CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4 **CX/AF 12/6/4 Add.1**
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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 GUIDELINES ON APPLICATION OF RISK ASSESSMENT FOR FEED

Comments at Step 3 of:

Australia, Brazil, Canada, Colombia, Costa Rica, European Union, Iran, Japan, New Zealand, Philippines, the United States of America and International Feed Industry Federation (IFIF)[1]

AUSTRALIA

General comments:

Australia is pleased to submit the following comments on CX/AF 12/6/4 Proposed draft Guidelines on application of risk assessment for feed.

We congratulate the drafters from Switzerland for the improvements made to the document.

Comments on paragraphs:

Paragraph	Comments
25	The purpose and intent of the text in square brackets is unclear. Australia requests further clarification or that the text be deleted. [Generally, the process of assessing exposure as part of a feed risk assessment is practically more achievable than a hazard assessment.]

BRAZIL

GENERAL COMMENTS

Brazil congratulates the Codex Task Force on Animal Feeding for providing the new drafts and would like to thank for the opportunity to submit its comments. Brazil considers that the revised document has improved and supports the recommendations in general. Brazil also suggests including a list of abbreviations as the previous document.

SPECIFIC COMMENTS

We realize some confusion regarding the definition and the use of the terms Feed and Feed Ingredients throughout the document.

Appendix I

SCOPE

4. The scope of these guidelines is to provide guidance on risk assessment methods for government bodies (member countries and regional authorities) that need to conduct risk assessments for **feed and** feed ingredients including feed additives and water as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 54/2004).

Rationale: The risk assessment applies only to the feed ingredients (including additives and water), or to feed in a generic way.

[1] These comments have been addressed by Switzerland in the revised version of Proposed draft Guidelines on Application of Risk Analysis to Feed (CX/AF 12/6/4 Add.2), circulated for comments at Step 3 in November 2011.

5. These guidelines are applicable to all hazards in the feed of food-producing animals. "Hazard" refers to any undesirable **agent** ~~substance~~ which adversely affects 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

~~**Animal Food:** see Feed.~~

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

~~**Contaminant:** Aany 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.~~[6]

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 nº 9".

Feed additive: Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which 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.)~~[10].

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.

PRINCIPLES OF RISK ASSESSMENT

14. .....These expert groups assess hazard and exposure to establish the amount of a given hazard which may ~~safely~~ **acceptably** be present in a given food.

Rationale: Introduce the concept of acceptability, once in some cases of contaminants you have to accept some risk that you can't avoid.

25. The fundamental activities in exposure assessment should include: (a) clear depiction or drawing of the exposure pathway; (b) detailing the necessary data requirements based on the pathway; (c) obtaining the necessary data, and (d) summarising the data. In feed risk assessment, this step focuses on estimating the concentration of a given hazard which is likely to appear in food after feeding it to food-producing animals. [Generally, the process of assessing exposure as part of a feed risk assessment is practically more achievable than a hazard **characterization** ~~assessment~~.]

Rationale: Change in the order for better understanding.

29. The level of detail of the exposure assessment, and consequently the data and/or model used, need to be decided on a case by case basis. If a low tier conservative estimate results in 'no concern', then there is no need for a sophisticated approach. On the other hand, when exposure via various routes and various sources needs to be assessed, this might require high tier models and high quality data. In the ideal case, the high tier exposure assessment results in exposure values that are close to realistic levels.

Rationale: We would like to ask for clarification about the terms low tier and high tier models.

CONDUCT OF FEED RISK ASSESSMENT

39. In many cases, insufficient data will be available for quantitative risk assessment of feed ~~or feed components~~. In these cases, a semi-quantitative approach may be the best option. This guidance presents an example of a semi-quantitative feed risk assessment. It is not intended to imply that this is the preferred approach but merely to illustrate ways in which semi-quantitative data can be handled if limited data are available.

Rationale: According to the feed definition, its components are also included in feed.

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. We recognize that the draft text provides a general path forward for using current risk assessment methodology as a basis for the application of risk assessment to feed purposes. We believe, however, further work is

required to make this guidance document more specific for feed risk assessment and to clarify its application to feed situations. In addition, more guidance on how to establish transfer factors of hazards to foods of animal origin, and on conducting an appropriate exposure assessment for animals.

(ii) Comments on paragraphs:

Paragraph	Comments
BACKGROUND	
Para 2.	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.
APPENDIX 1	
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 food-producing 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 to be 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.
Definition Para 8. Exposure Assessment	Canada feels that the definition used here should relate more closely to those points germane to an exposure assessment for feed, rather than the human exposure and suggests the wording should be consistent with that in paragraph 26 of this document. **In a feed risk assessment, exposure assessment focuses on estimating the concentration of a given hazard likely to carry-over from feed to food. This must take into account the common animal feeding practices, including the duration of feeding and the amount fed over a specified period of time.**
Definition Para 8. UndesirableSubstances	This definition references Codex document CAC/RCP 54-2004 Code of Practice on Good Animal Feeding, however, the it has been modified from the original text. Canada suggests that the definition should be consistent with that defined in the Code of Practice.
Para 11.	ML is mentioned but not defined. The definition from the Prioritised List of Hazards document should be incorporated.
Para 16.	Canada suggests the addition of a statement in the 5th lines as follows: ...from food producing animals. **National standards or Codex standards (MRLs) in foods of animal origin serve as a useful point of departure for the feed risk assessment.** ... Information on carry-over ~~transfer rates~~ from feed to food .....
Para 20.	Canada suggests the following be added to the end of this paragraph or as a separate paragraph**. Special consideration during the hazard identification step should be given to the source of the feed, and the potential for the introduction of contaminants during manufacturing. Many feed ingredients are produced as by-products from other production processes, e.g., distillers grains from the production of biofuel, food processing wastes, minerals recouped from industrial processes, etc. Additionally, sources with inputs that are neither food-grade nor feed-grade may introduce contamanints at a level of concern into the final ingredient.**
Para 21.	Canada suggests the following modification of the last sentence, as follows. Feed risk assessment **utilizes the same endpoints as used to conduct the** ~~considers the same hazards as~~ human risk assessment. **These include the standard battery of toxicological assays such as the LD_{50}, short term or chronic toxicity tests. The most relevant testing being those that are conducted using the repeat dose oral route of exposure, as this parallels the more typical delivery of the feed.**

