used for feed, but may be higher in some fish; contaminated fish meal in feed can result in elevated levels in edible products.

Toxins

12. 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, e.g. toxins from certain algae, particularly dinoflagellates

Mycotoxins

13. Mycotoxins are produced by fungi commonly found in cereals (especially wheat, sorghum and maize), oilseed meals and cakes, and silage.

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

15. Aflatoxin B1 can occur in copra, peanut cake, sunflower cakes, corn gluten, rice bran, cottonseed, palm kernel and soy beans. Aflatoxin B1 is metabolized in some food-producing animals to aflatoxin M1 which transfers to milk. Aflatoxin M1 is a human carcinogen.

16. Ochratoxin A is most commonly found in cereals such as rye, barley, maize and wheat, and to a lesser extent in peanuts and soybeans. Ochratoxin A is nephrotoxic. It transfers to edible products such as blood, liver and kidney and to a lesser extent meat, fat and milk. Ochratoxin A is nephrotoxic in humans.

17. Zearalenone, fumonisins, deoxynivalenol, T-2 and HT-2 toxin are rapidly metabolized and/or excreted by food-producing animals and are therefore not major contaminants of edible products.

Bacterial toxins

18. 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 possible but unlikely to be relevant.

Terrestrial plant toxins

19. Toxin-producing plants may occur in grasslands used for forage. Toxins can include pyrrizolidine 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.

Marine toxins

20. 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 fish meal. Transfer of ciguatera toxin to human milk after maternal poisoning has been reported, so transfer from feed to milk of food-producing animals is a possibility.

Organic chemicals

21. 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.

22. Polychlorinated dibenzodioxins (PCDD), dibenzofurans (PCDF) and dioxin-like polychlorinated biphenyls (DL-PCBs), commonly known as dioxins, and organochlorine pesticides such as aldrin, dieldrin, and DDT, are lipophilic and have long half-lives in the environment. 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.

Pesticides, veterinary drugs, feed additives and processing aids

23. Pesticides, veterinary drugs, feed additives and processing aids may contaminate feed by carry-over or cross-contamination during production, processing, transport or storage.

24. Unapproved use of pesticides and veterinary drugs may lead to excessive levels in feed and edible products (e.g. clenbuterol in meat).

TABLE 1: SUMMARY EXAMPLES OF POTENTIAL HAZARD/FEED/EDIBLE PRODUCT COMBINATIONS

Hazard	Sources and feeds affected	Edible products
Bacteria (e.g. *Salmonella, Brucella*)	Contamination of forages (pasture, hay, silage) by disease carriers, carry-over or cross-contamination by disease carriers (including cadavers) during production, processing, transport and storage.	Eggs, meat and meat products (*Salmonella*), milk and milk products (*Brucella*)
Endoparasites (e.g. *Toxoplasma gondii*, *Cysticercus*, *Trichinella*)	Contamination of forages (pasture, hay, silage) by disease carriers.	Various tissues containing infective cysts
Prions	Contamination of feed protein by protein from diseased cadaver.	Nervous system tissue
Radionuclides: strontium-90, iodine-131, caesium-134, caesium-137	Exogenous (nuclear powerplant accidental release), contamination of soil minerals and forage.	Milk (radioiodines, radiocesium), bone (radiostrontium), meat (radiocesium)
Arsenic (inorganic)	Naturally-occurring contaminant in sea plants, fish products and minerals.	Fish, other farmed aquatic animals
Cadmium	Naturally-occurring contaminant in soil minerals (e.g. phosphate and zinc sources), secondary contamination of forage/cereals. Exogenous soil contamination from 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	Naturally-occurring contaminant in minerals (e.g. copper sulphate, zinc sulphate, zinc oxide), and in soil, secondary contamination of forage/cereals. Exogenous soil contamination by industrial waste, water contamination.	Bone, brain and kidney
Mercury (organic)	Exogenous soil and water contamination from industrial waste, secondary contamination of forages, crops and aquatic organisms.	Liver, kidney, fish, other farmed aquatic animals
Mycotoxins	Produced by carbohydrate-catabolising fungi in high humidity conditions on cereals (e.g. wheat, sorghum, maize, rice, oats), in oilseeds (e.g. groundnut, soybean, sunflower, cotton) and silage.	Meat (deepoxy-deoxynivalenol, zearalenol, ochratoxins), liver, milk, eggs (aflatoxins)
Pyrrizolidine alkaloids, terpenes, glycosides	Naturally occurring botanical contaminants in forage (e.g. *Senecio jacobaea*) and oilseed (e.g. cottonseed producing gossypol).	Milk, meat
Other alkaloids	Naturally occurring botanical contaminants in forage (e.g. atropine, caffeine, cocaine, ephedrine, morphine, nicotine, solanine)	Milk, meat
Dioxins (polychlorinated dibenzodioxins, dibenzofurans and dioxin-like polychlorinated biphenyls)	Exogenous mineral and forage contamination from combustion sources (e.g. fossil fuel power stations, waste incineration plants, exhaust gases) or industrial waste.	Fat of meat, milk, egg yolk

