## CODEX ALIMENTARIUS COMMISSION





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**Agenda Item 5** 

CX/AF 12/6/5 Add.1 (original language only) November 2011

# JOINT FAO/WHO FOOD STANDARDS PROGRAMME AD-HOC INTERGOVERNMENTAL CODEX TASK FORCE ON ANIMAL FEEDING

Sixth Session Berne, Switzerland, 20-24 February 2012

## PROPOSED DRAFT PRIORITISED LIST OF HAZARDS IN FEED

Comments at Step 3 of:

Australia, Brazil, Canada, Colombia, Costa Rica, European Union, Iran, Japan, New Zealand, Philippines, the United States of America, International Feed Industry Federation (IFIF) and International Poultry Council (IPC)

## AUSTRALIA

#### **General comments:**

Australia is pleased to submit the following comments on CX/AF 12/6/5 Prioritised list of hazards in feed.

The drafters from Switzerland are to be congratulated in the draft circulated which reads well. Australia has only a few comments on paragraphs listed below.

## **Specific Comments:**

Paragraph	Comments
21	Suggest replace the first sentence by: The primary microbiological hazards in feed that may be transmitted to food and pose a hazard (health risk) to humans are <b>zoonotic</b> organisms such as <i>Salmonella</i> and <i>Brucella</i> which contaminate animal and vegetable protein meals fed directly to animals. Rationale: the existing text needs to be a more general introduction and puts too much emphasis on <i>Salmonella</i> and <i>Brucella</i> which are discussed in greater detail in following paragraphs.
27	Suggest modify first sentence: Some animal endoparasites, such as <i>Trichinella</i> , <i>Echinococcus</i> , <i>Toxoplasma gondii</i> , and <i>Cɨysticercus bovis</i> , are human health hazards. Rationale: correct the spelling of <i>Cysticercus</i> and add <i>bovis</i> as it is this species that is the human health concern not all <i>Cysticercus</i> spp.
39	Modify the text as indicated below.  Transfer from feed to food of animal origin has been demonstrated for various mycotoxins including aflatoxins, ochratoxins and zearalenone, of which aflatoxin is the most frequently reported hazard. The significance depends on the rate of transfer.  Rationale: Strictly speaking aflatoxins and ochratoxins are groups of compounds of which aflatoxin M1 and ochratocin A are examples, hence the need for the plural. While the text suggesting that aflatoxins are the most frequently reported mycotoxin hazard is true it is misleading as the main reason is they are often the only mycotoxin routinely analysed for in food of animal origin and then generally only aflatoxin M1 in milk. The last sentence of the paragraph is also misleading as significance depends of the prevalence and concentration in feed, the transfer from feed to food of animal origin and the relevance of the levels in food to human exposure when assessed against the relevant human health standard. The deleted text is unnecessary, may be misleading and therefore it is susggested to be deleted.
43	Suggest the paragraph needs clarification Rationale:

<sup>&</sup>lt;sup>1</sup> These comments have been addressed by Switzerland in the revised version of Proposed draft Prioritised List of Hazards in Feed (CX/AF 12/6/5 Add.2), circulated for comments at Step 3 in November 2011.

Paragraph	Comments
50	Suggest delete the last sentence of the paragraph.  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.  Rationale: while toxicokinetic models have been developed their utility is not general, rather specific models may need to be developed for each situation to reflect differences in the congener profile of the contamination source, and therefore transfer, the bioavailability of the residues and also the growth rate and composition (%body fat) of the animals involved.
91	Suggest the 1b (prions) needs to be included in the hazards for Fish, other marine animals under perhaps Contaminated environment and Inadequate treatment.  Rationale: Australia occasionally finds ruminant material in imported fish meal destined for animal feeding and has a testing program for imported feed derived from marine animals. We understand the EU through RASFF also reports such detections. Clearly ruminant material in fish meal is an issue.
100	Suggest change the name of the column headed "How to reduce" to <b>How to reduce in feed</b> and add another column headed <b>How to reduce in food</b> . The text in brackets can then be moved to the new column How to reduce in food and changed to hygiene during harvest or slaughter and processing of foods of animal origin. The wording change is needed to capture milk and eggs.  Rationale: Inclusion of practices to reduce the hazard in feed and food need to be separated to make the intent clear.
106	Suggest if inlcude the additional column suggested at 100, add an entry in the How toreduce in food column that reads "measure on suspicion"
109	Suggest add text to the How to reduce in feed column:  Raise soil pH, reduce soil chloride content, increase soil organic matter content, select low cadmium content fertilisers  Rationale: low soil pH, salination and low soil organic matter are all recognised risk factors for uptake of Cd by plants. Cadmium in phosphatic fertiliser is recognised as a significant source of cadmium in soils. Suggest delete text in the edible products column  Higher concentrations in shellfish, oysters, salmon, edible fungi, also kidney and liver. Lower concentrations in dairy products, meat, eggs, poultry.  Rationale. Oysters are n ot fed and so no control over cadmium levels other than to clsoe a fishery. Also they are low contributors to the total dietary exposure. Edible fungi are not a food of animal origin.
110	Suggest add text to the How to reduce in feed column:  Remove access to lead batteries and paints.  Obtain mineral supplements from reputable sources  Rationale: Australian experience in investigating high lead levels in kidney are that the above are the main exposure reduction strategies
113, 114, 155	Suggest delete the word therefore from the text in the Sources column: Produced by carbohydrate-eating fungi, therefore found in cereals (especially maize), cottonseed, peanut, copra Rationale: editorial Suggest combine the three paragraphs deleting the text from paragraphs 114 and 115 in the columns Hazard and Sources apart from the list of mycotoxins under Sources which can be merged. The other columns can be merged. The combined 113 would become: Hazard: Mycotoxins Sources: Produced by carbohydrate-eating fungi, therefore found in cereals (especially maize), cottonseed, peanut, copra (e.g. aflatoxins from Aspergillus flavus, ochratoxins from A. ochraceus, deoxynivalenol, zearalenone, fumonisins, trichothecenes) How to reduce: Caution if humidity high during growth and harvest; reduce fungal contamination in field by adhering to Good Agricultural Practices. Reduce humidity postharvest. Separate hull, tip cap and outer layers before milling. Edible products: Meat (DOM1, zearalenol), Liver, milk, eggs (aflatoxins), meat (ochratoxin) Rationale: while initially thought mycotoxins could be classified as in-field and in-storage fungi, it has in more recent times become apparent that this distinction is not true and unhelpful.

Paragraph	Comments
114, 115	Suggest combine 114 and 155 deleting the text delete the:  Raise soil pH, reduce soil chloride content, increase soil organic matter content, select low cadmium content fertilisers  Rationale: low soil pH, salination and low soil organic matter are all recognised risk factors for uptake of Cd by plants. Cadmium in phosphatic fertiliser is recognised as a significant source of cadmium in soils. Suggest delete text in the edible products column  Higher concentrations in shellfish, oysters, salmon, edible fungi, also kidney and liver. Lower concentrations in dairy products, meat, eggs, poultry.  Rationale. Oysters are not fed and so no control over cadmium levels other than to close a fishery. Also they are low contributors to the total dietary exposure. Edible fungi are not a food of animal origin.
119	Suggest modify text under Edible products column:  No Limited data suggest some , or no carry-over may occur demonstrated at sub-toxic concentrations  Rationale: There are literature and unpublished data that carry-over does occur when livestock are exposed to levels found in feed (gossypol, pyrrizolidine alkaloids etc)
123	Suggest need to expand to include potential pesticide residues in treated crops and cover cross-contamination of manufactured feed with veterinary drugs.  Sources: Milk of antibiotic-treated cows, nectar of antibiotic-treated fruit trees, cross-contamination of manufactured feed with veterinary drugs, meal from medicated fish and shrimps, fodder ,grain and by-products (e.g. grape pomace) from crops treated with pesticides  Veal, Meat, milk, eggs, honey, pork meat

## **BRAZIL**

#### **SCOPE**

5. "Hazard" refers to any substance agent 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.

Rationale: The term "substance" does not include all the hazards.

## **DEFINITIONS**

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

Rationale: For the purpose of this document this definition does not need to be so detailed. In other definitions such as Acceptable daily intake (ADI) and Acute reference dose (ARfD) this type of detail was not applied

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.

#### manter a sugestão anterior

Contaminant: Any biological or chemical agent, foreign matter or other substance not intentionally added to feed or food that may compromise feed and food safety or suitability.

*Rationale:* Suggestion to use the definition presented by "Good Practices for the Feed Industry Implementing the Codex Alimentarius Code of Practice on Good Animal Feeding manual. FAO n° 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 or the performance of animals. (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.).

Rationale: By adding that the feed additive also affects the performance of animals the definition gets broader, and there is no need for examples between brackets, that can lead to confusion.

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

*Rationale:* It is better to keep the original definitions regarding the physical agent as it was excluded from the scope of the document during the text.

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

Rationale: We suggest remove this definition as this term was not used during the text.

#### CRITERIA FOR PRIORITISING HAZARDS

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).

Rationale: Very is not a measurable parameter and should be avoided.

#### FEED HAZARD LIST

28. Some viruses such as hepatitis E may be pathogenic to both food-producing animals and humans<sup>19</sup>. 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 hygienie hygiene, including food heating.

Rationale: use the correct form.

53. Risks arising from the <u>intentional</u> intentional addition of chemicals in the production, of or directly to feed of food-producing animals are addressed in Codex Standards<sup>14</sup>. These provide maximum levels for:

Rationale: Do not highlight the word for better understanding of the text.

57. <u>Unintentional</u> 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)<sup>4</sup>.

Rationale: Do not highlight the word for better understanding of the text.

## **CANADA**

## (i) General comments:

Canada would like to thank the Secretariat for the development of this draft document and for the opportunity to provide comments. The document has compiled many sources of known contaminants into one reference document. The document is a significant step in identifying relevant hazards in animal feed and will serve as an important tool in coordinating the development of a prioritized list of hazards.

It is important to recognize the role of using safe feed ingredients in preventing further contamination of human food. A significant number of food contaminants may be traced back to contaminants in feed. Many of these may not be reduced to acceptable levels in food by washing, cooking, or further processing. Thus, it is germane to consider this fact when prioritizing hazards in feed that may be significant.