Paragraph	Comments
Para 25-6.	Canada considers the exposure assessment for the feed risk assessment as a two step approach. The first step involves estimating exposure to the animal as determined by the prevalance and concentration of the hazard in the daily ration of the feed or feed ingredient, feed consumption data and consideration of any processing effects which may minimize the hazard. Carry-over is then used to determine the concentration of the hazard in the resultant foods of animal origin. The second step involves estimating the exposure to humans via the ingestion of the hazard as a residue in foods of animal origin. The human exposure assessment has usually been completed during a food safety risk assessment, and the conclusions from this assessment may be used as point of departure for the feed risk assessment and risk management options. The Task Force may consider some of the text on exposure assessments as outlined in **the Report of the FAO/WHO Expert Meeting: Animal Feed Impact on Food Safety, Rome 2008, as a basis for discussion** "The exposure assessment is the step in which the concentration, frequency and duration of ... animal exposure is measured and estimated. Exposures will differ as a result of the formulation of the product, the use patterns of the product, and the exposure scenarios. Whether the ingredient has the potential to enter the food chain will depend on the rate and degree of absorption and how the ingredient is distributed, metabolized, excreted or bio-accumulated in the animal. . When there is an indication that bioaccumulation may result in an unacceptable residue level in foods of animal origin, direct feeding trials in livestock at appropriate levels are recommended to assess the potential carry-over from feed to food of animal origin. Residue studies should be conducted for the parent compound and its possible metabolites. In the case of microbial contaminants, studies on the transfer of potential pathogens from animals to food of animal origin may be needed. However, it is often not possible to conduct direct feeding trials to account for all feeding situations (e.g., multiple species, different sexes and different stages in animals' lives. Therefore, toxicokinetic or other models that can predict the transfer of potiential residues or pathogens from feed to foods may be used. "
Para 26.	The second bullet in this paragraph is very important to the risk assessment for feed as it informs both the hazard and exposure assessments. A list of physico-chemical characteristics of hazards with the ability to carry-over to foods of animal origin should be further defined in this paragraph. The list should include as a minimum: pKa/pKb, log Kow, water solubility, and thermostability.
Para 28.	Canada suggests the following addition to the end of the sentence as follows: .... should be considered **during the human exposure assessment**.
Para 34.	Canada suggests an additional bullet could be added to this paragraph underscoring the importance of defining uncertainty in the risk assessment, as follows: **The determination of uncertainty related to the data used throughout the risk assessment process should be documented in the risk assessment.**
Para 39.	Canada suggests that if insufficient data is available for a quantitative risk assessment, it may still be possible to conduct a risk assessment by over-estimating consumption rates in animals, and the carry-over values. Employing toxicokinetic or other models, if available, are valuable tools to employ in the absence of all data.
Para 40.	Canada notes that this method will not allow for a risk assessment, but rather would be useful for priortizing known hazards in feed and food for further consideration. The example cannot be used to establish standards for safe levels in feed..

COLOMBIA

Colombia tiene el agrado de presentar los siguientes comentarios al documento **ANTEPROYECTO PARA LAS DIRECTRICES SOBRE LA APLICACIÓN DE LA EVALUACIÓN DE RIESGOS EN LOS PIENSOS (Trámite 3 del Procedimiento)** del procedimiento, enviado por el secretariado de la comisión del codex alimentarius**.**

En adelante tomamos como referencia el documento anexo al CX/AF 12/6/4 en versión en español.

ANTENCEDENTES

3. En este punto se referencia el ALINORM 10/33/REP, Apéndice viii, sin embargo a nuestro parecer el siguiente párrafo contiene un error al indicar que: "*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. "*

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.

Ámbito de aplicación

7. Ya que las normas del Codex (*Principios de Aplicación Práctica para el Análisis de Riesgos Aplicables en el Marco del Codex Alimentarius*) y otras directrices reconocidas internacionalmente cubren los riesgos a la salud humana vinculados con peligros en alimentos, estas directrices para la evaluación de riesgos se concentran en evaluar el riesgo de transmisión por medio del pienso a los *alimentos de origen animal* de un determinado peligro para la salud humana

Determinación del peligro

18. Entre los peligros presentes en el pienso se incluyen: agentes biológicos (virus, bacterias, ~~endoparásitos~~ *parásitos*, priones) y ….. y plaguicidas ~~organoclorados …..~~

Se solicita ampliar el término a parásitos, teniendo en cuenta que el ciclo evolutivo de los mismos se desarrolla no solamente a nivel interno. En cuanto a plaguicidas al considerar su presencia como contaminante se solicita no excluir otro tipo de compuestos al establecer solamente como contaminante a plaguicidas organoclorados.

evaluación de la exposición

26. Las características físico-químicas del peligro, por ejemplo, estabilidad y solubilidad en el agua y en los lípidos. Evaluación de los componentes del pienso y de las ***características físico-químicas de los componentes del mismo*** y la evaluación de las condiciones y mecanismo a través de los cuales el peligro puede contaminar al pienso.

Se solicita adicionar la expresión las *características físico-químicas de los componentes del mismo* al considerarse que la transferencia de contaminantes en los piensos está sujeta a las características del mismo y a la capacidad de transferencia del peligro del pienso a los alimentos.

COSTA RICA

Costa Rica desea expresar su agradecimiento a Suiza por la elaboración de este documento, sin embargo no tiene comentarios.

EUROPEAN UNION

The European Union (EU) would like to congratulate Switzerland for the excellent work with this well structured, comprehensive and carefully drafted document. The document is a very good basis for discussion. The EU would like to submit the following comments:

(i) General comments

The EU would propose that the concept of hazard as defined in the Codex Alimentarius is used throughout the text. This notion includes chemical, biological and physical hazards.

The text should make more emphasis in indicating that quantitative methods should be used preferably over semi-quantitative methods. The EU notes that quite a large part of the document describes how to perform a semi-quantitative risk assessment. The EU would prefer that more attention is paid to quantitative risk assessment in the document as data needed to perform such a quantitative risk assessment could well be available in many occasions. Only in case such data cannot be provided for, or are not of sufficient quality, national governments should consider a semi-quantitative risk assessment. When the semi-quantitative methods are used as an alternative it should be appropriately emphasized that the results are less reliable.

(ii) Specific comments

The EU comments below are listed according to the paragraphs and the headings used in the Codex draft document.

Heading: Background

Although no comments are requested on 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:

"1. These guidelines 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 transfer through animal feed to food."

Justification: To align the text with the Codex definition of hazard.

Heading: Scope

p. 4: Proposed redrafting following more closely the text of *Code of Practice of Good Animal Feeding*.

"The scope of these guidelines is to provide guidance on risk assessment methods for government bodies (member countries and regional authorities) that need to conduct risk assessments for feed (feedingstuffs) or feed ingredients, including feed additives, as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 54/2004)."

p. 5 could be replaced by:

"5. These guidelines are applicable to all hazards in the feed of food-producing animals. "Hazard" (see also definition below) refers to any biological, chemical or physical agent which adversely affects human health.

5a. (**new**) Effects on animal health which have no impact on food safety are not considered in this document as they do not fall under the scope of Codex Alimentarius.

Issues of animal health and welfare other than food safety related are not considered in this document."

The **justification** is that the first sentence in p. 5 restricts the hazards only to substances and may not be entirely aligned with the Codex definition of hazard .The other sentence relates to another aspect (demarcating the hazards to food safety related issues) and that is why it is proposed to be put in a separate paragraph. This last sentence also appears in the scope of the *Code of Good Animal Feeding* (CAC/RCP 54 2004).

Regarding the risks relating to antimicrobial resistance it would be desirable to make a reference here in the scope to the recently adopted Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77/2011[2].