It is important to emphasize that these hazard/feed/edible combinations are illustrative examples and are not exhaustive.

ANNEX 2 EXAMPLE OF THE PRIORITIZATION PROCESS

This fictitious example is intended to show how to work with the prioritization steps. It is not meant to provide details of the procedures or exhaustive data.

Step 1. Identification of hazard/feed/edible product combinations

The following combinations were chosen based on feed hazard surveillance data from national and international competent bodies:

Aflatoxin B1(M1)-feed maize-cow milk
(based on surveillance data: several localised findings of feed maize contamination with aflatoxin B1)

Cadmium-mineral feed ingredient-cattle meat
(based on surveillance data: excessive levels of cadmium in an imported mineral shipment)

Radiocaesium-forage-sheep meat
(based on surveillance data: localised contamination of forage from nuclear fallout)

Brucella-forage-cow milk
(based on surveillance data: rare localised cases of brucellosis)

Step 2. Risk profiling

Aflatoxin B1(M1)-maize-dairy-cow milk: Contamination of feed maize with aflatoxin B1 has been repeatedly reported in localised areas, plausibly related to high humidity during growing and storage (scientific literature). Heterogeneous distribution of contamination makes it difficult to ascertain the regional or national extent of contamination (uncertainty, need for more data). From the scientific literature, it is known that aflatoxin B1 is metabolised in dairy cows to aflatoxin M1, which can transfer to milk; in humans, aflatoxin M1 is carcinogenic; hepatitis B carriers are a particularly sensitive subpopulation. There are existing regulatory limits for aflatoxin B1 in feed maize and aflatoxin M1 in milk.

Cadmium-mineral feed ingredient-cattle meat: Contamination of feed mineral supplements was reported in one imported shipment of phosphates. Food-producing animals may also be exposed via forage from locally contaminated soil (naturally-occurring or from sewage sludge used as fertilizer). There is transfer to edible products and accumulation, particularly in kidney and liver, less in meat. In humans, cadmium may induce kidney dysfunction, skeletal damage and reproductive disorders. There are existing regulatory limits for cadmium in both mineral feed ingredient and meat.

Radiocaesium-forage-sheep meat: Contamination of soil was reported in small localised areas by fallout from a nuclear accident with ^{137}Cs (radionuclide half-life 30 years); significant contamination of forage is likely only on peaty soil; transfer to edible product is known, biological half-life in sheep meat is 10-20 days; radiocaesium is highly toxic due to ionizing radiation. National precautionary limits are established in sheep meat).

Brucella-forage-cow milk: Isolated cases of confirmed *Brucella* spp. infections were reported in non-immunized cattle, contamination of pasture is suspected. *Brucella* causes disease and is reproductive toxicant in food-producing animals, transfers to milk and can cause chronic human disease, but is killed by milk pasteurization.

Step 3. Establishment of the criteria for hazard/feed/edible product combinations as basis for prioritization

The following criteria were chosen after consultation with experts.

