



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

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**PROPOSED DRAFT GUIDANCE FOR USE BY GOVERNMENTS IN PRIORITIZING THEIR NATIONAL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

Comments at Step 3 of

**Argentina, Brazil, Canada, Chile, Colombia, Egypt, European Union, Iran, Japan, Norway, Philippines
and United States of America**

ARGENTINA

Argentina thanks for the possibility to make the following comments.

GENERAL COMMENTS

First we would like to emphasize the need for a correct interpretation of the aim of this document in the framework of CODEX ALIMENTARIUS and the future implementation by governments.

Hazard prioritization, in the framework of Preliminary risk management activities, is a key step to set hazard priorities y then commission the risk assessments according to available resources.

In the work of the subsidiary management bodies of Codex, prioritization is key toe the limited human and financial resources to commission risk assessments on those hazards receiving a priority from countries.

In the case of governments, prioritization should have the same purpose and be a starting point for further risk assessments.

In the framework of the SPS Agreement, management by governments should be always in relation to risks and NOT HAZARDS, which necessarily implies risk assessments on identified hazards.

Paying attention to this, as specific comments some corrections will be presented on this criterion.

Furthermore, we would like to draw the attention to the absence of the CRITERIA FOR PRIORITIZATION in the text presented, which are widely known and agreed upon in CODEX. Even though there have been some questions on the interpretation of IMPACT ON TRADE, we consider that criteria used by governments should not differ from those used historically, therefore we suggest adding back the 3 criteria: RELEVANCE TO HUMAN HEALTH, EXTENT OF OCCURRENCE AND IMPACT ON TRADE.

With reference to the CRITERIA, we consider their definition and interpretation crucial. We also consider the document should incorporate a clear guidance on HOW they should be used in the framework of hazard prioritization, then it is of key importance that examples presented in ANNEX 2 reflect the procedure.

Finally, we would like to mention once more our questioning to the presentation of the LIST OF HAZARDS in ANNEX I.

The Task Force is a group of risk management and not of experts who could discuss on hazards in feed, being the reference to this work the Final Report of the Expert Group FAO/WHO from 2008.

We believe it is arbitrary to make reference to hazards that may occur in feed, which should be evaluated and reported by a specific group of experts, and in the best situation through an update of such work.

In this respect and without denying that the hazards mentioned may be correct, we suggest the document mention this work and immediately commission the update of said document.

SPECIFIC COMMENTS

PARAGRAPH 2

As expressed under general comments, reference to management activities is wrong; therefore we suggest the following change:

2. The purpose of prioritizing hazards in feed as described in this document is to ensure the conduction of risk assessments according to the established priority on identified hazards and available resources. the safety of foods of animal origin by optimizing the allocation of resources required for risk management activities.

PARAGRAPH 2-bis

We suggest including a NEW PARAGRAPH after paragraph 2.

X. Hazard prioritization should not lead to risk management without a prior specific risk assessment considering the triad hazard/feed-ingredient/edible product.

SCOPE

We think that paragraph making reference to the final purpose of this document is missing. In this respect we suggest the following text:

X. This document provides governments with guidance to prioritize hazards in feed in order to conduct the corresponding risk assessments in relation to their available resources.

PARAGRAPH 7 – DEFINITIONS

We consider that CARRY-OVER and CROSS-CONTAMINATION definitions are not correct and they are not connected to the present document. In this respect we suggest their removal.

Likewise, we consider that TRANSMISSION should be defined.

PARAGRAPH 9

The text presented is neither clear nor correct. It is proper to mention the preliminary risk management activities because the hazard prioritization is part of it, but contrary to risk management is confusing in this paragraph. In this regard and as expressed in general comments, we suggest the following correction:

*9. Risk management comprises preliminary risk management activities **such as hazard identification in feed safety problems feed, hazard prioritization, implementation of a risk assessment policy and the commissioning of such assessment.** ~~Identification of risk profiling and prioritization (for example, commissioning of risk assessment, risk communication), implementation of risk management options, monitoring and review.~~*

PARAGRAPH 10

This paragraph is repetitive in relation to 9; therefore we suggest its removal, leaving only the reference to CODEX document.

PARAGRAPH 11

As expressed under General Comments, we understand that prioritization should be based on established Criteria. In this sense we do not understand the reference to “multi-criteria” and suggest deleting it.

11 [...] (4) prioritization ~~by multi-criteria decision analysis~~ and (5) reporting of the process, methods and results.

PARAGRAPH 13

At the end of the paragraph it is mentioned the prioritization for management, which is wrong. We suggest the following correction:

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

PARAGRAPH 14

Under general comments we mention ANNEX I, therefore we suggest this paragraph only makes reference to the FAO/WHO REPORT from the Expert Groups.

PARAGRAPH 15

We consider that the reference to “environmental monitoring” is no related to the present document and suggest its removal.