Canada would like to recall the Task Force's terms of reference as agreed upon at the 33<sup>rd</sup> session of the CAC that of developing a prioritized list of hazards in feed ingredients and feed additives for government use. While this current list is exhaustive, Canada questions the need for all of these to be present on the primary list of prioritization. We are of the view that further criteria should be developed to allow for the hazards to be prioritized. We suggest that the list of criteria as presented in the Report of the FAO/WHO Expert Meeting: Animal Feed Impact on Food Safety, Rome 2008, be considered as a basis for beginning a dialogue. These are: the relevance of the hazard to public health; the extent of the occurrence of the hazard; and the impact of the hazard on international trade in food and feed.

Canada is recommending that another important step would be the development of a prioritized list of feed hazards to be presented for governmental use. Canada has addressed specific comments in the table below.

## (ii) Comments on paragraphs:

Paragraph	Comments
BACKGROUNI	)
Para 2.	This paragraph appears to have been taken from the document , "Proposed Draft Guidelines on Application of Risk Assessment for Feed", CX/AF 12/6/4, and is not appropriate as a background for this particular discussion. Perhaps text related to the role of feed as a mechanism for the introduction of hazards into the food chain is more appropriate. In addition, Canada questions why only feed hazards of animal/crop origin are cited in line 4 as minerals often contribute to incidents involving hazards and suggests that the sentence simply be stated as:human health impact of feed hazards of animal/crop origin via carry-over to food.
Para. 3.	It appears that the incorrect terms of reference was inadvertently added into this document. The correct reference should be:  Develop a prioritized list of hazards in feed ingredients and feed additives for governmental use. The list should contain hazards of international relevance that are reasonably likely to occur, and are thus likely to warrant future attention.  In doing so, due consideration should be given to the prioritized list of hazards as recommended by the FAO/WHO Expert meeting on Animal Feed Impact on Food Safety. Clear criteria should be used to prioritise the list of hazards and take account of the potential transfer of contaminants/residues in feed to edible animal products (e.g. meat, fish meat, milk and eggs).
APPENDIX 1	
Para 1.	The last sentence should include recognization that the prioritization of feed hazards should be amended to include the need to consult with feed experts such as nutritionists who are cognizant of feeding practices, as follows:  Feed prioritization may requires specialized support and/or training, particularly in countries without dedicated including both animal feeding specialists and risk analysis staff.
Para 4.	As feed is already defined in the definitions paragraph it does not need to be further defined here. Canada would suggest deleting this paragraph.
Para 5.	As this discussion is limited in scope to hazards to human health via food only, Canada suggests adding as follows:effects on animal health which have no impact on food safety, nor human health due to occupation exposure, are not considered as they do not fall under the scope of Codex Alimentarius.
Definition Para 8. Carry-over	Canada suggests slightly rewording the definition to read:  Transfer of a hazard from feed of a food producting animal to an edible product from a foodproducing animal
Definition Para 8. Contaminant	The concepts of Contaminant, Undesirable substance and hazard are all discussed in this document and there is some overlap. The term Contaminant, while defined in the CAC Procedural Manual, is not used in the Codex document CAC/RCP 54-2004 Code of Practice on Good Animal Feeding. Rather the latter document defines Undesirable Substances as "Contaminants and other substances which are present in and/or on feed and feed ingredients and which constitute a risk to consumers' health, including food safety related animal health issues."  Canada suggests a discussion tobe undertaken to determine whether more consistency can be achieved in the use of these terms.
Definition Para 8. Edible Product	Canada believes that fish is an important food commodity, and suggests it should be added to the list of examples.
Para 11.	Canada suggests that the last line in the paragraph be modified to refer prioritized lists of hazards to Codex rather than only new hazards. Many hazards of concern have not yet been addressed for feed by these bodies. The sentence could read:  The evaluation of new suspected hazards prioritized lists of hazards should generally be referred to such a body via the Codex Alimentarius Commission
Para 14.+ 15	Canada recognizes that not all of the texts referenced in these paragraphs may be relevant to hazards in feed and suggests they be reviewed for their importance to this discussion.
Para 16	While the trade in feed ingredients and additives is important, even more importantly is the international trade of foods of animal origin. Canada suggests modifying the paragraph as follows:

Paragraph	Comments
	Trade in primary feed ingredients and additives intended for food-producing animals, and especially the trade in foods of animal origin, is of worldwide economic importance. Animal feed is This document is intended to facilitate the international prioritisation and—comparability of feed hazards, thus promoting
Para 20.	As carry-over is already defined in paragraph 8., Canada suggests removing the definition in this paragraph, as follows:  Prioritisation depends crucially on the rates of trasnfer from feed to food (carry-over of the hazard to edible products. typically expressed as a trasnfer coefficient.
Para 21.	As bacterial pathogens may be present in many types of feeds, Canada suggests the following modifications to this paragraph.  The primary microbiological hazards in feed that may be transmitted to food and pose a hazard (health risk) to humans are organisms such as <i>Salmonella</i> and <i>Brucella</i> , which contaminate animal and vegetable protein meals fed directly to animals. They may be introduced into feed crops and/or forages from contaminated pasture land, may be present in animal materials used to produce rendered animal products, and/ or may be introduced to any complete feed or feed ingredients during processing, transport, and storage.
Para 22.	Salmonella is a worldwide human health concern. Salmonella in infected Infection in food-producing animals can be transmitted to humans via food the ingestion of edible products from these animals. Contaminated feed may can 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. For example, a limited number of serotypes predominate in human infections.
Para 23.	In countries where <i>Brucella</i> 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 conaminated forage is fed to miling animals Milk-producing animals may become infected by eating forage from contaminated pastures and excrete the microorganisms in their milk. If this milk is not pasteurized prior to consumption by humans, it may be a human health risk.
Para 24.	Other: Some silage-related bacteria may can infect milk-producing animals and contaminate milk via as a result of fecal contamination, and thus presenting a human health risk. The aerobic spore-forming bacteria belonging to aerobic or facultatively anaerobic Bacillus spp., the facultatively anaerobic Clostridium spp., and the non-sporogenic Listeria monocytogenes are the most important organisms of greatest concern. Spores ingested in silage are may be unaffected by passage through the gastrointestinal tract of the cow and are subsequently excreted in feces; they may be and transferred to milk mainly via fecal contamination of the udder or milking equipment. Spores present in raw milk may also survive druing processing and after germination and outgrowth subsequently germinate and grow to high levels in the milk and cause causing spoilage and human disease. Some serotypes of Escherichia coli for example, E.coli 0157, have been associated with human illness, and may contaminate animal feed and for edible products via fecal contamination. In feed may also be transmitted to food and pose a health risk to humans. For example, food products from animals infected with E. coli O157 may be contaminated via exposure to feces from the infected animals. 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).
Para 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 feeds. Ingestion of contaminated feeds by food-producing animals can result in the presence of infective cysts in edible products (e.g. meat). Particularly if such Ingestion of these organisms in edible products may pose a risk to human health, particularly if such products are not adequately heat treated prior to consumption. 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).
Para 28.	Some viruses, such as hepatitis E, may be are pathogenic to both food-producing animals and

Paragraph	Comments
	humans. Viral contamination of feed is possible Feeds may become contaminated by these viruses via contact with body fluids of infected animals and food-producing animals consuming the contaminated feeds may themselves become infected and contaminate edible products produced
	from them, probably through external, contamination with virus-containing faeces <b>from the animal</b> . Further discussion on the potential mechanisms of contamination is outside the terms of reference of the present document. The possibility of <b>human infection as a result of</b> such contamination can be minimized by practicing good food hygienic, including food heating <b>before consumption</b> .
Para 32.	Canada suggest that toxic may be deleted as it is redundant in this sentence. A number of elements may present a toxie hazard to humans
Para 33.	Canada suggests the following modification for clarity: Radionuclides including are relevant human hazards if when present in animal feed and forages as they may carry-over to edible products.
Para 34.	Arsenic fish products, and supplemental minerals, and misuse of arsenical drugs
Para 36.	Mycotoxins <u>present in feed</u> can <u>pass</u> <u>carry-over</u> from feed into edible products at levels that may represent a concern for human health.
Para 37.	Mycotoxins are produced are therefore found <b>most commonly</b> in cereals,
para 38.	Mycotoxin contamination in feed is not homogeneous.
Para 39.	Transfer Carry-over from feed to food The <u>human health risk</u> significance depends on the <u>ability of the mycotoxin to carry-over from feed to edible products</u> . rate of transfer.
Para 40.	There is some scientific evidence that mycotoxins
Para 42.	Canada suggests the rewording the paragraph as follows:  Toxins produced toxic to food-producing animals when ingested in feed and are therefore less likely to pass into edible products.  Residues of these toxins are, therefore, unlikely to be present in edible products from food-producing animals consuming these toxins in feed.
Para 43.	Canada suggests deleting this paragraph as the discussion may not be germane to the scope of this discussion.
Para 5359.	Canada suggests that the hazards from veterinary drug carry-over to edible products is of significant scope and occurrence that it warrents a discussion under a specific heading of veterinary drugs. All references to veterinary drugs within these paragraphs should be removed and placed under a new topic heading. It is important to note that hazards to edible products may result from both intentional and unintentional use of veterinary drugs in feed.
Para 62.	Canada appreciates the draft compilation of this information into the flowchart but suggests that perhaps the information is too condensed. The endpoints differ if one is looking at Plant- and Animal-derived ingredients versus the Other category. In the former case, the end-points refer to types of hazards which could result from the various steps. In the latter, the endpoints refer to guidelines. The title of the Figure also is misleading as the flowchart does not lead towards how to assess the likelihood of occurrence as much as serves as a means for consideration of where hazards could arise from. Perhaps a more suitable title could be: "Flowchart for the consideration of occurrence of major feed hazards".  In specific, the box under Minerals, including trace elements and binders – refers to these hazards not covered by these guidelines. These hazards are very much defined in the text of this document. As already outlined, heavy metals and organic chemicals are important hazards associated with these feed ingredients.
Para 60.	It is suggested that this paragraph be moved in its entirety to paragraph 61. Other chemicals.
Line 73.	Residues of veterinary drugs, pesticides and processing aids may very well be associated hazards in Milk Products. The last column should be marked as a +.
Line 74.	Land animal products may contain residues of organo-chlorine pesticides and should be marked as a +.
Line 75	Fish and other marine animals may contain residues of organo-chlorine pesticides and should be
	marked as a +.

Paragraph	Comments
	processing aids. If one is including ingredients such as Distillers grains, plant toxins may also result as a contaminant.
Line 78.	Fats and Oils may contain residues of heavy metals and should be marked as a +.
Line 79.	Water – not drinking water quality may contain residues of veterinary drugs, pesticides and processing aids and should be marked as a +.
Line 99. – 123.	Table 3 is an important summary of the potential sources for hazards. Canada would like to suggest, however, that the column on how to reduce the hazard is beyond the scope of this exercise and thus should be removed. Perhaps a better approach may be to reference the Good Manufacturing Practice guidelines which offer suggestions on hazard reduction. There are many options for each of these hazards, and it would be incorrect to only capture some of them. In addition, the listing of the edible products per hazard in the last column appears to be incomplete.