Criterion 1 (related to toxicity of the hazard): the measured or estimated level of hazard in edible product in relation to existing toxicology-based threshold values. If no measured level in edible product is available, it is estimated by calculation from the level in feed (measured), daily intake of hazard by the food-producing animal (estimated by feed specialists), and the transfer coefficient of hazard from feed to the edible product (scientific literature).

Criterion 2 (related to exposure to the hazard): potential extent of occurrence in edible product, measured as percentage of feed samples testing above defined limits at the national level.

Step 4. Prioritization

This table illustrates scoring of the combinations using criteria 1 and 2.

	Criterion 1	Criterion 2
Aflatoxin B1-maize-dairy cow milk	Aflatoxin M1, the proximate hazard in milk, is a genotoxic carcinogen with no toxicology threshold, therefore there is no toxicology-based limit values; used maximum tolerated level of 50 ng/L milk; estimated = 300 ng/L; score = 300/50 = 6.	1% (= score)
Cadmium-mineral feed ingredient-meat	Existing toxicology-based threshold value = 20 µg/kg meat; estimated = 30 µg/kg meat; score = 30/20 = 1.5	2% (= score)
Radiocaesium-forage-sheep meat	Radiocaesium is a genotoxic carcinogen with no toxicology threshold, therefore there is no toxicology-based limit value; used maximum limit value = 1000 Bq/kg meat; measured = 2000 Bq/kg meat; score = 2000/1000 = 2	0.5% (= score)
Brucella-forage-cow milk	*Brucella* is a microbiological hazard with proliferation potential, so there is no threshold value (i.e. *Brucella* spp. should not be present in milk); measured = present, score = 1	0.01% (= score)

The scores for criteria 1 and 2 are aggregated using multi-criteria decision analysis to yield a single overall score for each hazard/feed/edible product combination.

The method for aggregation of the scores must be chosen in consultation with experts; references describing possible methods are given in Annex 3.

The aggregated scores of the individual hazard/feed/edible product combinations determine their order of priority.

Step 5. Reporting

This is the most important step in the whole process.

ANNEX 3 ADDITIONAL REFERENCES

Useful sources of information on potential hazard/feed/edible product combinations include:

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/)

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/).

Notifications from the European Rapid Alert System for Food and Feed (EU RASFF); (https://webgate.ec.europa.eu/rasff-window/portal/index.cfm?event=notificationsList)

Some examples of prioritization frameworks, processes and methods are given in:

Cressey P, Lake R (2003). Ranking Food Safety Risks; A Discussion Document. Institute of Environmental Science & Research Limited, Christchurch Science Centre, New Zealand. Prepared as part of a New Zealand Food Safety Authority contract for scientific services, June 2003. (http://www.foodsafety.govt.nz/elibrary/industry/Risk_Profiles-Science_Research.pdf)

Cressey P, Lake R (2004). Ranking Food Safety Risks; A Prototype Methodology (revised October 2004). Institute of Environmental Science & Research Limited, Christchurch Science Centre, New Zealand. Prepared as part of a New Zealand Food Safety Authority contract for scientific services, October 2004. (http://www.foodsafety.govt.nz/elibrary/industry/Ranking_Food_Safety-Science_Research.pdf)

Eisenführ F, Weber M, Langer T (2010). Rational Decision Making. 1st Edition, 447 pp. Springer Verlag, ISBN 978-3-642-02850-2.
(http://www.springer.com/business+%26+management/operations+research/book/978-3-642-02850-2)

FDA 2011. Multi-Criteria Decision Analysis Methodology Used to Prioritize Inspection of Subject: Egg Farms for Monitoring Compliance with the Egg Safety Rule. U.S. Food and Drug Administration, Memorandum, August 9, 2011. (http://www.fda.gov/downloads/Food/FoodSafety/Product-SpecificInformation/EggSafety/UCM267597.pdf)