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

PARAGRAPH 16

In relation to knowledge gaps, we consider the text on risk manager is unclear; therefore we suggest the following modification:

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

PARAGRAPH 17

We suggest the following correction:

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

PARAGRAPH 18

This paragraph is fallacious in that the risk profile is essential for risk assessment but not for risk management decisions. In this sense, we suggest the following correction:

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

PARAGRAPH 20

We suggest corrections for better interpretation of the text:

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

STEP 3 – CRITERIA

According to the above mentioned in general comments we suggest including the 3 CRITERIA with their definition and interpretation.

PARAGRAPH 23

We suggest the following modification:

23. The application of the criteria needs to reflect relevant local and regional conditions and practices concerning feed and food.

PARAGRAPH 24

We suggest the following correction of the text:

24. If possible, criteria should be quantified ~~chosen must be objectively quantifiable~~ to enable scoring. This should be established in consultation with scientific experts.

PARAGRAPH 25

We suggest deleting the last part of the text and replace it in the following way:

25. If data relevant to a given criterion are not provided in the risk profiles, then, they should be generated as a previous condition to the conclusion of the risk profile. ~~then the risk profiles will have to be updated accordingly.~~

PARAGRAPH 27

We suggest deleting the reference to Multi-criteria, as well as the last sentence, which is unrelated to the text. We consider that a more detailed explanation on how to apply the 3 criteria is missing.

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

ANNEX 1

Reiterating what it has been mentioned in General Comments; we consider that this ANNEX should be deleted and only leave a reference to FAO/WHO Expert Group.

ANNEX 2

We believe that the examples are not clear, they have not used the Codex 3 basic CRITERIA and they do not clarify the methodology leading to hazard prioritization in feed.

Basically, we believe that only FEW EXAMPLES should be incorporated into the text (a chemical one and a biological one) describing the prioritization sequence step by step, detailing the cases, information of each criterion and the scoring procedure to grant a value that defines a priority.

If clarity is not possible, and faced with the possibility of generating confusion and misinterpretations of the document; we suggest NOT INCORPORATING EXAMPLES.

BRAZIL**GENERAL COMMENTS**

Brazil congratulates the Electronic Working Group on Redrafting the "Guidance for Governments on Prioritizing Hazards in Feed" and would like to extend its thanks for the opportunity to submit its comments.

Brazil considers that the proposed document has improved and supports the recommendations in general. However we believe that the document is overly concise and there are gaps of information, which are important to guide the governments so we suggest a greater detailing mainly to Annex 2 for better applicability.

SPECIFIC COMMENTS**SCOPE**

Brazil suggests the following text to the scope:

3 - This document provides guidance to governments on criteria for prioritization of hazards in feed and their application in the process of risk management.

~~3.4~~ - In this document, "feed" refers to both feed ingredients and feed.

5 - This guidance is applicable to all hazards in feed for food-producing animals. "Hazard" refers to any agent which may adversely affect human health. Agents, which may adversely affect animal health but which have no impact on food safety are not considered in this guidance, as they are not within the scope of the Codex Alimentarius.

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

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

Rationale: to give the context of the item and a better understanding.

DEFINITIONS

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

Processing aid: Any substance not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed ingredients to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the

substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed. (GOOD PRACTICES FOR THE FEED INDUSTRY)

Rationale: Brazil suggests using the definition from the Good practices for the feed industry because it is specific for feed. The definition suggested could cause confusion affirming that "In this guidance, the word "food" should be read as "feed"".

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food (Codex Alimentarius Commission: Procedural Manual). In this guidance, it may also refer to the probability that a hazard in feed eaten by a food-producing animal will transfer to an edible product at a level, which may cause an adverse health effect in humans.

Rationale: for a better understanding of the document.

PRIORITIZATION OF HAZARDS IN THE FRAMEWORK OF CODEX RISK ANALYSIS

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

Rationale: These steps are treated in detail in item 11

PRIORITIZATION PROCESS

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

Rationale: Brazil would like to request an explanation about the use of may instead must in this situation.

29 – Brazil suggests the inclusion of a reference to Annex II – Example of the prioritization process as it was not stated in the document.

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

Prions	Contamination of feed protein by protein from diseased <u>carcass</u> cadaver .	Nervous system tissue
Radionuclides: strontium-90, iodine-131, caesium-134, caesium-137	Exogenous (nuclear powerplant accidental release), contamination of soil minerals, <u>water</u> and forage.	Milk (radioiodines, radiocesium), bone (radiostrontium), meat (radiocesium)
Mycotoxins	Produced by carbohydrate-catabolising fungi in high humidity conditions on cereals (e.g. wheat, sorghum, maize, rice, oats), in oilseeds (e.g. groundnut, soybean, sunflower, cotton) and silage.	Meat (depoxy-deoxynivalenol, zearalenol, ochratoxins), liver, milk, eggs (aflatoxins)

ANNEX 2 EXAMPLE OF THE PRIORITIZATION PROCESS

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

Rationale: for a better understanding.