## **COLOMBIA**

En adelante tomamos como referencia el documento Anexo al CX/AF 12/6/5 en versión en español.

#### Antecedentes 3.

"La elaboración de directrices para los gobiernos sobre cómo aplicar las metodologías vigentes del Codex para la evaluación de riesgos a los distintos tipos de peligros relacionados con contaminantes o residuos presentes en ingredientes de piensos....Las directrices deberían incluir criterios de evaluación de riesgos específicos basados en la ciencia para aplicarse a contaminantes o residuos presentes en los piensos..."

"La elaboración de directrices para los gobiernos sobre cómo aplicar las metodologías vigentes del Codex para la evaluación de riesgos a los distintos tipos de peligros relacionados con contaminantes <del>o residuos</del> presentes en ingredientes de piensos....Las directrices deberían incluir criterios de evaluación de riesgos específicos basados en la ciencia para aplicarse a contaminantes <del>o residuos</del> presentes en los piensos..."

En sentido estricto solo debería conservarse la expresión *contaminante*, puesto que por la definición del Codex, el término residuo no resulta pertinente con la naturaleza de los piensos, dado que el residuo corresponde a una sustancia o su metabolito presente en los tejidos animales tras la ingesta o administración de tal sustancia a un animal.

## LISTA DE PELIGROS DE LOS PIENSOS

- 20. La priorización, en términos de los efectos sobre la salud humana, depende crucialmente de las tasas de transmisión del pienso al alimento ("transmisión", expresado típicamente como coeficiente de transmisión). Por lo tanto, es esencial disponer de alguna estimación de la transmisión de contaminantes y residuos del pienso a los productos comestibles de origen animal (como la carne, el pescado, la leche y los huevos). En caso de no disponer de información del Codex acerca de la transmisión correspondiente a un peligro determinado, los datos publicados por la literatura científica pueden proporcionar también datos pertinentes. No obstante, si tales datos son inadecuados o no están disponibles, puede ser necesario revisar la documentación al respecto o emprender estudios sobre la transferencia del pienso a los alimentos, caso por caso.
- 20. La priorización, en términos de los efectos sobre la salud humana, depende crucialmente de las tasas de transmisión transferencia del pienso al alimento ("transmisión transferencia", expresado típicamente como coeficiente de transmisión transferencia). Por lo tanto, es esencial disponer de alguna estimación de la transmisión transferencia de contaminantes y residuos del pienso a los productos comestibles de origen animal (como la carne, el pescado, la leche y los huevos). En caso de no disponer de información del Codex acerca de la transmisión transferencia correspondiente a un peligro determinado, los datos publicados por la literatura científica pueden proporcionar también datos pertinentes. No obstante, si tales datos son inadecuados o no están disponibles, puede ser necesario revisar la documenta-ción al respecto o emprender estudios sobre la transmisión transferencia del peligro del pienso a los alimentos, caso por caso

En el campo bilógico y de la salud, la transmisión es el proceso activo, mediante el cual un agente o sustancia de naturaleza bilógica pasa de un organismo a otro. Por ejemplo la trasmisión de una enfermedad, pasa de un individuo enfermo a otro sano. Por lo tanto en este caso se aplica más favorablemente la expresión "transmisión", que describiría el proceso mediante el cual una animal al ingerir un pienso contaminado o que contiene un determinado agente nocivo, puede a su vez contaminarse con el mismo. Lo anterior implica el paso del agente nocivo de un ente inanimado (pienso) a un organismo vivo (animal) y a los productos del mismo (alimentos de origen animal).

## Peligros biológicos

#### **Bacterias**

21. Los peligros microbiológicos primarios de los piensos que pueden transmitirse a los alimentos y que representan un peligro relacionado con la salud para los humanos son organismos tales como la Salmonella y la Brucella, que contaminan los alimentos con proteínas animales y vegetales, suministradas directamente a los animales. Estos organismos se pueden introducir en los piensos a través de tierras de pastoreo y/o forrajes contaminados, así como durante el procesamiento, el transporte y el almacenamiento.

21. Los peligros microbiológicos primarios de los piensos que pueden transmitirse transferirse o contaminar a los alimentos y que representan un peligro relacionado con la salud para los humanos son organismos microorganismos tales como la Salmonella y la Brucella, que contaminan los alimentos con proteínas animales y vegetales, suministradas directamente a los animales. Estos microorganismos se pueden introducir en los piensos a través de los suelos contaminados o tratados con abonos crudos o sin compostar o agua de riego contaminadas utilizados en cultivos destinados al pastoreo y/o a la fabricación de forrajes, Estos organismos se pueden introducir en los piensos a través de tierras de pastoreo y/o forrajes contaminados, así como durante el procesamiento, el transporte y el almacenamiento

#### Comentario

La contaminación es la expresión que define de manera más adecuada transferencia de un peligro de un pienso o forraje a un animal o a sus productos, en tanto que la transmisión es el fenómeno que implica el paso de un microorganismo o ente biológico de una animal o de sus productos a un ser humano o a otro animal.

## Endoparásitos

27. Algunos....

## **Endoparásitos**

#### **Parásitos**

27. Algunos....

## Comentario

La expresión genérica de <u>parásitos</u> indica y representa de manera genérica el peligro que representa para la salud humana la presencia de los mismos en un alimento. En tanto que la expresión <u>endoparásitos</u> indica que de manera preferente, parte del ciclo evolutivo de determinados parásitos se lleva a cabo en el organismo del huésped.

#### Toxinas bacterianas

- 43. Algunas toxinas bacterianas, como las producidas por *Escherichia coli* O157:H7, no causan enfermedades en los rumiantes porque carecen de un receptor para la toxina. Dichas bacterias pueden aparecer como comensales de la tripa del ganado...
- 43. Algunas toxinas bacterianas, como las producidas por *Escherichia coli* O157:H7, no causan enfermedades en los rumiantes porque carecen de un receptor para la toxina. Dichas bacterias pueden aparecer como comensales de <del>la tripa en el intestino</del> del ganado **y por lo tanto son más difíciles de detectar**, sin embargo al ser evacuada en la materia fecal y al eventualmente la misma ser utilizada como fertilizante, puede contaminar los vegetales destinados al consumos humano, generando un grave riesgo para la salud de los consumidores Para más información véase el Código de **Prácticas de Higiene para la Carne (CAC/RCP 58-2005)**

## Comentario

La expresión "tripa" es un término coloquial para describir las vísceras del un animal, en especial los intestinos. Al enunciar de manera tan general la toxina O157:H7, es conveniente aludir al riesgo que representa para la salud humana, a pesar de que se acompañe de la correspondiente referencia bibliográfica

57. La exposición involuntaria a residuos de plaguicidas en las cosechas puede ser consecuencia de la absorción de residuos en el suelo resultantes del tratamiento de una cosecha anterior o de la aplicación de plaguicidas fuera del objetivo (desplazamiento de la pulverización, volatilización) en cosechas adyacentes o cercanas. Puede que existan residuos de medicamentos veterinarios en los ingredientes del pienso pro-veniente de animales terrestres o material de acuicultura aunque por lo general esto no se considera una vía de exposición potencial de mayor importancia. Hay pruebas que sugieren que los antibióticos utilizados para controlar la contaminación microbiológica durante la fermentación del grano para la producción de etanol pueden concentrarse en los subproductos de granos de destilería (DDGS).

La exposición involuntaria a <del>residuos de</del> plaguicidas en las cosechas puede ser consecuencia de la absorción de los mismo en el suelo, como resultado <del>resultantes</del> del tratamiento de una cosecha anterior o de la aplicación de

plaguicidas fuera del objetivo (desplazamiento de la pulverización, volatilización) en cosechas adyacentes o cercanas. Puede que existan residuos—de medicamentos veterinarios en los ingredientes del pienso proveniente de animales terrestres o material de acuicultura, aunque por lo general esto no se considera una vía de exposición potencial de mayor importancia. Hay pruebas que sugieren que los antibióticos utilizados para controlar la contaminación microbiológica durante la fermentación del grano para la producción de etanol pueden concentrarse en los subproductos de granos de destilería (DDGS).

## Comentario

El término residuo corresponde a una sustancia o su metabolito presente en los tejidos animales tras la ingesta o administración de tal sustancia a un animal.

En este caso el párrafo alude seguramente a pequeñas concentraciones de plaguicidas o de medicamentos veterinarios que eventualmente pueden contaminar los piensos y lego ser ingeridos 'por lo animales.

58. Los residuos de medicamentos veterinarios y coadyuvantes de elaboración en el pienso también pueden resultar de la transferencia de contaminación durante la producción del pienso

Los residuos de Los medicamentos veterinarios y coadyuvantes *empleados en* de elaboración <del>en el</del> *de un pienso o de un pienso medicado* <del>también</del>, *pueden aparecer*– *como contaminantes en otro pienso fabricado posteriormente* <del>pueden resultar de la transferencia de contaminación durante la producción del pienso</del> el proceso de fabricación de piensos.

#### Comentario

El término residuo corresponde a una sustancia o su metabolito presente en los tejidos animales tras la ingesta o administración de tal sustancia a un animal. En este caso el párrafo brinda una orientación general para gestionar el riesgo relativo a la aparición de los medicamentos y coadyuvantes como contaminantes de los piensos.

59. El uso no aprobado de medicamentos que causen niveles excesivos <u>en los ingredientes</u> del pienso puede tener como resultado la transmisión de residuos a la carne, el pescado, la leche o los huevos (por ej. nitrofuranos en los langostinos, cloranfenicol en la leche en polvo).

El uso de no aprobado de medicamentos que causen niveles excesivos de <u>medicamentos no aprobados en la</u> <u>elaboración de del piensos</u> puede tener como resultado la generación de residuos la transmisión de residuos a en la carne, el pescado, la leche o los huevos (por ej. nitrofuranos en los langostinos, cloranfenicol en la leche en polvo).

## Comentario

El término residuo corresponde a una sustancia o su metabolito presente en los tejidos animales tras la ingesta o administración de tal sustancia a un animal. Estimamos que el párrafo debe indicar que existen medicamentos con principio activos expresamente prohibidos (por ejemplo por los nitrofuranos y el cloranfenicol), que no deben incluirse en la elaboración de piensos y que si se llegaran a emplear pueden generar residuos en los productos de origen animal.