Henson SJ, Caswell JA, Cranfield JAL, Fazil AF, Davidson VJ, Anders SM, Schmidt C (2007). A Multi-Factorial Risk Prioritisation Framework for Food-Borne Pathogens. University of Massachusetts, Amherst MA, Department of Resource Economics. Working Paper No. 2007-8, 21 May 2007 (http://people.umass.edu/resec/workingpapers/documents/ResEcWorkingPaper2007-8.pdf)

Lake R, Hudson A, Cressey P, Nortje G (2000). Risk Profiles For The Foods New Zealanders Eat: Project F13ra3. Prepared as part of a Ministry of Health contract for scientific services by ESR Risk Profile Project Team, November 2000. (http://www.foodsafety.govt.nz/elibrary/industry/Risk_Profiles-Science_Research.pdf)

New Zealand Ministry for Primary Industries, Food safety science group. Risk ranking. (http://www.foodsafety.govt.nz/science-risk/risk-assessment/risk-ranking.htm)

Rowley HV, Peters GM, Lundie S, Moore SJ (2012). Aggregating sustainability indicators: Beyond the weighted sum. J Environ Manage. 2012 Jul 17;111C:24-33.

Ruzante JM, Davidson VJ, Caswell J, Fazil A, Cranfield JA, Henson SJ, Anders SM, Schmidt C, Farber JM (2010). A multifactorial risk prioritization framework for foodborne pathogens. Risk Anal. 2010 May;30(5):724-42.

UK (2009). Multi-criteria analysis: a manual. UK Department for Communities and Local Government: London, January 2009. (http://www.communities.gov.uk/publications/corporate/multicriteriaanalysismanual; http://www.communities.gov.uk/documents/corporate/pdf/1132618.pdf)

Appendix II

List of participants registered for the TFAF 2012 eWG hosted by Switzerland

	CODEX MEMBERS		
		Representative	**Mail & CC**
1.	Argentina	Ms. Gabriela Catalani	Mail: gcatal@minagri.gob.ar & CC: codex@minagri.gob.ar
2.	Australia	Dugald Maclachlan Department of Agriculture, Fisheries and Forestry	Mail: dugald.maclachlan@daff.gov.au & CC: codex.contact@daff.gov.au
3.	Brazil	MS. Fernanda Marcussi Tucci Federal Inspector, Ministry of Agriculture, Livestock and Food Supply	Mail: fernanda.tucci@agricultura.gov.br
4.	Canada	Ms. Catherine Italiano Canadian Food Inspection Agency	Mail: Catherine.Italiano@inspection.gc.ca
5.	Chile	Juan Alarcón Muñoz Coordinador Unidad de Alimentos de Uso Animal, integrante del Subcomité del Codex en Chile Sobre Buena Alimentación Animal & Juan Manuel Leiva Riquelme Encargado de Calidad Skretting, integrante del Subcomité del Codex en Chile Sobre Buena Alimentación Animal & Roxana Inés Vera Muñoz Profesional de la Unidad de Acuerdos Internacionales, Coordinadora del Subcomité del Codex en Chile Sobre Buena Alimentación Animal & Christopher Hamilton-West Académico de la Facultad de Ciencias Veterinarias y Pecuarias de la Universidad de Chile, integrante del Subcomité del Codex en Chile Sobre Buena Alimentación Animal	Mail: juan.alarcon@sag.gob.cl & Mail: Juan.Manuel.Leiva@skretting.com & Mail: roxana.vera@sag.gob.cl & Mail: christopher.hamilton@veterinaria.uchile.cl
6.	Costa Rica	Mr Mauricio Nájera Ministry of Agriculture and Livestock	Mail: mnajera@feednet.ucr.ac.cr & CC: infocodex@meic.go.cr
7.	Croatia	Darija Vratarić Ministry of Agriculture, Veterinary Department	Mail: darija.vrataric@mps.hr
8.	Denmark	Ms Gitte RASMUSSEN Danish Veterinary and Food Administration & Ms Birgitte BROESBØL-JENSEN Danish Veterinary and Food Administration	Mail: giras@fvst.dk & Mail: bibje@fvst.dk
9.	Ecuador	Sonia Cabezas PANAVICOLA	Mail: panavicola@gmail.com & CC: codexecuador@inen.gob.ec
10.	European Union	Mr James Moynagh & Mr Miguel Granero Rosell	Mail: james.moynagh@ec.europa.eu & Mail: miguel-angel.granero-rosell@ec.europa.eu & CC: codex@ec.europa.eu