Heading: Definitions

All definitions which are in line with existing Codex definitions should be clearly indicated. The EU would like to suggest marking more clearly when there are modifications to these existing definitions, for instance by using bold text, in the draft documents. Also the EU would like to indicate that the definition of “contaminant” is currently under discussion in the electronic working group on Risk Analysis Principles of the CCCF.

p. 8: Definition of carry over. It is proposed to modify the term to "Transfer from feed to food". The definition could be transfer of a hazardous substance from feed of a food producing animal to an edible product of the animal (usually expressed as a transfer coefficient or transfer rate).

Justification: Carry over is a broad ambiguous term and it should be specified to which situation it is referred to as this is mentioned in the proposed alternative definition.

p. 8: Definition of contaminant: Typo: "Aany" should be replaced by "Any".

p.8: The definition of Control is taken from the document "Principles and guidelines for the conduct of microbiological risk assessment CAC/GL-30 (1999)". In that document this definition appears only as a footnote, as 'control' is mentioned in the definition of 'risk management'. However, the definition of 'risk management' in the Procedural Manual does not appear to contain such footnote. In addition, the reference in footnote 7 to the definition of control is the link to the above mentioned document ("Principles and guidelines for the conduct of microbiological risk assessment CAC/GL-30 (1999)") but it links to the French version, CXG_030f, not to the English version CXG_030e.

p. 8: Definition of Exposure assessment. It should be clearly indicated that only the first sentence is the definition taken from the Procedural Manual, possibly by advancing the footnote reference to the end of the first sentence, rather than putting it at the end of the paragraph. The second sentence is specific to this document. In addition in this second sentence the term "edible product" should be replaced with "edible product of animal origin".

The proposal would therefore read as follows:

"Exposure assessment: In human risk assessment, "the qualitative and/or quantitative evaluation of the likely human intake of biological, chemical or physical agent via food as well as exposures from other sources if relevant"[9 3]. In feed risk assessment, it may also refer to evaluation of the likely amount of a biological, chemical or physical agent in an edible product of animal origin, given its presence in a feed ingredient."

p. 8: Definition of edible products. It should be stated that the definition refers to "edible products of animal origin".

p. 8: Definition of Hazard. To use the definition in the 20th Edition of the Codex Procedural Manual and make the reference to it.

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[2] http://www.codexalimentarius.org/standards/list-of-standards/en/?provide=standards&orderField=fullReference&sort=asc&num1=CAC/GL

[3] *Codex Alimentarius Commission: Procedural Manual*

p. 8: Definition of undesirable substances. This definition is not identical to the one established in the Code of Practice of Good Animal Feeding but the reference is made to that text. It should either be completed with the missing parts or provided an explanation for the justification of the difference.

p. 8: Definitions. Addition of a definition. As the term "Codex Maximum Level" is used in this document, it is proposed to add this definition. It is already included in the document CX/AF 12/6/5.

Heading: Principles of Risk assessment

Heading: Feed Risk assessment procedure

Heading: Hazard identification

p.15: The EU suggests that the third sentence should read: "Risk assessors should review scientific literature from a range of sources and …."

Justification: This should minimize the risk that bias from one particular source should unfairly influence the assessment.

p. 16: For clarification the last sentence should be replaced with "Information on carry-over transfer rates of the different specific hazards from feed to food is particularly important."

p. 17: "Identification of human hazards in feed should be based on Codex standards, and as necessary scientific literature and on published data from government agencies, the feed and food industries, and relevant international organizations such as FAO[2,4]."

Could be replaced with:

"17. Identification of human hazards in feed should be based on Codex standards, and as necessary scientific literature, published data from government agencies, the feed and food industries, relevant international organizations such as FAO 2,4 [4] and international systems of exchange of information such as INFOSAN."

p.18: Physical hazards should also be mentioned under this point. Therefore, the sentence could be replaced with:

"18. Hazards in feed include biological agents (viruses, bacteria, endoparasites, prions), chemicals (toxins, radionuclides, "heavy metals", organic chemicals such as dioxins and organochlorine pesticides and residues of veterinary drugs, pesticides and additives) and physical agents."

p. 20: The term "feed components" should be replaced with "feed ingredients".

Heading: Hazard characterization

p. 21: The last sentence "Feed risk assessment considers the same hazards as human risk assessment" is unclear. The sentence relates to the first sentence and should in the same way explain what can be expected from a hazard characterization in animal feed risk assessment.

ps. 21 to 24: Here and also in several of the following sections, the draft text seems mainly focusing on chemical hazards while the document is about all hazards, therefore biological, chemical and physical hazards. For example in paragraph 22, last sentence "contaminant" should be replaced by "hazard". In paragraph 40 (semi quantitative risk assessment, point b), where it is mentioned "expected levels of undesirable substances" it should probably be "expected levels of hazards", assuming that the biological agents are not of the type that multiply.

p. 23: Replace "Codex Standards" with "Codex standards". In addition, it may be worth considering rather than making a general reference in the footnote to the website of the Codex (*www.codexalimentarius.org*) to be more specific, and make also reference in particular to the Codex documents that should be read in conjunction with this document mentioned in p. 3 in the Introduction.

Heading: Exposure assessment

p. 25: Clarify status and meaning of the sentence in square brackets at the end in p. 25.

p. 26: In the fourth indent the word "cumulation" could probably be replaced with "accumulation".

p. 27: First sentence – the term "the undesirable substance" is not included in the CODEX STAN 193-1995 and could here be replaced with "hazard".

p 27: It could be inserted a new sentence before the final sentence: "Care should be taken to gather data from a variety of sources to avoid bias."

Justification: This should minimize the risk that bias from one particular source should unfairly influence the assessment.

[4] Footnotes as in original text.

p. 29: The references to "low tier" and "high tier" methods should be explained as it is unclear what is meant precisely.

Heading: Risk characterization

p. 34: “Risk assessors should ensure that risk managers understand the impact of these aspects in the risk characterization”, seems to be repeated in p. 35.

p. 34: The sentence should end with "are:" rather than with "may be:"

p. 34: First indent. The examples in brackets (e.g. milk, meat) should also explicitly mention eggs and therefore be replaced with (e.g. milk, eggs, meat).

p. 35: There could be a new separate point on risk communication.

Heading: Conduct of Feed Risk Assessment

p. 39: Replace this paragraph with the following 3 paragraphs:

"39. In many cases, insufficient data will be available for a robust quantitative risk assessment of feed or feed ~~components~~ ingredients. In these cases, a semi-quantitative approach may be an alternative. However a semi-quantitative risk assessment often provides a limited basis for risk managers to define risk-proportionate measures to control the hazard.

39 a. Semi-quantitative risk assessment may be useful for certain situation as such as the approximate ranking or risks.

39 b. This guidance presents below an example of a semi-quantitative feed risk assessment. It is not intended to imply that this is the preferred approach but merely to illustrate ways in which semi-quantitative data can be handled if limited data are available. "

Justification: It is important to explore in what situations a semi-quantitative risk assessment may be useful and when not.