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

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

Rationale: Brazil would like to request a better detailed example where the considerations for a hazard identification are shown. For example, in this case the occurrence of a single event (contamination by cadmium in phosphate observed in just one shipment) was enough to identify it as a hazard to this first step. It was unclear whether there are other factors that combined with this occurrence led to the identification of this hazard.

Step 2. Risk profiling

The given examples are too superficial, which may lead to conclude that a simplistic analysis would be sufficient for the Risk Profiling. Several items exemplified in paragraph 20 were not addressed in this text.

Step 4. Prioritization

Brazil requests clarification how the values were determined for the criteria in Table 1. We suggest finishing the process by applying a decision analysis leading to aggregation of scores to determine the order of priorities of the dangers.

Step 5. Reporting

~~This is the most important step in the whole process.~~

Rationale: At this step, Brazil suggests the inclusion of items to be included at this stage.

CANADA**General Comments**

Canada notes that a very significant rewrite of the document was done by the Swiss Secretariat. We have focussed our remarks on key issues at this time and are reserving detailed commenting on Annex 2 for the meeting itself.

Canada does, in principle, support the new format and is of the view it will serve as a useful complement to the Guidelines on Application of Risk Assessment for Feed document. We are supportive of a text that minimizes repeating the content of the Guidelines on risk assessment.

Specific Comments**Section Definitions, Paragraph 7****Contaminant:**

The definition should be consistent with that contained in the "Proposed Draft Guidelines on Application of Risk Assessment for Feed" document. As such, the last statement should be added as follows:

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

Control:

The definition should be consistent with that contained in the "Proposed Draft Guidelines on Application of Risk Assessment for Feed". As such, the reference to human health should be deleted as follows:

The prevention, elimination, or reduction of hazards and/or minimization of risks ~~to human health~~. (*Principles and Guidelines for the Conduct of Microbiological Risk Assessment, CAC/GL 30-1999*).

Edible product

The definition should be consistent with that contained in the "Proposed Draft Guidelines on Application of Risk Assessment for Feed". As such, fish should be added to the definition as follows:

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

Transfer

The definition should be consistent with that contained in the "Proposed Draft Guidelines on Application of Risk Assessment for Feed". As such, the definition should be replaced as follows:

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

SECTION ON PRIORITIZATION PROCESS

Step 2. Risk Profiling

Paragraph 20

This paragraph contains very important information that may be overlooked in this format. Canada suggests itemizing each of these examples in a bullet format as follows:

Examples of information which may be collated in a risk profile include:

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

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

Paragraphs 22-25

These paragraphs discuss the criteria that are applicable to the hazards/feed/edible products combination for prioritization. However, we note that there are no references or linkage to Annex 2-Step 3, where criteria are provided as examples. Hence, we recommend that a formal reference be made in this section.

Paragraph 22

As this document serves as a guidance document rather than a requirement, Canada suggests the removal of the restrictive “must” in the sentence as follows:

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

Paragraph 24

As it is not always possible to rely on a quantifiable process during this prioritization exercise, Canada suggests the following modification to the restrictive tone of the current wording as follows:

The chosen criteria **should** ~~must~~ be objectively quantifiable to enable scoring **to the fullest extent possible.** This should be established in consultation with scientific experts.

Step 4. Prioritization

Paragraphs 26-28

These paragraphs discuss the prioritization process. However, we note that there are no references or linkage to Annex 2 - Step 4, where examples of prioritization are provided. Hence, we recommend that a formal reference be made in this section.

ANNEX 1 – Examples of Hazard/Feed/Edible Product Combinations with Potential Relevance for Human Health

Paragraph 3

The current text implies that only protein meals may be contaminated which is not the case. Hence, we suggest the following modifications:

3. The primary microbiological hazards in feed that **can** transfer to edible products of food-producing animals are zoonotic microorganisms ~~which contaminate~~ **contaminating feeds, particularly** animal and vegetable

protein meals fed to animals. **These microorganisms** They may be introduced into feed crops, forages and water from contaminated pasture land, may be present in animal materials which are used for feed, and may be introduced to feed by cross-contamination or carryover during processing, transport, and storage.

Paragraph 4

The transfer to edible products is not strain specific. Hence, we suggest the following modification:

4. *Salmonella* is a worldwide human health concern. Contaminated feed can represent a route of exposure of food-producing animals to *Salmonella*. However, the correlation between contaminated feed and infection of livestock by a given *Salmonella* strain and the contamination of edible products from these animals need to be established on a case-by-case basis. Adequate strain typing is necessary **to establish such correlations. Strain typing is also important to identify strain types that are more commonly associated with human pathogenicity.** ~~because transfer to edible products and human pathogenicity are typically strain-specific.~~

Paragraph 15

The occurrence of Aflatoxins is not limited to these examples. Hence, we suggest the following modification:

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

Paragraph 18

These other microorganisms may produce toxins but are not strongly associated with illness in animals, at least not as a direct intoxication. *C. perfringens*/ *difficile* might cause toxicoinfection. Hence, we suggest the following modifications:

18. **A limited number of toxins** ~~Toxins~~ produced by bacteria, such as *Clostridium botulinum*, *C. tetani* and *C. perfringens*, *Vibrio cholerae*, *Staphylococcus aureus*, *Yersinia enterocolitica*, and *Shigella dysenteriae* ~~are~~ **may be** acutely toxic to food producing animals when ingested with feed **but transfer** ~~Transfer of toxin to edible products is unlikely. possible but unlikely to be relevant.~~

TABLE 1: Summary Examples of Potential Hazard/Feed/Edible Product Combinations

Hazard – Bacteria: We suggest replacing the bolded and underlined terminology below to better reflect common usage:

Contaminated ~~in~~ of forages (pasture, hay, silage), **animal and vegetable protein meals and other feeds due to insufficient processing.** ~~by disease carriers,~~ carry-over or cross-contamination by **infected animals** ~~disease carriers (including **carcasses** ~~cadavers~~) during production, processing, transport and storage.~~

Hazard – Endoparasites: We suggest replacing the bolded and underlined terminology below to better reflect common usage:

Contamination of forages (pasture, hay, silage) by **infected animals** ~~disease carriers.~~

Hazard – Prions: We suggest replacing the bolded and underlined terminology to better reflect common usage:

Contamination of feed protein by protein from **infected carcasses** ~~diseased cadavers.~~

Hazard – Dioxins: This hazard should include all of the important examples as listed in Annex 1, paragraph 22. Fish should also be added to the “Edible products” listing for this hazard.

ANNEX 2 – Example of the Prioritization Process

Step 4. Prioritization

We note that this section has been simplified. However, it may be lacking the necessary information/guidance to be able to apply as consistently as possible the scoring for each of the criteria. In addition, it is unclear how one would develop a score using a toxicology based limit value. Perhaps a definition may be added to explain this term. We also suggest this section should be further developed to indicate how to use the 2 criteria together to yield a single overall score.

Step 5. Reporting

We question why this step is considered to be the most important in the whole process. Further elaboration

on what is expected at this step will be important so that common understanding and consistent application can unfold.

CHILE

General Comments

Comment 1. The document is accepted, however, there are specific comments that need to be pointed out.

Comment 2. It is suggested that a change be made throughout the document of the translation in Spanish of the term "Food safety", since it says "seguridad alimentaria" whereas it should mean "inocuidad de los alimentos", for example in:

SCOPE

5. Agents which may adversely affect animal health, but which have no impact on ~~food safety (seguridad alimentaria)~~ **food safety (inocuidad de los alimentos.)** are not considered.

Reasoning: The term seguridad alimentaria (food safety) refers to the availability of food, a more ample concept in its conception than the inocuidad de alimentos (food being safe), to which this document makes reference to. The former is consistent with one of the Codex Alimentarius objectives (food **safety**).

Specific Comments

Comment 1. It is suggested to add a definition of food

DEFINITIONS

Food: Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs. (Codex Alimentarius Commission: Procedural Manual).

Reasoning: To grant further clarity when making reference to the abovementioned in documentation that does not refer to animal food/feed.

Comment 2. It is suggested that the Spanish version should be modified so that it remains as follows:

DEFINITIONS

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

Reasoning: The proposal reflects the Proposed Draft's objective and what was expressed in the English version.

Comment 3. It is suggested that the Spanish version should be modified so that it remains as follows:

DEFINITIONS

Feedingstuff: Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to **food producing animals** ~~animals intended for human consumption~~ (Code of Practice on Good Animal Feeding. CAC/RCP 54-2004).

Reasoning: The proposal reflects the Proposed Draft's objective and what was mentioned in the English version.

Comment 4. It is suggested that the following sentence, at the end of the paragraph corresponding to the definition of Processing Aids, be deleted:

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

Reasoning: The term "food" is used in the text both as food for animals and as edible products for human consumption.

Comment 5. It is suggested that the paragraph be modified as follows:

11. In this guidance, the process for prioritizing hazards in feed involves the following steps: (1) identification of hazard/feed/edible product combinations potentially associated with food safety problems, (2) risk profiling

for selected hazard/feed/edible product combinations, (3) establishment of the criteria to be used for prioritization, (4) prioritization by multi-criteria decision analysis, and (5) reporting communication of the process, methods and results.

Reasoning: Avoid confusion with the risk analysis stage "risk communication".

Comment 6.

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

Reasoning: This is the usual term in scientific publications, so this alternative would adapt better to the English version.

Comment 7.

Step 2. Risk profiling

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

Reasoning: It is suggested that the concept "un ejercicio de alcance" ("scoping exercise") be specified or defined.

Comment 8.

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

24. The chosen criteria must be objectively quantifiable to enable scoring. This should be established ~~in consultation with scientific experts~~ by thoroughly explaining the scientific rationale used.

Reasoning: Provide better options based on national realities and offer alternatives such as the ones proposed in point 15 of this Proposed Draft.