Otros químicos

61. Los siguientes son sólo ejemplos: Los químicos que tienen relevancia para la salud humana se descri-ben como normas Codex.

Otros compuestos químicos

61. Los siguientes son sólo ejemplos: Los compuestos químicos que tienen relevancia para la salud humana se describen como normas Codex.

## Comentario

El sustantivo "químicos" para describir sustancias químicas, resulta una expresión coloquial. Por lo tanto en este contexto resulta más preciso el empleo de las palabras "compuestos químicos".

Figura 1 Diagrama de flujo para evaluar la posibilidad de incidencia de peligros en el pienso.

Rombo: derivados plantas.

Rectángulos: bacterias, micotoxinas endoparásitos.

Rectángulo: bacterias, endoparásitos.

Rombo: Otros.

Rombo: Minerales incluyendo oligoelementos y ligantes.

Figura 1 Diagrama de flujo para evaluar la posibilidad de incidencia de peligros en el pienso.

Rombo: derivados plantas.

Rectángulo: bacterias, micotoxinas <del>endoparásitos</del> parásitos.

Rectángulo: bacterias, endoparásitos parásitos.

Rombo: Otros Ingredientes y aditivos para la elaboración de piensos.

Peligros no cubiertos por estas directrices.

Véanse normas Codex.

Rombo: Minerales incluyendo oligoelementos y ligantes y otros aditivos piensos.

Rombo: Medicamentos veterinarios y residuos de plaguicidas.

## Comentario

La expresión genérica de <u>parásitos</u> indica y representa de manera genérica el peligro que representa para la salud humana la presencia de los mimos en un alimento. En tanto que la expresión <u>endoparásitos</u> indica que de manera preferente, parte del ciclo evolutivo de determinados parásitos se lleva a cabo en el organismo del huésped.

Consideramos como más adecuada la inclusión de la expresión "Ingredientes o ingredientes y aditivos para la elaboración de piensos" para identificar el rombo identificado como "Otros", dado que estimamos que en el contexto del diagrama de flujo, este rombo se relaciona con la gestión de riesgos asociados con la inclusión de aditivos o de medicamentos veterinarios en la elaboración de piensos. Situación claramente asociada a la elaboración de piensos o de piensos medicados, para la cual se dispone de directrices del Codex que pueden resultar de utilidad en la correspondiente gestión de riesgos.

En el rombo "Medicamentos veterinarios y residuos de plaguicidas", recomendamos eliminar la palabra residuos, debido a que en el caso de los residuos de plaguicidas, corresponde a una sustancia o su metabolito presente en los tejidos animales tras la administración o ingesta de tales sustancias a un animal. En este caso las normas y directrices del Codex en la materia brindan una orientación general para gestionar el riesgo relativo a la aparición de los plaguicidas como contaminantes de los piensos.

Tomado en consideración el sentido del diagrama de flujo, debe incluirse primero el rombo "Minerales incluyendo oligoelementos y ligantes y otros aditivos piensos", debe ir antes que el rombo con la leyenda "medicamentos veterinarios".

En el contexto de lo anteriormente expuesto nos referimos a los aditivos empleados en la elaboración de piensos según la definición que a continuación presentamos, la cual esta referenciada en las normas colombianas como Resolución ICA 1056 de 1996.

ADITIVO. Sustancia o producto no alimenticio, utilizado para dar sabor, pigmentar, conservar, prevenir la compactación, la oxidación, producir emulsificación o acidificación en los alimentos.

## Detección

64. Si se desarrolla un nuevo ensayo, los métodos deben cumplir con un conjunto de criterios específicos, tales como exactitud, aplicabilidad (matriz y gama de concentración), límites de detección y determinación, precisión, posibilidad de repetirlo y reproducirlo.

Si se desarrolla un nuevo ensayo, los métodos deben cumplir con un conjunto de criterios *de validación de las técnicas* analíticas de detección, confirmación y/o cuantificación específicas, tales como exactitud, aplicabilidad (matriz y gama de concentración), límites de detección y determinación, precisión, posibilidad de repetirlo y reproducirlo

## Comentario

La expresión validación de métodos analíticos es reconocida en el ámbito técnico científico relacionado con los sistemas de aseguramiento de calidad de los laboratorios que realizan ensayos

#### Documentación

65. La priorización del peligro debe documentarse de forma completa y sistemática. Se debe preparar un registro formal, que incluya un resumen, disponible para las partes interesadas de modo que otros asesores puedan revisarlo de forma crítica y, en caso de ser necesario, repetir la evaluación.

La priorización del peligro debe documentarse de forma completa y sistemática. Se debe preparar un registro formal, que incluya un resumen, disponible para las partes interesadas de modo que otros asesores *o auditores* puedan revisarlo de forma crítica y, en caso de ser necesario, repetir la evaluación.

#### Comentario

Es importante concebir todo el proceso de gestión de riesgos asociados a la elaboración de piensos en el marco de un sistema de aseguramiento de calidad, el cual pude ser auditado y adecuadamente respaldado por evidencias documentales

#### TABLA 3: FUENTES DE LOS PELIGROS DE RELEVANCIA

Productos comestibles

101. Endoparásitos (por ej. Echinococcus, Toxoplasma gondii, Cisticercus, Trichinella).

113. Micotoxinas

Producidas por hongos fagocitadores de carbohidratos, encontrados por lo tanto en los cereales (especialmente el maíz), la semilla de algodón, el

cacahuete y la copra (pulpa seca del coco).

114. (de los hongos de campo)

Producidos por hongos (de campo) patógenos de las plantas provenientes de esporas/conidios del suelo, transportados por el aire o los insectos (también posible la contaminación en almacenamiento secundario); la micotoxina se acumula en las partes internas de la pepita en condiciones de humedad (por ej. Deoxinivalenol, zearalenona, fumonisinas, tricotecenos)

115. (de los hongos de almacenamiento)

Producidos por hongos (de almacenamiento) saprofíticos del suelo y las áreas de almacenamiento contaminadas que infectan las pepitas desde el exterior, micotoxina más concentrada en la cascarilla, la punta del grano y las capas externas, de modo que la contaminación depende del sistema de molienda (por ej. Aflatoxinas de Aspergillus flavus, ocratoxinas de A. ochraceus)

Productos comestibles Tejidos o productos comestibles de origen animal en que puede presentarse

#### Comentario

Estas frases facilitan el uso de la información de esta tabla.

o Riesgo de presencia en tejidos o productos comestibles de origen animal

Endoparásitos Parásitos (por ej. Echinococcus, Toxoplasma gondii, Cisticercus, Trichinella).

#### Comentario

La expresión genérica de <u>parásitos</u> indica y representa de manera genérica el peligro que representa para la salud humana la presencia de los mimos en un alimento. En tanto que la expresión <u>endoparásitos</u> indica que de manera preferente, parte del ciclo evolutivo de determinados parásitos se lleva a cabo en el organismo del huésped.

Producidas por hongos <del>fagocitadores de carbohidratos</del> que utilizan como sustrato carbohidratos y que por lo tanto <del>se</del> <del>encontrados por lo tanto</del> se encuentran en los cereales (especialmente el maíz), la semilla de algodón, el cacahuete y la copra (pulpa seca del coco).

#### Comentario.

La fagocitosis es una propiedad característica y propia de las células blancas de los animales, por el cual los leucocitos polimorfonucleares de la sangre engloban las bacterias u otros materiales extraños al organismo.

Producidos por hongos (de campo) patógenos de las plantas provenientes de esporas/conidios del suelo, transportados por el aire o los insectos (también posible la contaminación en almacenamiento secundario); la micotoxina se acumula en las partes internas de la pepita de la semilla en condiciones de humedad (por ej. Deoxinivalenol, zearalenona, fumonisinas, tricotecenos)

Producidos por hongos (de almacenamiento) saprofíticos del suelo y las áreas de almacenamiento contaminadas que infectan las pepitas semillas o granos desde el exterior, micotoxina más concentrada en la cascarilla, la punta del grano y las capas externas, de modo que la contaminación depende del sistema de molienda (por ej. Aflatoxinas de Aspergillus flavus, ocratoxinas de A. ochraceus).

#### Comentario.

La expresión "pepita" es una expresión coloquial. La expresión "pepita" es una expresión coloquial. En este caso las palabras semilla o grano (habida cuenta que se llevó a cabo la cosecha), podrían resultar más apropiadas.

Es importante incluir y destacar los aspectos correspondientes a la gestión de riesgo asociada a la posible contaminación de los piensos por micotoxinas en bodegas en las bodegas o sitios de acopio para tal efecto se disponen de directrices y recomendaciones del Codex

#### **COSTA RICA**

Costa Rica desea expresar su agradecimiento a Suiza por la elaboración de este documento y desea emitir los siguientes comentarios:

#### **Comentarios Generales:**

- Cuando se haga mención a los riesgos sobre la salud humana, Costa Rica propone incluir en todo el texto, "riesgos sobre la salud animal y humana".
- Costa Rica considera que aunque en la lista de peligros, se describen todos los peligros conocidos; se debería mencionar la necesidad de identificar y citar peligros que pueden acarrear los materiales de limpieza y aceites industriales que se utilizan durante los procesos de elaboración de alimentos para animales (esto requiere mayor) investigación; por lo que la lista no puede ser definitiva.

## Comentarios específicos:

1. En antecedentes párrafo 1, Costa Rica propone a partir de la tercera línea del párrafo lo siguiente: "Las sustancias no deseadas <u>e incluso, las deseadas</u> que se encuentran en piensos ingeridos por animales destinados a la producción de alimentos y transmitidos a productos comestibles"....pueden presentar un riesgo a la salud humana <u>animal y al medio ambiente</u>".

**Justificación:** Costa Rica propone considerar los siguientes aspectos:

- Respecto a las sustancias adicionadas a los piensos, se debe tener en cuenta que, incluso las sustancias deseadas, si se utilizan de una manera inadecuada, (por ejemplo, sobre o subdosificación de medicamentos veterinarios), pueden representar peligros o riesgos.
- El peligro primera o directamente afecta a la salud animal y luego, paralela o indirectamente afecta la salud humana. Es importante considerar que no en pocas ocasiones causa daño al medio ambiente, por ejemplo con una inadecuada utilización de úrea como suplemente alimenticio y el proceso metabólico que sufre el nitrógeno y su posterior eliminación al medio ambiente.
- 2. Referente al Párrafo 2, Costa Rica tiene la siguiente inquietud:

**Justificación:** la frase "ofrecen criterios amplios y estructurados para tratar el impacto causado a la salud humana por los peligros en la alimentación de animales/cultivos a consecuencia..." no es clara, porque no se entiende la inclusión de la palabra "cultivos", están hablando de alimentación de animales y alimentación de cultivos? No hay claridad

3. En la última parte del párrafo 3 de los antecedentes, proponemos incorporar la siguiente modificación leyéndose de la siguiente manera:

"Las directrices también deberían......el establecimiento de los niveles de transmisión y acumulación <u>de las sustancias</u> <u>que componen los piensos o sus residuos</u>, en los tejidos comestibles..."