Heading: Suggested procedure for semi-quantitative risk assessment

There are a number of points where the proposed procedure is not clear.

p. 37. There is a mention of a given "threshold". However, it is not specified what it is. It might be a concentration level of the hazard in feed, a concentration level of the hazard in the animal derived food, or it might be also a total intake amount by the animal or the human. May be parts of the explanations given in p. 42 for "threshold level" could be included already in p. 37 or under the heading "suggested procedure", but not within an "example".

ps. 41 and 42: Indicate that the threshold levels could be maximum concentrations or tolerable intake levels. The text should use clearer terminology. It is not the same thing to compare levels of presence or occurrence in food with maximum or guidance concentrations than to compare levels of presence with intakes as, in the latter case, there is a need to use a conversion to take into account the consumption (and other possible sources of the same hazard from other foods of animal origin or from other foods). Intakes and concentrations are measured in different units.

ps. 42 and 43 mention "threshold exposure levels", which are seemingly different than the "threshold levels".

It is unclear in the section examples if what is compared are concentration levels in food with exposure threshold levels.

A threshold level should refer to a maximum level (feed and food) and a threshold exposure level should refer to a tolerable intake.

In an attempt to clarify the text, the following paragraph:

Example of exposure assessment scoring with reference to a threshold level

High	Significant probability that the concentration in food will exceed threshold level.
Moderate	Some probability that concentration in food will exceed threshold level.
Negligible	Virtually no probability that the concentration of hazard in food will exceed threshold level

could be replaced with:

Example of exposure assessment scoring with reference to an exposure threshold level

High	Significant probability that human exposure to a hazard in animal derived food will exceed exposure threshold level.
Moderate	Some probability that human exposure to a hazard in animal derived food will exceed exposure threshold level.

Negligible Virtually no probability that human exposure to a hazard in animal derived food will exceed exposure threshold level.

Or /and

Example of exposure assessment scoring with reference to a threshold level in food

High Significant probability that a hazard in animal derived food will exceed threshold level.

Moderate Some probability that a hazard in animal derived food will exceed threshold level.

Negligible Virtually no probability that a hazard in animal derived food will exceed threshold level.

The example parts from ps. 40 to 46 are illustrative, but might be placed in a separate annex. As it stands in the flow of the document, p. 46 and also ps. 47 – 49 look detached from the rest of the document.

It might be worth to test the procedure with three examples of real hazards, possibly taken from the other document. One example could be one for which there are Codex Maximum Levels in feed, another for which there are Codex Maximum Levels in food but not in feed, and another for which there are only acceptable (ADI) or tolerable intakes (such as TDI, PTWI) established by JECFA or similar expert committees, in order to see if the process and the terminology is sufficiently clear. One simple example of the second case could be lead. It could be included in the text, possibly in an annex, illustrating the methodology. It could be considered to use for the third case the example of cadmium and for the first case melamine.

There should also be one example of a quantitative risk assessment. Some of the ones mentioned above can in fact be used as examples of quantitative risk assessment. These guidelines could refer to relevant Codex documents or literature in order to clarify the principle of semi-quantitative risk assessment.

Heading: Example of risk characterisation output

p. 45 Replace the current wording:

"45. The risk characterization output example of a food safety risk assessment from feed is summarized in Table 1. This example provides a clear range of risk assessment results, from “negligible risk” to “very high risk” ".

IRAN

Iran approve this document

JAPAN

(i) General comments:

Japan would like to thank Switzerland for preparing the draft guidelines on application of risk assessment for feed. The draft guidelines describe the risk assessment methods in line with the existing Codex documents and Japan supports the draft. To refine the draft, we would like to propose the following modifications.

(ii) Comments on paragraphs:

Paragraph	Comments
3	“*Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011)” should be added in the list of reference guidelines since the risk analysis of antimicrobial resistant microorganisms and determinants in feed is covered by these guidelines.
8	(Proposal) “Hazard: A biological or chemical agent in, or condition of, feed or food with the potential to cause an adverse human health effect. In case of feed risk assessment, a hazard which has the potential to transfer from feed to foods of animal origin should be considered.” (Rationale) To clarify that a hazard which does not transfer from feed to food is not included in the scope of the guidelines. With regard to the definition of “Risk”, the meaning of the last word “(proc)” is not clear. If the“(proc)” stands for “*Procedural Manual* ”, it would be better to simply add the footnote to make it consistent with other description. The reference of the definitions “Dose-response assessment”and “Risk” should be modified from “ 8”(adapted from Working Principles For Risk Analysis For Food Safety For Application By Governments) to “6” (adapted from the *Procedural Manual)*, as those definitions are adapted from the *Procedural Manual*.
9	(Proposal) Figure: Structure of Risk Analysis

Paragraph	Comments
	Risk management • Pleliminary risk management activities~~Risk evaluation~~ • Evaluation of risk management options~~Option assessment~~ • Implementation of risk management option~~Option implementation~~ • Monitoring & review (Rationale) To ensure consistency with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.(p 108, Paragraph 28, Procedural Manual 20th edition)
27	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.

NEW ZEALAND

General comments

New Zealand is in general agreement with the structure and content of the draft guidelines as set out in Appendix 1 of CX/AF 12/6/4. New Zealand does however have significant reservations about the inclusion of reference to semi quantitative risk assessment. We believe that the concept of semi quantitative risk assessment is seriously flawed and is of questionable value in a document that is intended to provide guidance to members on how to assess food safety related risks arising from feed. New Zealand also has a few other suggestions for amendment which are set out in the format requested

Para 3- New Zealand suggests that reference could be made to the principles and methods for the risk assessment of chemicals in food 2009 developed under the auspices of WHO International Programme on Chemical Safety Environmental Health Criteria 240.

Para 13- We recommend deletion of the term semi quantitative in the second sentence as follows:

The selection of qualitative, ~~semi quantitative~~ or quantitative approach should be made……

***Rationale*:** for the reasons set out in the general comments section

Para 18- New Zealand suggests that it would be useful to include another class of toxins, namely natural toxins in plants and animals. We suggest amending the text in second parenthesis as follows:

(~~toxins~~ natural toxins and environmental contaminants including toxic elements……..)

***Rationale*:** to ensure that the text covers the various classes of toxins.

Para 38: Suggest amending second sentence as follows:

In such cases, transparently documented decisions have to be made on how to complete the risk assessment process ~~with semi- quantitative~~ qualitatively and with the careful use of uncertainty factors.

***Rationale*:** changes proposed are in line with above comments on the use of semi quantitative methods.

Para 39: Recommend amending this para as follows:

In many cases, insufficient data will be available for quantitative risk assessment of feed or feed components. In such cases, a ~~semi quantitative~~ qualitative approach may be the best option. ~~This guidance presents an example of a semi-quantitative feed risk assessment. It is not intended to imply that this is the preferred approach but merely to illustrated ways in which semi-quantitative data can be handled if limited data are available.~~

***Rationale*:** While semi quantitative methods are superficially appealing, there are, however significant problems as the numbers are often assigned and combined arbitrarily without adequate transparency. Inconsistent outcomes frequently arise and conclusions are reached that may be statistically and logically incorrect. These methods do not offer any advantages over a well researched, transparent, peer reviewed qualitative approach.

Paras 40-46: New Zealand suggests deletion of these paras relating to semi quantitative risk assessment

***Rationale*:** For the reasons explained above in relation to para 39.

PHILIPPINES

(i) General comments:

Philippines appreciates the opportunity to provide comments on the "Proposed Draft Guidelines on Application of Risk Assessment for 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 steps that would be beneficial for the risk assessment application on feed. However, aimed at strengthening the proposed guidelines, we do have some specific comments below.