Comment 9.

Step 5. ~~Reporting~~ Reporting on the process, the methods and the results.

Reasoning: Avoid confusion with what has been defined as "comunicación de riesgo" ("risk communication").

COLOMBIA

Original document:

11. In this guidance, the process for prioritizing hazards in feed involves the following steps: (1) Identification of hazard/feed/edible product combinations potentially associated with food safety problems, (2) risk profiling for selected hazard/feed/edible product combinations,

11. In this guidance, the process for prioritizing hazards in feed, taking risk as the basis, includes the following steps: **(1) Identification of hazard/feed/edible product combinations potentially associated with food safety problems, (2) risk profiling for selected hazard/feed/edible product combinations,**

Original document:

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

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

Suggestion:

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

22. The criteria chosen for the evaluation of hazard/feed/edible product combinations to prioritize feed hazards must reflect the overall purpose of ~~ensuring the safety of foods of animal origin.~~ Identifying the hazards in feed and aim towards the achievement of food safety.

Prions

... . Carry-over from prion-contaminated feed to edible products has been demonstrated.

Prions

This type of contamination requires further explanation, once the contamination is generalized.

Experimental transmissibility of BSE to cattle has been demonstrated following parenteral and oral exposures to brain tissue from affected cattle (20, 90). There is no evidence of horizontal transmission of BSE between cattle and little data to support the existence of maternal transmission (27).

*It is suggested that the certainty of the contamination in the various sections of the document be revised, **as** the risk analysis aims at determining the presence of possible hazards in feed but it does not guarantee the safety of foods of animal origin.*

EGYPT

Page 4 under definition 7 the term " Carry – over".

We suggest to add more details to avoid confusion with the term " cross-contamination".

Page 4 under definition 7 the term "Feed ingredient".

We suggest to add the phrase "might not include dried bone nor dried blood " after "animal origin".

Page 5 under definition 7 the term" Hazard"

We suggest to add the term "Risk" after the term" Hazard" as in Codex Alimentarius Commission Procedural Manual twentieth edition =.

EUROPEAN UNION

General remarks

The EU would like the introduction and the common criteria, which could be useful for all governments, reinstated in the document, as discussed in the two first rounds of comments in the electronic Working Group (eWG).

In general, the EU considers the proposed prioritization process too mechanistic. It should be considered as a tool to help making risk management decisions rather than determining them. As stated in the eWG, the EU favours a non-numeric method of aggregation of the different aspects discussed in the document. Scoring the different criteria used in terms of high, medium, or low rather than figures may provide a more illustrative picture than a simple figure. In addition, the EU considers that Annex 2 is unclear.

The reintroduction of a reference on how priorities are established in the Codex system in this document may also be appropriate. These are the Codex Procedural Manual Criteria for the Establishment of Work Priorities and those used by specific Codex Committees, e.g. the Codex Committees on Contaminants and Food Additives. This is useful background information.

The EU would like to propose the re-introduction of the section specifying what to consider as hazards.

Specific comments

INTRODUCTION

Paragraph 2

The EU suggests modifying the paragraph as follows:

The purpose of prioritizing hazards in feed as described in this document **is should be to contribute** to ensuring the safety of foods of animal origin ~~by optimizing of the resources required for risk management activities.~~

SCOPE

Paragraph 3

This paragraph could be deleted, since it is always the case and since it is also mentioned under paragraph 7.

Paragraph 4

To ensure consistency with the document "Proposed guidelines on application of risk assessment for feed",

this paragraph should be identical to paragraph 18 of that document.

Paragraph 5

This paragraph should be consistent with the corresponding text in paragraph 6 of the document 'Proposed draft guidelines on application of risk assessment for feed'. The text should therefore read as follows:

"Agents which may adversely affect animal health, but which have no impact on food safety, are not considered in this document, as they are not within the scope of the Codex Alimentarius."

DEFINITIONS

Definitions should be identical in this document and the "Proposed draft guidelines on application of risk assessment for feed."

The EU would like to propose inclusion of a **definition for biotransformation** as follows: ***"Biotransformation is the process by which a hazard is converted by metabolic process in the body into other molecules."***

In the definition of processing aids the text "in this guidance, the word "food" should be read as "feed", and "in this guidance" should either be deleted, or "guidance" should be changed to "definition". The easiest solution could be to write "feed" in the definition instead of "food" and in the reference write (*parallel to Codex Animal Feeding*)

Processing aid (in feed): Means any substance or material, not including apparatus or utensils, and not consumed as a **feed** by itself, intentionally used in the processing of **feed** to fulfil a certain technological purpose during treatment or processing and which may result in the non intentional but unavoidable presence of residues or derivatives in the final product (Specification of the definition of processing aid in the *Codex Alimentarius Commission: Procedural Manual*)

Definition of 'Risk' from the 'Proposed draft guidelines on application of risk assessment for feed' should also be included in this document.