**Fundamento:** Los piensos no se acumulan por sí mismos, más bien son las sustancias o los residuos de estas sustancias los que se acumulan en los tejidos.

4. En la página 7, tema: CRITERIOS PARA PRIORIZAR LOS PELIGROS

Costa Rica propone incluir las siguientes viñetas:

- relevancia para la salud animal
- impacto en la economía de los sistemas de producción pecuaria.

Costa Rica considera importante tomar en cuenta las siguientes observaciones:

- Como se mencionó anteriormente, el animal por sí mismo es un organismo y que, con mucha más relevancia en la actualidad, requiere ser tratado como tal. Es decir que el efecto de cualquier peligro se da primero en el animal. Mencionamos otro ejemplo, en una alimentación con piensos contaminados con micotoxinas, aunque podría no generar síntomas inmediatos, va produciendo una degeneración de órganos y tejidos del cuerpo animal que afectan negativamente su salud. Insistimos que el primer efecto a considerar debe ser el que se produzca sobre la salud animal..
- Cuando los animales ven restringida su salud, los mecanismos de defensa afectan su productividad en cuanto a
  producción de alimentos de origen animal para consumo humano (se limita la ganancia de peso o producción de
  carne, la producción de leche, la producción de huevos, etc.). Estas disminuciones en los índices de

productividad, afectan la economía de los sistemas de producción pecuaria. El efecto sobre esta economía depende del tipo de peligro (no causa el mismo efecto negativo, una subdosificación de un medicamente veterinario que el suministro de un alimento altamente contaminado con Ocratoxina).

5. En la página 9, cuando se hace referencia a los peligros biológicos y se describe la Salmonella, Costa Rica desea expresar su total apoyo a la siguiente redacción: "pero la correlación entre el pienso contaminado y la infección del ganado por las mismas cepas de Salmonella y la contaminación de la carne, la leche y los huevos producidos por estos animales debe establecerse necesariamente caso por caso"

**Fundamento:** se conocen estudios de la poca prevalencia de alimentos para animales o piensos contaminados con Salmonella, que causen riesgos a la salud animal y humana, sin que se pretenda expresar que los piensos están libres de contaminación por Salmonella. También es importante mencionar que la tipificación es de suma relevancia ya que existen cepas que no son patógenas, o que lo son para unas especies animales pero no para otras y en la actualidad, se toman medidas sanitarias restrictivas independientemente del tipo de Salmonella encontrada, lo que podría significar pérdidas innecesarias para los productores. Dado lo anterior costa Rica considera que debe ser estudiado a fondo con grupos multidisciplinarios (microbiólogos, zootecnistas y veterinarios, por ejemplo).

#### **EUROPEAN UNION**

The European Union (EU) would like to thank Switzerland for preparing this document which forms a good basis for further discussion. The EU would like to submit the following comments:

#### (i) General comments

The document at present does not attempt to develop a prioritised list of hazards, only lists them and provides criteria to carry out the prioritization. This should be clarified.

Although not necessarily directly applicable, the following existing work prioritization criteria within Codex are useful resources when further developing the criteria for prioritisation of hazards:

- Criteria for the Establishment of Work Priorities;
- Guideline on the Application of the Criteria for the Establishment of Work Priorities;
- Prioritization criteria as used for the priority list for JECFA (i.e. para. 20 of the Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods).

It could be made more clear in the text, in the flowchart and also in the tables, which substances or agents are covered and relevant in the list and which are not. Substances found in feed that are not transferred to animal products should either not be listed or be listed as substances that are known not to be relevant for food safety. If this information is included it could meet the requirement of prioritisation.

There should be a better linkage between the flowchart, the Tables 1, 2 and 3 and the text. In its present form, it is not easy to read the five elements at the same time and to avoid inconsistencies. There is a need to consider if and how Figure 1, the Flowchart and Tables 1 and 2 can be simplified to facilitate reading and understanding.

The draft is rather confusing as regards veterinary drugs – it is not clear whether the hazards listed include the regular use of veterinary drugs as medicated feed. It should be clarified in the paper whether medicated feed should not be included since considerations about it are already addressed in the Codex documents on veterinary drugs. As regards residues of veterinary drugs in feed of animal origin - are there any examples that the concentrations are so high in the "next animal in the food chain" that it can cause any hazard for humans?

Same question relating to pesticides. Can residues of pesticides in feed result in significant residues in food of animal origin? Another question can of course be illegal use or abuse.

The presence of residues of feed additives in food of animal origin could be relevant and should be addressed more clearly in the document.

There is a need to consider including hazards which may enter the food chain via feed such as residues of certain antibiotics used as processing aids and other compounds in co-products and by-products from the biofuel, oleochemical and more in general chemical industries.

Throughout the text the terms minerals, mineral supplements, supplemental minerals are used in several places. While there are in some places some explanations about what is meant, taking into account that there does not seem to be definitions for them at present, it may be good to examine carefully if it is understood to mean the same for all readers of the documents.

The EU comments on Tables 1, 2 and 3 are of a preliminary nature at this stage due to the vast array of subjects mentioned and its complexity, requiring very diverse expertise. Therefore, the EU may later suggest further clarifications and suggestions to the ones included here.

## (ii) Specific comments

## Heading: Background

Although no comments are requested for the background of the document, the EU wishes to make the following remarks to clarify certain issues.

- p. 1: "... including primary production": It should be clarified if the term "primary production" refers to food or feed or both
- p. 1 could be replaced with the following paragraph:
- "1. This prioritised list of hazards provide a structured framework based on existing Codex risk assessment methods to address the risks to human health associated with the presence of hazardous chemical, biological and physical agents in animal feed and their transmission through animal feed to food."

Justification: To align it better with the Codex definition of hazard.

p. 3: The text in italics with the mandate should be replaced with the appropriate mandate, following the text from ALINORM 33/10 rep:

Develop a prioritised list of hazards in feed ingredients and feed additives for governmental use. The list should contain hazards of international relevance that are reasonably likely to occur, and are thus likely to warrant future attention.

In doing so, due consideration should be given to the prioritised list of hazards as recommended by the FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety. Clear criteria should be used to prioritise the list of hazards and take account of the potential transfer of contaminants/residues in feed to edible animal products (e.g. meat, fish meat, milk, and eggs).

#### Heading: Scope

ps. 4 and 5: Could be mistaken as being definitions. They should be perhaps formulated as in the other document on the draft guidelines.

The same EU comments as submitted in the other document relating to the term hazard are applicable here.

p.7: Physical hazards seem outright excluded. However, there should be a mention of physical hazards such as botanical impurities, which may be of relevance from a food safety point of view, particularly due to the presence of natural inherent toxins, which are chemical hazards. Those physical hazards which do not result in food safety hazards should be mentioned and clearly excluded.

## **Heading:** Definitions

- p. 8: Definition of "undesirable substances": not identical to the definition in the <u>Code of Practice on Good Animal Feeding (CAC/RCP 54/2004)</u>.
- p. 8: Definition of carry over. Same comment as in the other document regarding this definition.
- p. 8: Definition of "edible product" should be in fact the definition of an "edible product of animal origin", as proposed also in the comments to the first document.

#### Heading: Relevance to human health

p. 10: Same comment as on p. 23 of the other document.

## **Heading:** Extent of occurrence

- p. 12: Typo: outlines should be replaced with outlining.
- p. 15: Reference (footnote 16) for radionuclide contamination is made to the FAO document "Radionuclide contamination of foods: FAO recommended limits". It would be appropriate to also make reference to the Codex guideline levels for radionuclides which have been established in the <u>General Standard for Contaminants and Toxins in</u> Food and Feed (CODEX STAN 193-1995).
- p. 16: It is proposed to delete the word "primary".

## **Heading FOOD HAZARD LIST**

p. 18. The EU suggests amending the first sentence as follows: "The following list of human health hazards <u>potentially</u> associated with animal feed ....".

Heading: Biological hazards

Heading: Bacteria

- p. 20: To hyphenate "coefficient" i.e. "co-efficient" in first sentence.
- p. 21: The EU is proposing the following amendment:
- "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 <u>may</u> contaminate animal and vegetable protein meals fed directly to animals. They may be introduced into feed from contaminated pasture land, <u>forages and/or meals</u> and during processing, transport, and storage."
- p. 23: In the final sentence to delete "be" and replace with "pose".

## Heading: Other

p. 24:

Describes the direct contamination of products of animal origin by feces and not feed. However, this direct contamination by feces is not within the scope of the guidelines or the prioritised list. Therefore, the EU would like to suggest focusing this paragraph on feed only.

The EU suggests also that the fourth sentence is amended as follows:

"Spores present in raw milk may survive during processing, and after germination and outgrowth, <u>increase</u> to high levels <u>that</u> may cause spoilage and human disease."

## **Heading:** Endoparasites

p. 27: Delete the word "compound".

#### Heading: Viruses

p. 28: Last sentence replace "hygienic" with "hygiene".

#### Heading: Prions

p.29: The EU suggests that the second sentence is amended as follows:

"Prions are responsible for the <u>Transmissible Spongiform Encephalopathies (TSEs)</u> in a variety of mammals, including <u>Bovine Spongiform Encephalopathy (BSE)</u> in cattle and variant Creutzfeldt–Jakob <u>Disease</u> in humans."

#### Heading: Elements

The EU suggests that the heading is amended to "Chemical elements".

p. 32: Suggestion to amend the first sentence follows:

"A number of elements may present a toxic hazard to humans, depending on their ionie form and ligands."

p. 33: Suggestion to amend the last sentence as follows:

"Carry over Transfer of radioiodines to milk, radiostrontium to bone, and radiocaesium to milk, eggs and meat has been demonstrated."