(ii) Comments on paragraphs:

Paragraph	Comments
1	Insert "hazardous biological and chemical agents" before "in animal feed" to read as follows: These guidelines provide a structured framework based on existing Codex risk assessment methods to address the risks to human health associated with the presence **of hazardous biological and chemical agents** in animal feed, and **its** ~~the~~ transmission through animal feed to food~~., of hazardous biological and chemical agents.~~ Rationale: This is to make the text more comprehensible.
2	Editorial comment Insert the word "and" between "feed hazards" and "to facilitate" to read as follows: The purpose of these guidelines is to provide practical guidance on how to assess risks associated with feed hazards~~,~~ **and** to facilitate international comparability of feed risk assessments.
3	Editorial comment "CCVDF" should perhaps be "CCRVDF" - Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods (CC**R**VDF); and
6	Editorial comment "is" should be "are" after "pesticides" to read as follows: These guidelines consider exposure of food-producing animals only via feed, i.e. by the oral route. Dermal and inhalation exposure to hazards such as environmental contaminants, topical veterinary drugs and pesticides ~~is~~ **are** not considered.
8	Editorial comment Delete "a" in "Aany" to read as follows: Contaminant: A~~a~~ny substance not intentionally added to feed or food, which is present in such feed or food as a result of the production
8	In the definition of "Exposure assessment", insert "it" before "may also refer to" to read as follows: In feed risk assessment, **it** may also refer to evaluation of the likely amount of a biological or chemical agent in an edible product, given its presence in a feed ingredient.
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
8	We recommend inclusion of a definition for "hazard identification" as defined by the Codex Procedural Manual since the term is repeatedly used in the document and is therefore important that the reader has a clear understanding of its meaning and should be read as follows: **Hazard identification: The identification of biological or chemical agents capable of causing adverse health effects and which may be present in a particular food or group of foods. [9]**
18	Editorial comment

Paragraph	Comments
	Delete "and" between "heavy metals" and "organic chemicals" to read as follows: Hazards in feed include biological agents (viruses, bacteria, endoparasites, prions) and chemicals (toxins, toxic elements such as radionuclides and "heavy metals", ~~and~~ organic chemicals such as dioxins and organochlorine pesticides**,** and also excessive levels of veterinary drugs, pesticides**,** and additives).
23	Change "inadequate" to "limited" to read as follows: Information on characterization of specific hazards is included in Codex Standards[15] and in the Codex General Standard for Contaminants and Toxins in Food and Feed, CODEX STAN 193-1995). If **limited** ~~inadequate~~ data are available to characterize a hazard in feed, it may be necessary to launch such activities at Codex level. Rationale: This is to make the text more comprehensible
26	Editorial comment Insert "ac" before "cumulation" and insert "and" after "(CODEX STAN 193-1995));" to read as follows: - The frequency and amount of feed eaten by the food-producing animal. Feeding specialists should be consulted for this information. For substances with a long half-life (due to slow metabolism and/or excretion), **ac**cumulation may occur even if the hazard is only ingested at long intervals. (For this reason, human Provisional Maximum Tolerable Intake of hazards is given per day, per week or per month, depending on the biological half-life of the hazard) (General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)); **and**
30	Editorial comment Delete "s" in "outputs" to read as follows: ..... The form that the risk characterization takes and the output~~s~~ it produces will vary from assessment to assessment as a function of the risk management request.
38	Insert "as much as possible" before "to reduce uncertainty" to read as follows: ~~As much~~ **H**~~h~~igh quality quantitative information ~~as possible~~ should be included **as much as possible** to reduce uncertainty and increase the reliability of the risk estimate. Rationale: This is to make the text more comprehensible.

UNITED STATES OF AMERICA

I. GENERAL COMMENTS

The United States of America (U.S.) appreciates the opportunity to comment on the *Proposed Draft Guidelines on Application of Risk Assessment for Feed.* The U.S. is supportive of the content of these Guidelines in terms of its overall approach, its focused scope, and adherence to the terms of reference and Codex mandate.

The U.S. proposes a few areas for revision. As a general comment, we note that there are multiple references to other organizations (e.g. footnotes 14, 16, 17) without a technical review for compatibility with Codex texts. Similarly, there are numerous references to other Codex text that need to be fact-checked to avoid confusion. 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 U.S. proposes the following revisions for the Task Force Committee's consideration:

INTRODUCTION

Paragraph 1: We recommend the following change to the first sentence:

"~~**These**~~ **This** guideline~~s~~.."

Rationale: This editorial change makes it clearer that the guideline directly refers to this proposed draft guideline on the application of risk assessment for feed.

Paragraph 3: We recommend inserting "Code of Practice on Good Animal Feeding to the top of the guideline reference list.

Rationale: This is the most relevant document to this guideline and therefore should be listed first.

SCOPE

Paragraph 6: We recommend deleting the last sentence:

> ~~Such unintentional environmental and human risk exposure may be minimized by appropriate hygiene measures~~.

Rationale: Unintentional environmental and human risk exposure is an issue outside the scope of this Task Force.

Paragraph 7: We recommend the following change:

> "As the risks to human health associated with hazards in food are already covered by existing Codex Standards (*Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius)* ~~internationally recognized guidelines~~, this guideline focuses on estimating the risk that a given **hazard to** human health ~~hazard~~ will be transferred from feed to food."

Rationale: We suggest that the phrase "internationally recognized guidelines" be deleted because it is too vague a reference. The revision to include "hazard to human health," is more consistent with the scope and terms of reference since this Task Force is focused on hazards to human health, not all human health hazards.

DEFINITIONS

Paragraph 8: We suggest correcting the following typographical error and inserting the following definitions:

> **Contaminant: A~~a~~ny substance**:

Rationale: This is a typographical error.

> **Exposure Assessment: The qualitative and/or quantitative evaluation of the likely human intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.**

Rationale: This definition should be retained as it is necessary for the explanation describing exposure assessment under paragraphs 25-29.

> **Transparent - Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgments, decisions, limitations and uncertainties of the expressed determination carefully and systematically stated, documented, and accessible for review.**

Rationale: This definition should be retained as it is necessary for the explanation describing the conduct of feed risk assessment under paragraphs 37-43.

> **~~Semi-quantitative risk assessment~~ Qualitative risk assessment:** A risk assessment based on data which, while forming an inadequate basis for numerical risk estimates, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties, permits risk ranking or separation into descriptive categories of risk.
>
> **All references to the term 'semi-quantitative' in this document should be replaced by 'qualitative.'**

Rationale: This definition should be referred to as a qualitative risk assessment for consistency with other Codex texts. This definition is referred to as 'qualitative' in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* CAC/GL-30 (1999), which is cited in this definition.

Paragraph 9: We suggest adding the following phrase to the last sentence:

> "Risk assessment considers hazard type and exposure; it forms a solid basis for adequate risk management and communication to reduce, eliminate or prevent risks, ~~and~~ enhance consumer protection and **promote fair practices in the food trade.** "

Rationale: The impact on trade should be taken into consideration in developing risk management options. This revision is also consistent with the risk management definition in the glossary of this guideline.