The **definitions of transfer** in the two documents are not identical at present. Additionally, the definition should cover more clearly both the transfer of a chemical hazard and the transmission of a biological hazard. It should also include a note about the metabolism or biotransformation of the hazard in the animal. The EU would ask whether it is necessary to indicate under which circumstances a transfer rate can be established (steady state, regular consumption of the feed by the animal or of the edible product by humans, etc.).

Definition of undesirable substances: The EU proposes re-insertion of this definition as it is a term used in the EU amendment proposed for paragraph 24 of Annex I.

PRIORITIZATION OF HAZARDS IN THE FRAMEWORK OF CODEX RISK ANALYSIS

PRIORITIZATION PROCESS

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

Paragraph 24

The EU suggests modifying the first sentence EU as follows: "*The chosen criteria ~~must be objectively quantifiable to enable scoring.~~ should ideally be objectively quantifiable when scoring is used.*"

The EU proposes to add a new paragraph:

(Paragraph 24 bis). "The relevance to human health, the extent of occurrence and the economic impact on the market are examples of criteria that can be used for prioritization."

Step 4 Prioritization

Paragraph 26

The EU proposes to replace the current text with the following paragraph:

"Prioritization of selected hazard/feed/edible product combinations is based on the global consideration of the criteria defined in step 3. This can be done for example by allocating high, medium, or low values to each criterion in order to obtain a global overview or by allocating numerical scores and aggregating the criteria in a numerical figure."

Paragraph 27

The reference to examples is not clear, as the reference is the whole of Annex 3.

Paragraph 28

The EU suggests replacing the term "*determine*" with the terms "*may help in the determination*" as follows:

~~"The aggregated~~**Aggregating** scores of individual hazard/feed/edible product combinations ~~determine~~ **may help in the determination of an** ~~the~~ order of priority for ~~the national~~ risk management activities."

ANNEX 1: EXAMPLES OF HAZARD/FEED/EDIBLE PRODUCTS COMBINATIONS WITH POTENTIAL RELEVANCE FOR HUMAN HEALTH**Paragraph 2**

It is proposed to add at the end of the paragraph the following sentence: "***The following examples are listed according to the types of hazards.***"

Paragraph 4

The EU proposes to add at the end of the paragraph the following sentence: ***In the absence of the establishment of such correlation or of strain typing, any contamination of feed with Salmonella should be considered as a hazard.***

Paragraph 9

The EU would like to propose the following change:

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

Elements can be present in ionic forms and ligands and in other forms also.

Paragraph 11

"*Lead may occur in grain or forage grown on contaminated soil*" should be changed to: "*Lead may occur in grain or forage grown **in areas with air pollution or on contaminated soil***" because lead is transported from soil to plants to a much lesser extent than e.g. cadmium. Same comment to the text regarding lead in Table 1.

Paragraphs 14 and 17

The sentences concerning zearalenone do not seem to be consistent as regards its transferability. The EU considers that the transfer of zearalenone from feed into food of animal origin is very low. The EU proposes to delete the word zearalenone in paragraphs 14 and 17.

Paragraph 15

The EU proposes to add the term "**e.g.**" *Aflatoxin B₁ can occur in "e.g. copra....."*

Paragraph 19

The correct name of the substance mentioned is *pyrrolizidine alkaloids*.

Paragraph 22

The following change is proposed:

Polychlorinated dibenzodioxins (PCDD), dibenzofurans (PCDF) and dioxin-like polychlorinated biphenyls (DL-PCBs), commonly known as dioxins, and organochlorine pesticides such as aldrin, dieldrin, and DDT, are lipophilic and have long half-lives in the environment. Dioxins in feed may arise by contamination, for example from dioxin-containing preservatives in wood, from combustion sources (e.g. waste incineration plants, fossil fuel power stations, bush fires, exhaust gases) **or by chemical reactions during processing involving solvents containing chlorine**. Dioxins may be present as contaminants in mineral sources, such as clays, recuperated copper sulphate, zinc oxide, and in food by-products, including fish by-products such as fish meal and fish oils

Paragraph 22 bis

A text on non dioxin-like PCBs should be added in a **new paragraph 22 bis**. The following text is proposed:

Non dioxin-like PCBs have been widely used in a number of industrial and commercial applications. Although the manufacture, processing and distribution of PCBs have been prohibited in almost all industrial countries since the 1980s, their entry into the environment still occurs. Following exposure of farmed animals, including aquaculture, non dioxin-like PCBs will accumulate in meat, liver and

particularly in fat tissues. Occupational exposures to PCBs have been reported to be associated with an increased risk of cancer of the digestive system and possibly other sites."

Paragraph 24

The EU proposes the following wording:

Unapproved use of pesticides, ~~and~~ veterinary drugs, feed additives, and processing aids and the presence of other undesirable substances may lead to excessive levels in feed and edible products (e.g. clenbuterol in meat).

Table I of Annex1

The EU suggests **deletion of Table 1** and insertion of the relevant information of the table into the text.

In some places the table contains different information to that in the text. There needs to be a consistent approach.