	CODEX MEMBERS		
11.	Finland	Ms Marita Aalto Ministry of Agriculture and Forestry	Mail: marita.aalto@mmm.fi
12.	France	Melle Gaël CABASSUT Direction Générale de l'Alimentation & Anne COULOMBE Direction Générale de la Consommation, de la Concurrence et de la Répression des Fraudes & Lucile TALLEU SNIA & Chloé HOMBOURGER Direction Générale de la Consommation, de la Concurrence et de la Répression des Fraudes	Mail: gael.cabassut@agriculture.gouv.fr & Mail: anne.coulombe@dgccrf.finances.gouv.fr & Mail: L.Talleu@nutritionanimale.org & Mail: chloe.hombourger@dgccrf.finances.gouv.fr
13.	Germany	Sabine Kruse Federal Ministry of Food, Agriculture and Consumer Protection	Mail: 324@bmelv.bund.de & Mail: Sabine.Kruse@bmelv.bund.de
14.	Iran	Maziar TAGHAVI Secretary of national codex committee for Animal Feeding& ISIRI expert	Mail: mtaghavi@isiri.org.ir
15.	Ireland	Liam Hyde Dept. of Agriculture, Food and the Marine, Feeding Stuffs Division & Tim Camon Agricultural Officer, Food Safety Authority of Ireland	Mail: liam.hyde@agriculture.gov.ie & Mail: tcamon@fsai.ie
16.	Israël	Dr. Shimon Barel Toxicology Dept.-Feed Safety.Lab. Kimron Veterinary Institute Ministry of Agriculture Bet Dagan, P.O.Box 12 50250 ISRAEL	Mail: shimonba@moag.gov.il & Mail: barelshi@gmail.com
17.	Japan	Yumiko SAKURAI Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries	Mail: yumiko_sakurai2@nm.maff.go.jp & CC: codex_maff@nm.maff.go.jp
18.	Republic of Korea	Shin, Kyeongmi Ministry for Food, Agriculture, Forestry and Fisheries	Mail: codex1@korea.kr
19.	Malaysia	Quaza Nizamuddin HASSAN NIZAM Department of Veterinary Services & Alifah Ismail Department of Veterinary Services	Mail: quaza@dvs.gov.my & Mail: alifah@dvs.gov.my & Mail: dralifah@gmail.com & CC: ccp_malaysia@moh.gov.my
20.	Mexico	Mr. Gerardo Cruz Galán & María del Rocío Reyes Reyes, Departamento de Regulación y Registro de Productos Veterinarios, SENASICA-SAGARPA	Mail: gerardo.cruz@senasica.gob.mx & Mail: rocio.reyes@senasica.gob.mx & Mail: rocio_rreyes@hotmail.com & CC: codexmex@economia.gob.mx