PRINCIPLES OF RISK ASSESSMENT

Paragraph 11: We suggest deleting this paragraph.

Rationale: Most of the references listed in this paragraph are also listed in paragraph 14. This revision avoids duplication.

Food risk assessment procedure

Paragraph 14: In the first sentence, we suggest inserting the following editorial change:

> "Food risk assessments are conducted **for use by** Codex,….."

Rationale: As currently drafted, the guideline inadvertently suggests that FAO/WHO actually carries out risk assessment at the request of industry directly. The following editorial change avoids this confusion.

Feed risk assessment procedure

Paragraph 15: We suggest the following changes:

> "Feed risk assessment is comprised of hazard identification, hazard characterization, exposure assessment, and a **risk characterization**."

Rationale: The first sentence on risk assessment omits the fourth element, risk characterization. Including this fourth element is consistent with the glossary definition of hazard identification.

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

> "The purpose of feed hazard identification is to **define** ~~describe~~ the hazard… from surveillance programs to identify the ~~physical~~, chemical.. "

Rationale: The word 'define' instead of 'describe' is a more accurate word choice. Removal of 'physical' is consistent with the Exposure Assessment definition, and physical hazards are not included in the prioritized list of hazards.

Paragraph 16: We suggest the following changes to the first and second sentence:

> "As there are existing Codex standards ~~internationally recognized guidelines~~ which consider human exposure to a given hazard in food."

Rationale: We suggest deleting this reference because it is too vague.

> "…document. ~~Instead~~, ~~r~~Risk assessment and risk characterization in this feed risk assessment guidance focus~~es~~ on the **degree to which** ~~estimated amount of a~~ given human health hazard which will be present in edible products from food-producing animals."

Rationale: These editorial changes more accurately reflect the function and characterization of a risk assessment and risk characterization. As currently drafted, this statement is too open-ended.

Hazard identification

Paragraph 18: We suggest the following redraft:

> "**Hazards in feed include biological agents (viruses, bacteria, endoparasites, 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 (and certain of their residues).** "

Rationale: This suggested redraft delineates more clearly the types of hazards. Tthis section should also be consistent with paragraph 7 of the *Draft Prioritised List of Hazards.*

Hazard characterization

Paragraph 21: We suggest that last sentence should be redrafted to read:

> ~~Feed risk assessment considers the same hazards as human risk assessment.~~ "Hazard characterization for feed is carried out in the same way as for food, and considers the same hazards as for food."

Rationale: This paragraph deals with risk characterization and points out that hazard characterization for feeds is done the same way as for foods. This revision more accurately reflects this purpose.

Paragraph 23: We suggest the following editorial changes:

> "If inadequate data are available to characterize a hazard in feed, it may be necessary to ~~launch~~ **undertake** such activities at a Codex **Committee**. "

Rationale: This a suggested editorial change.

> "A Member State can request action at a Codex **and/ or national** level."

Rationale: This would appropriately broaden the statement to apply to national levels.

> "A Member State can request action at the appropriate Codex ~~level~~ **Committee** and suggest feed-specific hazard data to be considered, usually compiling scientific data for consideration by the relevant scientific body such as JECFA." The appropriate Codex Committee is determined by its established scope and terms of reference.

Rationale: This revision is more specific in terms of the Codex procedure for referral of matters to other Committees.

Exposure assessment

Paragraph 25: We suggest the following change:

> "[Generally, the process of assessing exposure as part of a feed risk assessment is practically more achievable than a ~~hazard assessment~~ hazard characterization.]"

Rationale: We agree with the statement and propose removing the brackets with the above editorial change.

Paragraph 26: We suggest the following changes:

> "In the absence of this, estimates of ~~food levels~~ **levels in food** may be obtained from monitoring data on feel levels combined with carry-over models to enable estimates of corresponding ~~food levels~~ **levels in food**."

Rationale: This rephrasing is more precise than what is currently drafted.

Paragraphs 28 and 29: We suggest the following deletion and replacement:

28. ~~The various potential sources of a given hazard in food should be considered.~~

~~29. The level of detail of the exposure assessment, and consequently the data and/or model used, need to be decided on a case by case basis. If a low tier conservative estimate results in 'no concern', then there is no need for a sophisticated approach. On the other hand, when exposure via various routes and various sources needs to be assessed, this might require high tier models and high quality data. In the ideal case, the high tier exposure assessment results in exposure values that are close to realistic levels.~~

28. Potential sources and routes of a given hazard in food should be considered as the level of detail of the exposure assessment, and consequently the data and/or model used, are influenced by this information.

Rationale: The use of the terms 'low-tier 'and 'high-tier'are not well understood nor defined within the document.

Risk characterization

Paragraph 31: Suggested editorial change:

> "… have been defined in the ~~commissioning~~ **initiation** of a feed risk assessment.."

Rationale: This is an editorial suggestion.

Paragraph 32: Suggested changes:

> "In a feed risk assessment the ~~plausible~~ endpoint is the likelihood that a given hazard in feed will be transferred to food in a concentration which, for example, exceeds its Codex maximum level or maximum level or maximum residue limit, ~~since these levels and limits reflect, at least partly, human risk assessment data~~."

Rationale: The suggested changes make this paragraph more precise and less open-ended.

Paragraph 34: We suggest the following editorial change:

> "Other elements to consider in association with risk characterization, depending upon the purpose of the risk assessment and the details necessary to adequately characterize the risk**, include,** ~~may be"~~

Rationale: The suggested wording is more precise. As currently drafted, this paragraph is too open-ended.

CONDUCT OF FEED RISK ASSESSMENT

Paragraph 37: We propose the following change and replacement text:

37. There should be a clear statement on the purpose and scope of the risk assessment at the beginning of the work, and the type of result which is required should be well defined. For example, the desired output might be an estimate of the maximum amount of an undesirable substance in a specific feed ingredient which will not lead to exceeding a given ~~threshold~~ **level** in a given edible product over a given time period, as a function of feed type, target food-producing species and feeding regimes

Rationale: The suggested word change is more precise. The use of the word 'threshold' may be confusing to those who use the distinction between 'threshold' and 'non -threshold' effects in risk assessments.

Paragraph 38: We propose the following change and replacement text:

~~38.As much high quality quantitative information as possible should be included to reduce uncertainty and increase the reliability of the risk estimate. In practice, scientific evidence may be limited, incomplete or conflicting. In such cases, transparently documented decisions have to be made on how to complete the risk assessment process with semi-quantitative data. The formal record of the risk assessment should include an evaluation of the impact of resource constraints on the reliability of the risk assessment.~~

38: **Quantitative information should be included to reduce uncertainty and increase the reliability of the risk estimate. In practice, scientific evidence may be limited, incomplete, or conflicting. In such cases, underlying assumptions in the risk assessment should be transparently documented.**

Rationale: The proposed edits are clearer than the original while still capturing the essential concepts of the original text.