- p.34: "lead paints" are not feed. Therefore, either they should not be mentioned or at least this point should be stated. The text could read: ".... lead paints (could contaminate feed by leaching of lead to liquid feed or by sprinkling into the feed in a silo), ....".
- p. 34: If presence of mercury in terrestrial animals is usually low (presumably when these animals are used as feed) then this should be made clearer and concluded in terms of the result of prioritization.
- p. 34: In addition p. 34 is not consistent in its content.
  - For arsenic: a number of feed materials are mentioned in which arsenic may occur. It is not clear from the wording if the feed materials are mentioned as examples or being the main feed materials in which arsenic occurs or if the list is aimed to be exhaustive
  - For cadmium: a relative comprehensive list of feed materials in which cadmium might occur seems to be provided.
  - For lead: besides feed materials in which they might occur also sources of lead contamination are provided. Furthermore, the list of feed materials in which lead occurs is certainly not exhaustive and even the main feed materials are not provided (e.g. forages / grass roughages).
  - For mercury: see comment made above.

## ps. 36-40. Replace as follows:

"36. 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.

- 37. Mycotoxins are produced by fungi which catabolise carbohydrates, and are therefore found in cereals (especially maize), cottonseed, peanut, and copra.
- 38. There is some evidence that mycotoxins in grain which is fermented for ethanol production may concentrate in Distillers' Dried Grains with Solubles (DDGS).
- 39. As the Codex General Standard for Contaminants and Toxins in Food and Feed (Codex Standard 193-1995)] contains further information on mycotoxin contamination it could be made a reference to this document under this point."
- p. 40: It is proposed to amend "Distiller's" to "Distillers".
- p. 41: Insert colon after "include".
- p. 41, third point: Typo "And" should read "and".

## **Heading:** Bacterial toxins

p. 42: If the conclusion is that these hazards are unlikely to result into edible products of animal origin, this should be made clear. Therefore, they should be deleted or have a low rank in terms of prioritisation.

## **Heading:** Terrestrial plant toxins

- p. 43: Marine toxins can not only be produced in tropical and subtropical but also in temperate waters.
- p. 44: Second sentence is a bit confusing as it refers to "alkaloids" and "pyrrolizidine alkaloids" which are also alkaloids. Therefore, it would be appropriate to first mention pyrrolizidine alkaloids and then mention "other alkaloids".

It would also be appropriate to spell out THC: "tetrahydrocannabinol" and replace "carry-over" with "transfer".

#### Heading: Marine toxins

- p. 46: Delete the words "feed supplements" and eliminate the brackets around "fish meal" as fish meal can be used for several types of animals both as a supplement and as a meal.
- p. 47: Marine toxins can not only be produced in tropical and subtropical areas but also in temperate waters.

## Heading: Organic chemicals

- p. 49: The examples given for dioxins formed during heat processing are not correct:
  - The lime used in the contaminated citrus pulp was a by-product of the polyvinylchloride (PVC) production and the lime got contaminated with high levels of dioxins during the PVC production.
  - The directly dried bakery waste got contaminated as the fuel used for direct drying, whereby the combustion gases come in direct contact with the material to be dried, was contaminated with PCBs. Therefore, the contamination was not the consequence of heat processing but because of making use of an inappropriate combustion material.
  - Also non-dioxin-like PCB's (sum of 6 indicator-PCB's) should be mentioned here.

Same comments to table 3, p. 121.

- p. 49: The first sentence, namely "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" should be replaced with:
- "49. <u>Dibenzodioxins (PCDD)</u>, <u>dibenzofurans (PCDF)</u>, <u>dioxin-like polychlorinated biphenyls (DL-PCBs)</u>, <u>hereafter referred to as dioxins</u>, and non-dioxin-like polychlorinated biphenyls (NDL-PCBs) are related groups of compounds and congeners which are more or less toxic to mammals including humans."

## Justification: More accurate terminology.

- p. 50: Insert "and are very persistent" after "degree" in the first sentence.
- p. 52: Replace current wording with:
- "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 appear in feed and thus result in transfer and accumulation in the fat tissues of food-producing animals."

p. 53: Colourants intended to colour the flesh of salmon or eggs or other foods of animal origin are not processing aids and therefore seem not to be properly covered in this p. 53. They are considered to be feed additives in the EU.

A wording such as "<u>feed additives such as colourants intended to color the flesh of salmon, eggs or other foods of animal origin, other residues of feed additives and certain processing aids are generally within the terms of reference of the Codex Committee on Food Additives."</u>

p. 58: An additional sentence could be added to the end of the paragraph, as follows:

"As regards processing aids, measures should be undertaken to avoid their presence in feed."

- p. 59: The reference to unapproved uses may be necessary to be qualified as not all countries and regions may have the same legal status for all veterinary medicines.
- p. 61: As regards the risks from acrylamide, the transfer of acrylamide from contaminated feed to eggs appears to be very limited (even if a certain transfer has been demonstrated) and is in any case of little relevance and it would be appropriate to mention this in case acrylamide is kept as example (low in terms of priority).

## **Heading:** Procedure

p. 62: Flowchart.

Overall the flowchart should be made more consistent and simplified. Furthermore, the usefulness of such a flow-chart needs to be demonstrated.

There is no box or indication how to deal with feed additives.

The box "minerals, including trace elements, and binders" should be split into three boxes separating the different concepts: one for mineral feeds in general, another one for nutritional feed additives (trace elements, aminoacids and vitamins) and another one for technological feed additives (binders, emulsifiers) and possibly also sensory additives such as flavourings and colourants. The purpose to address issues relating to feed additives to the relevant other Codex Committees or documents should be made clearer in the text.

The flowchart does not seem to work very well for chemicals added and produced by synthesis as they are not plant derived or animal derived. They would likely fall under the box "Other". However, the outcome of that box can be "yes" or "not" but it is not explained on the basis of what the answer to "Other" can be "yes" or "not".

The box "other" is in general very unclear.

When the outcome in the flowchart in some parts leads to "hazard not covered by these guidelines", it should be indicated which Codex document or Committee would deal with this hazard, as the reason why they are excluded usually is either because they are excluded from the list of hazards, because they are covered already somewhere else, because they are not relevant for food safety or because they are not dealt with at all.

There is only in one case that this is mentioned in the case of the veterinary drugs, pesticide residues where it is mentioned see Codex Standards. There are also Codex standards for mycotoxins in feed, and also Codex standards for other hazards in foods.

It is unclear how the flowchart deals with mycotoxins. Are mycotoxins considered plant derived?

## <u>Table 1</u>

p. 69: Consider adding at last column "likely residues of veterinary drugs, pesticides, feed additives and processing aids".

A lot of proposed entries are unclear and require clarification. Hereafter follow some but not exhaustive comments.

- p. 70: Query "manure can be spread to land which could contain viruses, endoparasites and prions". Also in last column add "likely residues of pesticides".
- ps. 71 to 78: The "-" in the column on organochlorine pesticides should be clarified.
- p. 72: The meaning of the + in the column dioxins PCBs should: clarified. It could be probably replaced with (+).
- p. 73: The meaning of the "+" in the columns mycotoxins and plant toxins should be explained.
- p. 73: The meaning of the "-" in the column "residues of veterinary drugs, pesticides, processing aids" should be explained. May be it should be replaced with a "+", particularly taking into account possibility of residues of veterinary drugs.
- p. 77: The meaning of the "-" in columns plant toxins and heavy metals should be clarified.

The "-" in the column residues of veterinary drugs, pesticides, processing aids should be replaced by a (+) in order to be in accordance with paragraph 57 of the document (e.g. residues of antibiotics in DDGS).

- p. 78: The meaning of the "-" in the columns mycotoxins and plant toxins should be clarified.
- p. 79: Mycotoxins in drinking water. Are there data to show that mycotoxins have been detected in drinking water?

## Table 2

## Table 3

In general: Bones as edible tissues should be explained (used for broth).

- p. 98: The heading of the 3<sup>rd</sup> column should be completed. Probably it is meant "How to reduce risk".
- p. 98: The heading of the 4<sup>th</sup> columns should be "edible products of animal origin."
- p. 100, 4th column, "poultry products" should be replaced with "meat and meat products".
- p. 104 should be a blank space.
- p.106, 1st column: the isotope 134Cs should be added.
- p. 106 typo: To amend radiocesium to radiocaesium.
- p. 106, 2<sup>nd</sup> column: To delete the word "animal".
- p. 109, 4<sup>th</sup> column: edible fungi are no edible products of animal origin and should therefore be deleted.
- p. 110, 4<sup>th</sup> column: Bones could only be edible products presumably if consumed in broths. Milk products can contain also lead. Is brain a relevant food to be mentioned as being contaminated by lead?
- p. 110: Lead could be reduced by not using lead in paint and plumbing systems.
- p. 114, 2<sup>nd</sup> column: Deoxynivalenol is a trichothecene, therefore, it would be appropriate to mention it as follows: e.g. trichothecenes (such as deoxynivalenol)
- 4<sup>th</sup> column: it would be appropriate to explain what DOM1 stands for. It seems it should be DON1 and then it should be mentioned in full.
- p. 118: Fodder is not defined in Codex documents and could be replaced by feed.

In line with comments made on paragraph 44, it would be appropriate to reverse the order between p. 118 and p. 119 and to replace "Alkaloids" by "Other alkaloids".

- p.121, 3<sup>rd</sup> column: It is unclear how the description "lipophilic, so assay oil/fat feed component" can be explained as a way to reduce contamination.
- p. 121: add "and use uncontaminated batches" in "how to reduce risk" column.
- p. 123, 2<sup>nd</sup> column: "Crops treated with pesticides" should be added.
- "Nectar of antibiotic-treated fruit trees" is that relevant? Or reflected in the document? Should processing aids of feed also included?
- p. 123, 3<sup>rd</sup> column: The term "wait times" should be replaced with "withdrawal period" or "period of time allowing for elimination of the residue from the edible product of animal origin".
- p. 123, 4<sup>th</sup> column: Veal and pork meat should be replaced by "all animal products" or similar.

Taxonomical names should be mentioned in italics throughout the document (such as in ps. 35, *Staphylococcus* and also 100, 101).