	CODEX MEMBERS		
21.	Namibia	Mr. Erich Petrus Chief Agricultural Extension Officer responsible for Plant Health and Biosafety	Mail: petruse@mawf.gov.na
22.	the Netherlands	Mr F.A.J. (Frank) Gort Productschap Diervoeder & Mr Eduard DECKERS Ministry of Economic Affairs, Agriculture and Innovation & Ms Astrid BULDER RIVM	Mail: f.a.j.gort@hpa.agro.nl & Mail: e.r.deckers@mineleni.nl & Mail: astrid.bulder@rivm.nl
23.	New Zealand	Raj Rajasekar Senior Programme Manager (Codex), Ministry of Agriculture & Forestry	Mail: raj.rajasekar@maf.govt.nz
24.	Nigeria	Godwin Oyedele Oyediji	Mail: oyedeleoyediji@yahoo.com & Mail: codexng@sononline.org & CC: bob_king_george@yahoo.com
25.	Norway	Ms Jorunn MADSEN Norwegian Food Safety Authority	Mail: jorunn.madsen@mattilsynet.no & Mail: Jomad@mattilsynet.no
26.	Poland	Mr Krzysztof KWIATEK National Veterinary Research Institute, Department of Feed Hygiene	Mail: kwiatekk@piwet.pulawy.pl
27.	Singapore	Lim Chee Wee Agri-Food & Veterinary Authority of Singapore & Anna Wong Agri-Food & Veterinary Authority of Singapore	Mail: Lim_Chee_Wee@ava.gov.sg & Mail: Anna_Wong@ava.gov.sg
28.	Spain	Mr Francisco Javier Piquer Vidal Ministry of Agriculture, Food and Environment & Ms Patricia Pertejo Alonso Ministry of Agriculture, Food and Environment	Mail: fjpiquer@magrama.es & Mail: ppertejo@magrama.es
29.	Sweden	Kjell Wejdemar Swedish Board of Agriculture	Mail: kjell.wejdemar@jordbruksverket.se
30.	Switzerland	Mr Rex FitzGerald SCAHT, Swiss Centre for Applied Human Toxicology University of Basel & Mr Pascal Zaffarano FOAG, Federal Office for Agriculture	Mail: rex.fitzgerald@scaht.org & Mail: pascal.zaffarano@blw.admin.ch & CC: codex@bag.admin.ch
31.	United Kingdom	Mr Keith Millar UK Food Standards Agency	Mail: keith.millar@foodstandards.gsi.gov.uk
32.	USA	Mr Jon F. Scheid Food and Drug Administration & Patty Bennett Deputy Director, Risk Assessment Division Office of Public Health Science & Daniel G. McChesney Director, Office of Surveillance and Compliance Center for Veterinary Medicine	Mail: jon.scheid@fda.hhs.gov & Mail: patty.bennett@fsis.usda.gov & Mail: daniel.mcchesney@fda.hhs.gov

	INTERNATIONAL NON GOVERNMENTAL ORGANIZATIONS		
		Representative	**Mail & CC**
1.	Comité Européen des Fabricants de Sucre (CEFS)	Ms. Emilie Leibovitch Scientific & Regulatory Affairs Adviser	Mail: emilie.leibovitch@cefs.org
2.	Food and Agriculture Organization of the United Nations (FAO)	Daniela Battaglia	Mail: daniela.battaglia@fao.org
3.	FEFAC	Mr Alexander Döring Secretary General	Mail: adoring@fefac.eu
4.	International Dairy Federation (IDF)	Mr. Koenraad Duhem R&D Director, CNIEL & Mr. Joerg Seifert Technical Director, International Dairy Federation	Mail: kduhem@cniel.com & Mail: JSeifert@fil-idf.org
5.	The International Egg Commission	Vincent Guyonnet Scientific Advisor The International Egg Commission	Mail: vincent@internationalegg.com
6.	IFAH (International Federation for Animal Health)	Barbara FREISCHEM Executive Director IFAH (International Federation for Animal Health) & Dr Olivier ESPEISSE Directeur Général - Vétérinaire Responsable ELANCO SANTE ANIMALE	Mail: ifah@ifahsec.org & Mail: espeisse_olivier@lilly.com
7.	International Feed Industry Federation (IFIF)	Ms Alexandra de Athayde	Mail: alexandra.athayde@ifif.org
8.	OIE World Organisation for Animal Health	Gillian Mylrea Deputy Head, Department of International Trade	Mail: g.mylrea@oie.int
9.	WRO & EFPRA	Mr Stephen Woodgate WRO 1st vice President EFPRA Executive Board member	Mail: swoodgate@fabra.co.uk

Appendix III

GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

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

(i) General Comments

(ii) Specific Comments

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

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

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

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