Paragraph 39: We propose the following change and replacement text:

~~39.In many cases, insufficient data will be available for quantitative risk assessment of feed or feed components. In these cases, a semi-quantitative approach may be the best option. This guidance presents an example of a semi-quantitative feed risk assessment. It is not intended to imply that this is the preferred approach but merely to illustrate ways in which semi-quantitative data can be handled if limited data are available.~~

39. There are various types of risk assessment (e.g., qualitative, semi-quantitative, and or quantitative) approaches to inform risk management options. While a quantitative risk assessment is the most preferred, the availability of data determines the risk assessment approache (s) that are available and most appropriate. When appropriate data are available, a risk assessment approach can provide an estimate of a maximum amount of an undesirable substance in a specific feed ingredient.

Rationale: Risk assessment approaches constitute a continuum of approaches. This document needs to acknowledge this continuum and emphasize that the choice of the approach is data driven and not a subjective decision.

Paragraphs 40-46 – Remove from document.

Rationale: Qualitative / semi-quantitative approaches are risk assessment approaches along a continuum and should not be singled out. Using one approach as the example may infer that it is approach preferred by Codex. The approach should fit the data and needs of those completing the assessment.

Paragraph 49: We propose the following change:

49. If new relevant scientific information becomes available, for example from food contamination monitoring or human health surveillance programs, previously completed feed risk assessments may have to be be checked and, if necessary, revised to incorporate new findings. This emphasizes the ~~dynamic~~ iterative nature of risk assessment.

Rationale: The proposed edit is an editorial change.

INTERNATIONAL FEED INDUSTRY FEDERATION (IFIF)

Paragraph 3

Move *Code of Practice on Good Animal Feeding* to top of guideline reference list

Paragraph 4

We recommend including feed in the sentence that would read: "…that need to conduct risk assessments for feed and feed ingredients, including feed additives and water as defined…" The title of the ToR mentions feed.

We recommend the following rewording: and regional authorities) for their use in conducting ~~that need to conduct~~ risk assessments

Paragraph 6

We recommend the following rewording: ~~Such unintentional environmental and human risk exposure may be minimized by appropriate hygiene measures –~~ this is redundant to the previous sentence and outside scope of document and task force

Paragraph 7

We recommend the following rewording: …focus on estimating the risk that a given hazard to human health ~~hazard~~.

Paragraph 8

We recommend deletion of the term "Animal Food" as the term is not used further in the guideline, thus there is no need to maintain it.

We note the following spelling correction: Contaminant - Any substance not intentionally…

We recommend the following addition/deletion to the bottom of the Hazard definition as follows: Based on the risk assessments 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. ~~Clarify that 'physical' hazard is not a food safety issues but an animal health issue based on the risk assessments done to date.~~

We would recommend <u>not</u> to use the term "Carry-over" to describe the transfer from feed to food. "Carry-over" is the technical term widely used in the feed manufacturing process to describe the transfer of the residual amount of the manufacturing batch to the following batch after the mixing step, this could give rise to confusion in particular at the level of translation in other COCEDX language versions. The term "transfer" is unambiguous and scientifically correct.

We would therefore recommend introducing the terms "Transfer", Cross-Contamination and Carry-over (new definition) into the Definitions section with the following descriptions;

- **Transfer**: passage of feed-borne hazards via the oral route to tissues of food-producing animals destined for human consumption (usually expressed quantitatively as a transfer coefficient or transfer rate).
- **Cross-Contamination:** The undesired introduction of traces and/or impurities of a chemical, botanical, physical or microbiological nature into feed during production, processing, sampling, packaging, storage or transport.
- **Carry-Over:** The transfer of any substance or product form one feed production batch to the following batch in a particular step of the manufacturing process (i.e. the mixer or hand-add point)

We recommend rewording the definition of Risk as follows: ~~A function of~~ The probability of an adverse <u>human</u> health effect ~~and the severity of that effect , consequential to~~ <u>resulting from the presence of</u> a hazard (s) in <u>feed or</u> food.~~(proc).~~

We recommend the addition of the definitions for ML and MRL to this document (as those used in the List of Hazards document) since these terms are used within the document.

<u>Paragraph 9</u>

We recommend the following rewording: … Risk assessment considers hazard type<u>, exposure</u> and <u>risk characterization;</u> it forms a solid basis for adequate risk management and communication to reduce, eliminate or prevent risks, ~~and~~ enhance consumer <u>protection and facilitate international trade.</u>

The first change matches the figure on Structure of Risk Analysis and international trade should be added back because it supports risk management process and would also make it consistent with the risk management definition (was in original document and deleted)

<u>Paragraph 11</u> We propose adding the following additional key steps in the risk assessment process that have been overlooked in this document.

PRELIMINARY ANIMAL FEED/HUMAN FOOD SAFEY RISK MANAGEMENT ACTIVITIES

Risk management activities may be initiated when food safety hazards are present in animal feed at levels that adversely affect human health when transmitted to humans in foods of animal origin. The risk manager initiates the risk management process with the preliminary risk management activities to determine the scope and magnitude of the food safety issue and, where necessary, to commence activities to manage the identified risk.

Identification of the food safety issue

This is the initial step, in which risk managers identify and briefly describe the animal feed/human food safety issue, i.e. the defined combination of the hazard(s) and the human health issue arising from consumption of foods of animal origin.

Development of the risk profile

The risk profile is a description of a food safety problem and its context. This risk profile presents, in a concise form, the current state of knowledge related to the food safety issue, describes current control measures and RMOs that have been identified to date and the food safety policy context that will influence further possible actions. It is important to note that the risk profile is a scoping exercise to describe and define the pertinent factors that may influence the risk posed by the hazard**.** It is not intended to be an abbreviated version of a risk assessment. The risk profile usually is developed by personnel with specific scientific expertise on the food safety issue of concern and understanding of risk assessment techniques. Interested parties who are familiar with the relevant food production chain and related production techniques should be consulted.

The depth and breadth of the risk profile may vary, depending on the needs of the risk managers and the complexity and urgency of the food safety issue. Additional risk profile elements can be found in The Principles and Guidelines for the Conduct of Microbiological Risk Management [CAC GL/63-2007].

Consideration of the information given in the risk profile may result in options leading to a range of initial decisions, such as determining that no further action is needed, commissioning a risk assessment, establishing additional information gathering pathways or implementing immediate risk mitigation management.

Ranking of the food safety issues and setting priorities for risk assessment and management

Given the potentially high resource costs associated with conducting risk assessments and or implementing risk management decisions, the risk profile provides the principal resource that should be used by risk managers in risk ranking or prioritization of this feed or feed ingredient food safety issue among numerous other food safety issues.

Beyond the description of the food safety issue provided by the risk profile, other criteria may be used for ranking or prioritization. These are generally determined by the risk managers in conjunction with interested parties and in consultation with risk assessors on scientific aspects of the issues.

Establishment of preliminary risk management goals

Following development of the risk profile and the ranking of the feed or feed ingredient food safety issues for risk assessment/risk management priority, risk managers should decide on the preliminary risk management goals that determine the next steps to be taken, if any, to address the identified food safety issue.