## **IRAN**

## **General comments:**

Iran approve this document

## Comments on paragraphs:

Paragraph	Comments
7	Add "inorganic chemicals" to the line 2.
9	Add one more criteria with the name <u>"relevance to Environment Protection"</u> to this section. ( <u>kinds of feeds which produce methane and other gases</u> )
21	Add <u>"drinking water</u> " to the line 3 of paragraph.: " <u>They may introduced into drinking water and feed from,"</u>

Paragraph	Comments
	1-Add <u>'sillage'</u> and to the end of the text 2- Replacement " <u>oilseed meals and cakes</u> " instead of " <u>cottonseed</u> "
52	change to :Some organic chemicals such as organochlorine , organophosphors and pyrethroids pesticide

## **J**APAN

## (i) General comments:

Japan would like to thank Switzerland for preparing the draft prioritized list of hazards in feed. Japan supports the draft. Considering the diversity of feeding condition among Members, it is important to note that feed safety authorities in member countries and regional organization prioritize feed hazards taking the specific local conditions of feed into account. Since the scope of the document is to provide guidance on prioritization of hazards in feed, we would like to propose to modify the title of the document to "Guidance on prioritization of hazards in feed". In addition, to make the document more practical, we propose to modify the draft as follows:

## (ii) Comments on paragraphs:

Paragraph	Comments
20	Appropriate references to the term "Codex information on carry-over" need to be added for the ease of readers. If the term refers to the information in JECFA reports and evaluations, Japan requests the Government of Switzerland to add the reference or URL in the paragraph or footnote.
37	(Proposal) "especially wheat, sorghum or maize" (Rationale) Wheat should be added because the reference CAC/RCP 51-2003 says wheat and maize have been found to be particularly susceptible to Fusarium species. In addition, Japan proposes to add sorghum in accordance with our experience of detecting zearalenone above 3mg/kg in imported sorghum. In 2002, 46 samples out of 51 were detected positive (LOD, 20μg/kg) for zearalenone. Among those positive samples, 11 samples contained more than 1mg/kg of zearalenone, with 2 samples above 3 mg/kg.
Table 1	Compared to the previus draft prepared by the informal consultation, the rows under the column "Residues of veterinary drugs, pesticides, processing aids" were misplaced. Please find attached the corrected table.
Table 2	(Proposal) "1ed" (Rationale) "1e" in the draft in the informal consultation was replaced with "1d".
Table 3 106	(Proposal) "Radionuclides: 134Cs, 137Cs, 90Sr, 131I" (Rationale) To make the text in line with paragraph 33.
112	"Tin" should be deleted since it is deleted from paragraph 34.
123	(Proposal)  "Veal, pork meat meat, fish, milk, eggs, honey" (Rationale)  To ensure consistency with paragraph 59.

## **NEW ZEALAND**

New Zealand is pleased to offer the following specific comments on the Proposed draft prioritised list of hazards in feed.

## Para 10: Suggest amend the second sentence as follows:

It is important to note these limits are <u>often not</u> based on estimated human adverse effects (in terms of Acceptable Daily Intake (ADI), Acute Reference Dose (ARfD), etc) but are <del>also</del> adjusted to take account of .....

*Rationale:* the above amendments to provide greater clarity around the basis for setting maximum limits in Codex.

## Paras 21-26: New Zealand recommends deletion of these paragraphs

**Rationale:** Of the biological hazards listed in the paragraphs the only food borne bacterial toxins that infect animals are those of *Clostridium botulinum*. To our knowledge even in the highly unlikely event that food were produced from animals suffering from botulism, those food products would not present a risk of human food borne toxicosis( as described in paragraph 42)

**Para 28:** The statement that the most likely route of contamination of edible products of food producing animals is probably external via faecal contamination and that this is outside the terms of reference of the present document is at odds with the comments made in para 24. We suggest further examination of both paragraphs for consistency.

Rationale: for the reasons explained above.

Para 32: Suggest adding a third sentence as follows:

Many of these hazards are present in the environment as a result of natural phenomena such as volcanic activity.

Rationale: to improve clarity.

**Para 34:** Suggest delete the first sentence as the form of Arsenic in fish products is the much less toxic organic form and is unlikely to pose a risk to human health.

**Rationale:** For reasons explained above.

Para 49: Suggest amend the first sentence as follows:

Dioxins, dibenzofurans and dioxin-like polychlorinated biphenyls (PCBs) are related groups of compounds and congeners which are more or less toxic have wide ranging toxicity to mammals including humans.

**Rationale:** For precision and clarity

Para 61: Suggest delete this paragraph

**Rationale:** Nitrite/Nitrate toxicity is not transmitted as a hazard in foods derived from affected animals suffering nitrite/nitrate toxicosis. Human food borne nitrite toxicosis results from the post harvest/slaughter use of nitrites as preservatives.

**Figure 1:** It is not clear where naturally occurring plant (pyrrolizidine alkaloids) and animal (tetrodotoxins in puffer fish) toxins are covered in the diagram. We also think some of the wording in the diagram may need review. For example the answer "no" under the "other" diamond would surely equate to no hazard (as it does not arise from plants, animals or other sources) rather than the hazard not being covered by these guidelines.

## **PHILIPPINES**

## (i) General comments:

Philippines appreciates the opportunity to provide comments on the "Proposed Draft Prioritised List of Hazards in Feed" at step 3 of the Procedure. Also, Philippines commends the work of Switzerland in preparing the proposed draft.

Philippines acknowledges that the proposed draft contains comprehensive list of hazards in feed. However, aimed at strengthening the proposed draft, we do have some specific comments below.

## (ii) Comments on paragraphs:

Paragraph	Comments
	Editorial comment Insert "and" after "(CAC/RCP 57-2004); " to read as follows:  Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004); and Code of Hygienic Practice for Eggs and Eggs Products (CAC/RCP 15-1976);
	Editorial comment "is" should be "are" after "pesticides" to read as follows:  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 <u>are</u> is not considered.
	Scope Insert "but not limited to" before "sharp objects" to read as follows: Physical feed contaminants such as, <b>but not limited to,</b> sharp objects, stones and animal fur are not considered in this document. Rationale: The statement can include other physical feed contaminants not covered under sharp objects,

Paragraph	Comments
	stones and animal fur like metal, wood, etc.`
7	Scope Insert "in solid or liquid form" before "whether or not" to read as follows: Feed ingredient: A component part or constituent of any combination or mixture making up a feed, in solid or liquid form, whether or not it has a nutritional value in the animal's diet, including feed additives. Rationale: This is to clarify that liquid feed ingredients are covered or included in the scope of the definition.
8	Insert definition of "feed" before "feed additive" Rationale: This is to make the definitions in chronological approach.
8	Insert definition of "hazard" before "hazard characterization" Rationale: This is to make the definitions in chronological approach.
11	Editorial comment "is" should be "are" after "done" to read as follows:  Normally, identification and characterization of a given hazard with respect to human health <u>are</u> is done as part of risk assessment for Codex by independent scientific expert bodies,
12	Editorial comment Insert "that" before "outlines" to read as follows: Figure 1 in this document provides a schematic flowchart that outlines the conditions under which the major feed hazards may be expected to occur. Rationale: This is to make the text more comprehensible.
28	Insert "adhering to" before "good food hygienic" and insert "practice" after "hygienic" to read as follows: The possibility of such contamination can be minimized by <b>adhering to</b> practicing good food hygienic <b>practice</b> , including food heating. Rationale: This is to make the text more comprehensible.
34	Insert "however" before "the use of fish meal" to read as follows:  Mercury (and/or methylmercury) levels in terrestrial animals and plants are usually very low; <a href="https://however">however</a> the use of fish meal as animal feed can <a href="however">however</a> also lead to higher (methyl)mercury levels in edible products.
	Rationale: This is to make the text more comprehensible.

## UNITED STATES OF AMERICA

## I. GENERAL COMMENTS:

The United States of America (U.S.) is pleased to submit comments on the *Proposed Draft List of Hazards in Feed* (at Step 3 of the Procedure.) The U.S. commends Switzerland for the useful guidance provided by this document and the document's adherence to the terms of reference for the Task Force, which is "to provide descriptive guidance for feed safety bodies ......who need to prioritize hazards..." (See paragraph 3 of the *Proposed Draft List of Hazards in Feed* (at Step 3 of the Procedure.)

The United States submits the following general comments:

- Because of its format, content, and similarity to the WHO/FAO Report on Animal Feed, this document should be considered as an informational paper for reference by other committees and not the type of Codex document that is subject to the step process.
- Since this document is presented as a list, it will be difficult to update and maintain by this time-limited Task Force. Other related Codex committees may be tasked to update this list, where necessary.
- There are references to other organizations, such as footnote 7 of this document, without a technical review for compatibility with Codex texts. There are also numerous references to other Codex texts, which references need to be fact-checked. Assuring the delegates at the start of the meeting that the "fact-checking" has been accomplished should contribute to the efficiency of the meeting.

## II. SPECIFIC COMMENTS:

The United States has the suggested below revisions for the Task Force's consideration.

## INTRODUCTION AND SCOPE

**Paragraph 1-3.** We suggest that the original paragraphs 1-4 from the May 13<sup>th</sup> draft of the Prioritized List of Hazards be used since they are more relevant to this document.

Rationale: These paragraphs as currently drafted, specifically relate to the *Proposed Draft Guidelines on the Application of Risk Assessment Methodologies in Animal Feeding (for governmental use)*. The original paragraphs 1-4 from the May 13<sup>th</sup> draft are more relevant.

#### **SCOPE**

**Paragraph 4:** We recommend deleting this paragraph.

Rationale: This is already included in the list of definitions. Also, the language is inconsistent across both documents.

**Paragraph 5:** We recommend deleting this paragraph

Rationale: This is already included in the list of definitions. Also, the language is inconsistent across both documents.

**Paragraph 7**: We suggest the following rewrite:

"Hazards in feed include biological agents (viruses, bacteria, endoparasities, and prions), toxic elements such as radionuclides, inorganic heavy metals, and organic chemicals including toxins, chemical contaminants such as dioxins and PCBs, and excessive levels of pesticides, veterinary drugs and additives."

Rationale: This paragraph could be made clearer in delineating examples of biological hazards.

#### **DEFINITIONS**

**Paragraph 8:** We recommend the suggested rewrite:

"ALARA: Reduction of hazards to levels as low as reasonably achievable through level possible the use of best practices such as Good Agricultural Practice (GAP) and Good Manufacturing Practice (GMP)."

Rationale: This revision is consistent with the *Codex General Standard for Contaminants and Toxins in Food and Feed* (Codex Stan 193-1995), which is cited in this paragraph.

#### CRITERIA FOR PRIORITISING HAZARD

## **Extent of occurrence**

**Paragraph 15:** We suggest the following deletion:

Information on the control of hazards of animal and human health importance in animal feed is included in the OIE Terrestrial Animal Health Code and the OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety.

Rationale: These documents are not relevant to hazards in feed that would result in human food safety concerns, and thus are outside the scope of the terms of reference for this Task Force.

## **Biological hazards**

## Bacteria

Paragraph 22: We have the following suggested editorial changes to the second sentence:

Contaminated feed may represent aimportant route of exposure...... human pathogenicity are typically strain-specific.