When incorporating the table in the text, the EU suggests correcting the name of pyrrolizidine alkaloids, and referring to all alkaloids as natural toxins and not as botanical contaminants.

Table 1 and Annex 2, Step 2 on mycotoxins/ aflatoxin

Mycotoxin formation is not only connected to humidity. For example draught plants can be vulnerable to fungi that lead to high concentrations of aflatoxin B₁.

ANNEX 2: EXAMPLES OF THE PRIORITIZATION PROCESS

The text of this annex is confusing. The EU suggests that it should be thoroughly revised. It is difficult to suggest concrete wording at present, however the EU offers the following comments.

There are several fictitious examples proposed and therefore the first sentence should be modified accordingly. If the examples are fictitious then it should not be indicated that the choice is based on surveillance data. If on the contrary, the suggestion is that the procedure should be done taking into account surveillance data, this should be in the body of the text describing the procedure and not only in this annex.

Step 1

The examples proposed seem to refer to localised individual situations (a contamination episode, a particular shipment, an accident) and less to an overall situation of a hazard/feed/edible product combination in a country. It is the likelihood of repeated occurrence of different hazard/feed/edible product combinations affecting food safety that may trigger an established formal risk analysis in order to develop long term control measures. Prioritization seems more relevant in these cases rather than in the case of particular incidents.

The examples should be of a more general nature and not refer to particular incidents.

The text from Annex 2, step 2, should be inserted into the text.

Step 3

The examples of criteria mentioned are not very clear. The definition of the criteria and the figures used to characterise them are also vague.

As indicated above the EU proposes to mention in this annex the criteria in earlier versions of the document as examples i.e. relevance to human health and extent of occurrence.

Criterion 2 is related to defined levels at national level. Such levels often do not exist and their exceedence also does not give an indication of the potential extent of exposure. This alone indicates that the prioritization process as described in this example is much less precise than is implied.

The EU suggests that examples used in this annex should use fictitious values and not values corresponding to existing statutory levels in some countries, or in Codex, in some cases and not in others, as it is the case in the current text. If real figures were to be used then they should be properly identified and referenced and they should be Codex figures.

Step 4

The meaning of the percentages for criterion 2 in the table is not clear.

Additionally, it is not clear how the two criteria are aggregated and where the aggregated figure for each of the cases is located.

Overall, the scores and their aggregation are not clear.

There are references made to literature, but it should be taken into account that the document is intended as guidance for governments and should be understandable not only by specialists.

IRAN

General comments:

Iran supports this document and would like to thank Switzerland for preparing the draft of the guidance for use by governments in prioritizing their national feed hazards.

Specific Comments on paragraphs:

Paragraph 20-line1 - **colon (:)** must be deleted because the rest of the sentence is in the same line.

Paragraph 20- line 4 - We suggest to add **packing** after processing to show the chain entirely.

Paragraph 23 - Due to the impact of international trading on national hazards, It is suggested to add **international** after regional.

Annex 1-parag 5, line5 - Such as parag 20

Annex 1-parag 6, line1 - To make harmonization in given examples, It is suggested to change **Toxoplasma gondii** to **Toxoplasma**.

Annex 1-parag 11, line5 - It is suggested to add **air** to sources of lead.

Annex 1-parag 12, line1- **colon (:)** is needed in the end of line.

Table 1, Raw 'lead' - Adding **fish** and **milk** to edible products..

JAPAN

Japan thanks Switzerland for its excellent work to revise the draft. We support Switzerland's approach to simply provide prioritization process in the main text. .

We provide our specific comments on the draft for further discussion as follows:

SPECIFIC COMMENTS

Please find the following specific comments of which proposed insertion is underlined and proposed deletion is ~~struck-out~~:

Annex 2 EXAMPLE OF THE PRIORITIZATION PROCESS

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

(Proposal)

Delete paragraphs under Criterion 1 and 2. Add new tables to each Criterion.

(Proposed Text)

Criterion 1: Toxicity of the hazard

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

	<u>Biological hazards</u>	<u>Chemical hazards</u>
<u>High</u> (score: 5)	<u>High mortality rate</u>	<u>High severity of the adverse health effect (small toxicological guidance value)</u>
<u>Medium</u> (score: 3)	<u>Medium mortality rate</u>	<u>· Medium severity of the adverse health effect (medium toxicological guidance value)</u> <u>· No information on toxicity of the hazard</u>
<u>Low</u> (score: 1)	<u>Low mortality rate</u>	<u>Low severity of the adverse health effect (large toxicological guidance value)</u>

Criterion 2: Exposure to the hazard

~~Potential extent of occurrence in edible product, measured as percentage of feed samples testing above defined limits at the national level~~

	<u>Biological hazards</u>	<u>Chemical hazards</u>
<u>High</u> (score: 5)	<u>High prevalence in the edible product</u>	<u>High ratio of human dietary intake of the hazard* through the consumption of animal products to the toxicological guidance value</u>
<u>Medium</u> (score: 3)	<u>Medium prevalence in the edible product</u>	<ul style="list-style-type: none"> • <u>Medium ratio of human dietary intake of the hazard* through the consumption of animal products to the toxicological guidance value</u> • <u>No information on toxicological guidance value</u>
<u>Low</u> (score: 1)	<u>Low prevalence in the edible product</u>	<u>Low ratio of human dietary intake of the hazard* through the consumption of animal products to the toxicological guidance value</u>

* The amount of human dietary intake of the hazard may be estimated with four components; concentration of the hazard in feed, intake of the feed by food-producing animal, distribution of the hazard in edible tissues, and human consumption of these edible tissues.