Establishment of a risk assessment policy

Following a decision as to the need for a risk assessment, risk assessment policy should be established by risk managers in advance of commissioning the risk assessment. The risk assessment policy should be developed in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent. The mandate given by risk managers to risk assessors should be as clear as possible and provide guidance as to the scope of the risk assessment, the need to address uncertainty and what assumptions to use when the available data are inconsistent or incomplete. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different RMOs.

Commission a risk assessment

Risk managers may commission a risk assessment to provide a transparent, systematic evaluation of relevant scientific knowledge to help make an informed decision regarding appropriate risk management activities.

Information that may be documented in the commissioning of the risk assessment includes:

- A description of the specific animal feed/human food safety issue (as defined in the risk profile);
- The scope and purpose of the risk assessment;
- The specific questions to be answered by the risk assessment;
- The preferred type (e.g. quantitative or qualitative) of risk assessment to be conducted;
- The expertise and resources required to carry out the risk assessment; and
- Timelines for milestones and completion of the risk assessment and its review.

Paragraph 14 & 15

We believe that one of the primary objectives of this document is to achieve global risk assessment consistency. To accomplish this, we recommend that this Task Force plan to:

- Confirm that JECFA, JMPR and JEMRA, or other technical bodies, are the appropriate bodies to complete risk assessments for the hazards in feed and feed ingredients that are reasonably likely to occur and would transfer to a hazard to human health.
- Consider the use of an Ad Hoc risk assessment group where the above bodies are not appropriate or are not able to complete the risk assessment in a timely basis for a given potential hazard.

Paragraph 15

We recommend the following rewording of this paragraph: … The purpose of feed hazard identification is to define ~~describe~~ the hazard …_ … from surveillance programs to identify the ~~physical~~, chemical, … - removal of physical hazard is consistent with the Exposure Assessment definition and is not included in the prioritized list of hazards.

Paragraph 16

We recommend the following rewording of this paragraph: As there are existing Codex standards ~~or internationally recognized guidelines~~ which consider human exposure to a given hazard in food, consideration of human exposure is not emphasized in the present document. ~~Instead,~~ Risk ~~exposure~~ assessment and risk characterization in this ~~feed risk assessment~~ guidance focuses on the degree to which ~~estimated amount of~~ a given health hazard, which originated from feed and feed ingredients, will be present in edible products from food-producing animals. Information on carry over transfer rates from feed to food is particularly important.

We recommend that a list of key scientific information reference sources be included (possibly as an annex) that provides governments and stakeholders with information such as transfer rates from feed to food and food consumption data.

We recommend the following rewording As there are existing Codex standards ~~or internationally recognized guidelines~~ which consider …

… document. ~~Instead, r~~ Risk assessment and risk characterization in this feed risk assessment guidance focus~~es~~ on the degree to which ~~estimated amount of a~~ given human health hazard which will be present in edible products from food-producing animals.

Paragraph 18

We recommend the deletion of the text: "and also excessive levels of veterinary drugs, pesticides and additives" because we consider toxins and peptides as biological agents rather than chemicals, and these substances are regulated separately and any excessive level is thus prohibited.

Paragraph 25

We **recommend deleting** the text in brackets at the end of this paragraph.

Paragraph 26

We recommend the following rewording: … estimates of corresponding levels in food ~~food levels~~. Factors to be …

Paragraph 27

We recommend the addition at the end of the second sentence as follows: (e.g. meat, milk and eggs)

Paragraph 28

We recommend combining Paragraphs 28 and 29.

Paragraph 29

We recommend that the definition of "low tier" and "high tier" needs to be defined. Is this standard language in risk assessment or other Codex documents? We understand there is considerable disagreement among risk assessors on the use or proper application of these terms in risk assessment.

Paragraph 31

We recommend the following rewording: … have been defined in the initiation ~~purpose~~ of a feed risk assessment …

Paragraph 32

We recommend the following rewording: In a feed risk assessment the ~~a plausible~~ endpoint is the likelihood that a given hazard in feed will be transferred to food in a concentration which, for example, exceeds its Codex ~~maximum level or~~ maximum residue limit.~~, since these levels and limits reflect, at least partly, human risk assessment data.~~

Paragraph 34

We recommend the following rewording: … to adequately characterize the risk, include ~~may be.~~

Paragraph 36

We recommend adding the word feed in the sentence as follows: The feed risk assessment may also identify areas of research needed to fill key gaps in scientific knowledge on a particular risk or risks associated with a given feed or feed ingredient.

Paragraph 37

We recommend adding the word feed in the sentence as follows: "For example, the desired output might be an estimate of the maximum amount of an undesirable substance in a specific feed or feed ingredient which will not lead to exceeding a given threshold in a given edible product…"

Paragraph 39

General Comment: We believe it should be made clear to the users of this document that the gold standard of risk assessment is a quantitative risk assessment and that a semi-quantitative risk assessment is only an option for an intermediate risk assessment. This is supported by the fact that SPS requirements (article 5.7) obligate the risk assessor to complete a science-based risk assessment; and if sufficient data is not available, to take the necessary steps to obtain the data. While a semi-quantitative risk assessment may be a preferred alternative when sufficient data is not available, it is only meant to be an intermediate assessment while the data collection and quantitative risk assessment is completed and the semi-quantitative assessment is amended. We would further propose that the Suggested Procedure for Semi-

quantitative Risk Assessment section of this document should be an Annex to the document and clearly defined as an interim Plan B, not an alternative to the gold standard.

We recommend the following rewording: In ~~many~~ cases where insufficient data is ~~will be~~ available for quantitative risk assessment of feed or feed components~~. In these cases,~~ a semi-quantitative approach may be an intermediate ~~be the best~~ option.

In addition to these changes, we recommend a paragraph be added between 38 & 39 to explain that under SPS Requirements (Article 5.7) there is an obligation to perform a science based risk assessment, and if the data is not sufficient to accomplish this, steps need to be taken to obtain that data. Thus, the Option B of using a semi-quantitative approach is an interim step until the data is obtained and the quantitative risk assessment replaces this interim step. It should be further stated that Option B is not the preferred approach, that it is an interim not an alternative approach, and we also recommend that an Annex be included which provides guidance steps when sufficient data is not available.

Paragraph 40c

We recommend removing the last sentence: "For example, will the risk manager need to know if "moderate" exposure to a "moderate" hazard is worse than "high" exposure to a "slight" hazard?"

Paragraphs 40 & 41 AND 44 & 45

General Comment: Our experience with feed safety risk assessments carried out by government and private sector bodies shows that the CODEX food safety recommendation for the hazard characterization in a semi-quantitative risk assessment is often too limiting. This would prevent risk managers from defining a risk-proportionate risk management approach to control the hazard. Hence many feed safety risk assessors have introduced a more differentiated scoring system adding at least one additional risk category called "moderate high". Due to the complexity of food and feed ingredient manufacturing processes and the multi-feed ingredient matrix of compound feed, feed safety risk assessors do require a more differentiated risk-assessment mode. We consider that the area of the conduct of feed risk assessment is one of the key challenges for the TFAF in view of proposing globally harmonized guidance for risk assessment bodies given the current huge divergence in conducting feed safety risk assessments by competent government and private sector bodies.