Rationale: This revision is more accurate. The current research from the FAO Expert Consultation found little scientific information available on 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.

**Paragraph 24:** We suggest the following deletions from this paragraph (first sentence and second to last sentence of this paragraph):

Some silage related bacteria may contaminate milk via fecal contamination and present a human health risk.

Some serotypes of Escherichia coli, for example E. coli 0157, 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;

Rationale: This should be deleted because E-coli 0157 H7contamination of meat is a topical contamination at slaughter, and fecal contamination of food is outside the terms of reference for this Task Force.

## **Endoparasites**

## Paragraph 27: Delete paragraph 27.

Rationale: Although contaminated pastures may cause animal infection, humans acquire *Echinocuccus* infections only from ingestion of eggs, not from ingestion of larval stages in foods of animal origin.

#### **Bacterial toxins**

Paragraph 42 and 43: We suggest deleting both paragraphs.

Rationale: As currently stated, these paragraphs statements are not entirely accurate since bacterial toxins are not a hazard transferred from feed to food, and there is no data to support this as a hazard reasonably likely to occur.

Paragraph 50: We suggest the following revision:

Dioxims accumulate in fat to a high degree, so even....

Rationale: While dioxins do accumulate in fat, the amount is dependent on the amount and duration of exposure, so "to a high degree" is an overstatement of what actual occurs.

**Paragraph 62**: We recommend that this paragraph be expanded to provide more explanation on how to use the flowchart and tables in the risk assessment process. We also recommend that this flowchart and tables undergo an indepth technical review to ensure they represent current science.

Rationale: The current identification of hazards in feed components and factors affecting presence of hazards as well as sources of relevant hazards do not reflect correctly evidence obtained by private sector feed safety risk assessment and public rapid alert systems. We also would seek clarification from the Codex Alimentarius Commission on which Codex Committee will be mandated to update these tables, once finalized by the Task Force, in the light of new scientific evidence and Rapid alert (INFOSAN) information on emerging feed safety risks.

**Paragraph 62, Figure 1**: The mention of endoparasites in the 3<sup>rd</sup> box in Plant Derived feedstuffs should be deleted.

Rationale: The parasite eggs would have to be part of the contaminated environment, and having moisture pre/post-harvest would not introduce parasite eggs.

## INTERNATIONAL FEED INDUSTRY FEDERATION (IFIF)

**General comment:** Should this document possibly be a "white paper" since Codex does not have the capacity to maintain and update lists? Or should this document be assigned to a standing Codex Committee when completed with the responsibility of periodic future updates and maintenance?

## Paragraph 1 – 3

The Background in these paragraphs needs to be replaced with the original wording of the initial document, which is consistent with the initial TOR (apparently this wording was inserted from the "Guidelines" document in error).

## Paragraph 4

We recommend eliminating this definition because it is already included in the list of definitions and is inconsistent.

## Paragraph 5

We recommend eliminating this definition because it is already included in the list of definitions and is inconsistent.

#### Paragraph 6

We recommend eliminating this paragraph because it is outside the scope of this document and the Task Force TOR.

## Paragraph 7

We recommend that toxins and peptides would be more appropriately classified as biological hazards than chemical hazards.

## Paragraph 7

We recommend that this paragraph needs to be replaced with Paragraph 18 from the "Guidelines on Application of Risk Assessment" document (with our recommended amendments), so they are identical

## Paragraph 8

We would recommend introducing the terms "Transfer", Cross-Contamination and Carry-over (new definition) into the Definitions section, consistent with our recommendation for Document A.

We recommend the following addition to the end of the <u>Hazard</u> definition: <u>Based on the risk assessments</u> completed to-date, physical agents are not known to be a hazard reasonably likely to cause an adverse risk to humans; but rather may cause a risk to animal health, which is outside the scope of this TOR.

We recommend the following rewording of the definition of <u>CODEX maximum level (ML)</u>: The maximum concentration of a pesticide contaminant in a food <u>feed</u> or feed <u>ingredient</u> <del>commodity</del> ...

We recommend the definition of <u>As low as reasonably achievable (ALARA)</u> should be deleted because this term is used in risk management (which is outside the TOR), but not risk assessment and is not scientific based.

#### Paragraph 12

**General comment:** We need a better explanation of the purpose of this flowchart and tables, including how they would be used in the risk assessment process. If appropriate for this document, we recommend a more detailed explanation be added on how to use them.

We also recommend correcting the sentence as follows: "Figure 1 in this document provides a schematic flowchart which outlines the conditions under which the major feed hazards may be expected to occur."

## Paragraph 20

We recommend the following rewording: Prioritization in terms of effects on human health, depends crucially on rates of transfer from feed to food ("earry-over", typically expressed as a transfer coefficient)

#### Paragraph 22

We recommend the following rewording: Contaminated feed may represent a n-important route of exposure ...... human pathogenicity are typically strain-specific. It should be noted that the FAO Expert Consultation found that there is little scientific information available about 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.

#### Paragraph 24

We recommend the following rewording: ... Some serotypes of Escherichia coli, for example E. coli 0157, have been associated with human illness, and may contaminate animal feed and/or edible products via feeal contamination. The risk of such contamination ... - E-coli 0157 contamination of meat is topical contamination at slaughter and fecal contamination of food is outside the TOR for this Task Force.

## Paragraph 27

WE recommend the paragraph be reworded as follows: Some animal endoparasites are human health hazards and may be transmitted to animals via feed. Pastures, forages or other feedstuffs may be contaminated by eggs of *Taenia solium*, *Taenia saginata*, or *Toxoplasma gondii* resulting in infections in animals that may be transmitted to humans via consumption of undercooked animal products. Animal feeds that include uncooked muscle tissues containing cysts of *Trichinella* or *Toxoplasma* could result in animal infections that could subsequently be transmitted to humans via consumption of undercooked animal products. Methods for on-farm prevention of such infections are giving in the OIE Terrestrial Animal Health Code, etc. . . . .

Rationale: this provides more accurate reflection of the life cycles and epidemiology of the endoparasites cited. *Echinococcus* is excluded from this description since although contaminated pastures may cause animal infection; humans acquire *Echinococcus* infections only from ingestion of eggs, not from ingestion of larval stages in foods of animal origin.

#### Paragraph 28

We recommend the following rewording: "the possibility of such contamination can be minimized by practicing good food <a href="https://www.hygiene">hygiene</a>, including food heating."

## Paragraphs 42 & 43

**WE recommend deleting both paragraphs:** As stated, bacterial toxins are not a hazard transferred from feed to food and there is no data to support this as a hazard reasonably likely to occur, and the paragraph statements are not entirely accurate.

## Paragraph 49:

We would recommend the following addition to this paragraph: "The scientific data to-date demonstrate that dioxins from man-made sources have diminished considerably in developed countries and hence in feed and feed ingredients. The very few events of dioxin in feed have either been fraudulent instances of intentional adulteration, naturally occurring in very unusual and rare deposits or in a couple of instances manufactured by processes not well understood (also very rare). Testing by both the EU and the US FDA have demonstrated very, very low levels on rare occasions in feed and feed ingredients. The overwhelming majority fall well below the tolerance levels established by the EU. However, implementing appropriate controls for dioxins in feed represents an important step towards reducing dioxins in the food chain."

## Paragraph 50

We recommend this paragraph be deleted: because dioxins are not hazards reasonably likely to occur in feed, except where there has been fraudulent practices involved.

"Dioxins accumulate in fat to a high degree" - Dioxin does bioaccumulate in adipose since it is lipophillic; however, there is a very large body of data in the U.S. and in Europe, indicating that high levels of dioxin do NOT exist in lipid-containing foods, dioxin arising from animal feed. Animal feed does not require dioxin control, because elevated dioxin in food is the rare exception, only identified under the very low limits imposed by the EU. Codex has not established dioxin MRLs for food or feed.

## Feed Hazard List - 29. Prions

**We recommend** reference be made to the relevant Risk assessment guidance in the OIE Terrestrial Animal Health Code

## Feed Hazard List - 57.

**Europe:** Antibiotic residues from ethanol production (sugarcane) have also been found in yeast culture used in the process which were then sold as deactivated, dehydrated protein feed source.

## Paragraph 62

We recommend: that this paragraph be expanded to provide more explanation on how to use the flowchart and tables in the risk assessment process. We also recommend that this flowchart and tables need to undergo an in-depth review: the current identification of hazards in feed components and factors affecting presence of hazards as well as sources of relevant hazards do not reflect correctly evidence obtained by private sector feed safety risk assessment and public rapid alert systems. More attention needs to be given to feed ingredient manufacturing processes as source of hazards both from food industry and non-food industries, like biofuels, the oleochemical and chemical sector. Particular attention should be given to certain surplus food recycling processes (drying). We also would ask CAC to provide clarification on who will be mandated at CODEX level to update, i.e. review these tables, once finalized by the Task Force, in the light of new scientific evidence and Rapid alert (INFOSAN) information on emerging feed safety risks.

## Figure 1:

We recommend that this chart needs to be reviewed and edited for technical accuracy. We can provide several examples of what we feel are inaccuracies or changes needed in the table.

## INTERNATIONAL POULTRY COUNCIL (IPC)

To the Proposed Draft Prioritised list of hazards in feed (at Step 3 of the Procedure) prepared by Switzerland please find below the (ii) specific comments which we would like to be considered in the final draft:

#### (ii) Specific Comments:

§ 20. 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.

Do we have a common understanding on case-by-case basis or would be a further explanation appropriate?

§ 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.

Is an explanation needed, what is meant by 'on a case-by-case basis'?

Can the correlation between contaminated feed and infected livestock only be established on a case-by-case basis?

Can't be an estimate used? 2

It gives the impression that the potential correlation is denied and has to be proven every time again and that the feed industry may use this as a hide behind?

§ 34. Lead may occur in contaminated soil, lead paints, water from lead-containing plumbing systems, and also as a contaminant in mineral supplements. 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.

Why are dioxins (PCBs) and organochlorine pesticides not mentioned? These substances are a hazard in feed with reference to dioxin cases linked to feed and the existence of a code of practice for the prevention and reduction of dioxin.

§57. 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)<sup>4</sup>.

Is this unintentional or intentional? How this practice relates to the guidance on responsible and prudent use of antimicrobial agents?

TABLE 3: SOURCES OF RELEVANT HAZARDS, § 100. Eggs, poultry products (Salmonella), milk and milk products (Brucella, Listeria monocytogenes).

Why are other animal products as pork and beef not mentioned since they can also contain Salmonella?