(Rationale)

We propose developing separate scoring criteria for chemical and biological hazards to enable unbiased scoring of biological hazards which have no threshold value due to their proliferation potential.

Step 4. Prioritization

(Proposal)

Replace description of columns for Criterion 1 and 2 with following description.

(Proposed text)

	<u>Criterion 1</u>	<u>Criterion 2</u>
<u>Aflatoxin B1- maize - dairy cow milk</u>	<u>No toxicological guidance value; and highly toxic nature (increasing the potential for liver cancer).</u> <u>Score 5</u>	<u>Medium amount of human intake, but no toxicological guidance value.</u> <u>Score 3</u>
<u>Cadmium - mineral feed ingredient - meat</u>	<u>PTMI 25 µg/kg bw; and medium toxic nature (inducing renal dysfunction).</u> <u>Score 3</u>	<u>Low ratio of human dietary intake of the hazard through the consumption of animal products to PTMI.</u> <u>Score 1</u>
<u>Radiocaesium – forage - sheep meat</u>	<u>No toxicological guidance value to compare with other hazards; and medium toxic nature (damaging cells in human body due to ionizing radiation).</u> <u>Score 3</u>	<u>Medium ratio of human dietary intake of the hazard through the consumption of animal products to the toxicological guidance value.</u> <u>Score 3</u>
<u>Brucella - forage - cow milk</u>	<u>Low mortality rate.</u> <u>Score 1</u>	<u>Low prevalence.</u> <u>Score 1</u>

(Rationale)

To make it consistent with our proposal on step 3 above.

NORWAY

We would like to thank Switzerland and the electronic working group for the good work done on the revised *draft of guidance for governments on prioritizing hazards in feed*. This document has been further improved. Anyhow, we do have a few remarks.

Comments to the Proposed draft guidance for governments on prioritizing hazards in feed:

Specific comments:

Point 26.

We have the opinion that the prioritization process has become too technical. **Instead of ending up with a figure based on the scores on the criteria in step 3, we would recommend to use values as high, medium and low.** In this way it would be less technical and hopefully easier to apply and still be illustrative.

Table 1: Summary examples of potential hazard/feed/edible product combinations:

It is important to ensure that the sentence below table 1, which says “it is important to emphasize that these hazard/feed/edible combinations are illustrative examples and are not exhaustive” should be presented/ highlighted in a way that ensure that the reader will have no doubt on how the table should be interpreted.

Heading definitions

Definitions should be identical in the two documents.

The *document: Proposed draft guidelines on application of risk assessment for feed* seem to be an useful guidance for feed risk assessment by governments in accordance with Codex principles. **We would put in mind that it is important that this document and the document on guidance for governments on prioritizing hazards in feed are using the same definitions and terminology. Otherwise the impression would be inconsistent.**

Specific comment:

The definition of “transfer” in the two documents is not identical at present.

PHILIPPINES

General comments: The Philippines appreciates the work of the electronic Working Group (eWG) led by Switzerland in redrafting the Proposed Draft Guidance for Use by Governments in Prioritizing their National Feed Hazards.

The Philippines supports the Proposed Draft Guidance at Step 3.

Comments on paragraphs:**Appendix I**

Title: Proposed Draft Guidance for ~~Governments on Prioritizing Hazards in Feed~~

Proposed Draft Guidance for **Use by Governments in Prioritizing their National Feed Hazards**

Rationale: This is to be consistent with the revised title of the proposed draft. (Editorial)

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Definitions

Contaminant: ~~Contaminant means~~ any substance not intentionally....

Contaminant: **any substance** not intentionally...

Rationale: This is to be consistent with the format of the other terms defined under the Definitions where the term being defined is not repeated. (Editorial)

Para 8

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

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

Rationale: This is to arrange the components of risk analysis in proper order wherein risk assessment always comes first before risk management. (Editorial)

Annex 2

Example of the Prioritization Process

This ~~fictitious~~ example is intended how to work....

This example is intended how to work....

Rationale: This is to make the text more comprehensible. (Editorial)

UNITED STATES OF AMERICA

Step 4. Prioritization

The United States suggests that further explanation be provided on the process for arriving at the number for criteria 2, and on how the scores from criteria 1 and 2 in annex 2 could be combined. This would help to understand the examples provided in the document.