



**Food and Agriculture  
Organization of  
the United Nations**



**World Health  
Organization**

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**Agenda Item 4**

**CX/AF 12/6/4 Add.3**

**January 2012**

## **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**

**(Revised version)**

**Comments at Step 3 of:**

**Argentina, Canada, Chile, Iran, Japan, Norway, Thailand, United States of America, FAO, IDF, IFIF and OIE**

#### **ARGENTINA**

Argentina would like to congratulate SWITZERLAND for its work performed on this document in the framework of the working group and appreciates the opportunity given to provide the following comments.

#### **GENERAL COMMENTS**

Argentina would like to draw attention to the mandate given for this document, which is SPECIFICALLY focused on RISK ASSESSMENT and its implementation by GOVERNMENTS. To this extent, we consider that the document is not clear enough. Instead, it is ambiguous, since it includes references to documents for implementation within the Codex scope as well as recommendations corresponding to the context of the procedure for the adoption of Codex Standards, but which should not be intended for its implementation by GOVERNMENTS.

On this basis, Argentina considers that it is appropriate to observe the specific MANDATE given for this work, i.e. working on the development of a document for governments. If it is considered appropriate that the document should address other issues, one should examine whether or not they fall within the current mandate; otherwise it should be reviewed during the commission.

Along this line and to avoid future controversies, the scope should be specified in the heading according to the Mandate: "PROPOSED DRAFT GUIDELINES ON APPLICATION OF RISK ASSESSMENT FOR FEED **BY GOVERNMENTS**"

Before establishing if a specific hazard really involves food-safety risks for humans, Argentina would like to highlight the need to consider every factor that must be taken into account when assessing a feed hazard. Otherwise, we will only be building concealed barriers against international commerce, instead of science-based measures.

Argentina notes that, despite this assessment approach, the document confuses aspects of risk management and communication, besides mentioning Codex documents related to these steps, which should be deleted from the draft since they are not within the scope of the mandate.

As regards the specific contents, we understand that the document should provide guidance on the different factors associated with each of the 4 steps of risk assessment (hazard identification, hazard characterization, exposure assessment and risk characterization), which should be considered and quantified when governments make use of these guidelines to consider feed risks on a national basis.

In this sense, the different variables resulting in a specific TRANSFER RATE should be examined when assessing exposure. Regarding this, we consider that they should include, among others: production (farming, cattle breeding, industrial activities, etc.) and handling practices, the Chemistry and/or Biology of the risks involved, pharmacokinetics and pharmacodynamics (in the case of chemical hazards), the animal species and category involved, the type of animal production system, the specific tissue which will become a foodstuff for human consumption, etc. Processes by which raw materials and ingredients will be processed before becoming a commodity intended for human consumption. We would also like to point out that there is a notorious difference in this process between the evaluation of a "feed" and that of a "feed ingredient" when it refers to the exposure level they can represent.

Once again we understand that this document, on evaluating risk assessment, should focus on specific risk assessments for particular hazards in 1 or more feed, consumed by a specific animal species/category (produced in a specific way), and in terms of how it specifically creates a food risk by way of edible tissue for human consumption.

Finally, Argentina would like to highlight the relevance of the review of the SPANISH text translation, since it has led to an important set of mistakes regarding the interpretation of the contents of the issue. Along these lines, and understanding the importance of references in each paragraph or definition on the source of the proposed text, Argentina considers that, once a consensus on the final text is reached, certain references to other Codex documents should be deleted.

Argentina considers this document to be of major relevance in terms of the extent the text should have to refer to multiple variables associated with the different risks that may be present in feed, and therefore we consider it is essential to perform an overall approach of each of the risk assessment stages which effectively guide governments in the evaluation procedure.

## **SPECIFIC COMMENTS**

### **PARAGRAPH 2**

Argentina considers that, since this document is focused on feed risk assessments of hazards linked to food safety in commodities intended for human consumption, the second sentence would not be applicable, and suggests its complete deletion. Finally, we consider that this paragraph should be in line with the specific consideration of feed hazards scientifically associated with the safety of food intended for human consumption, creating a risk for consumers.

Suggested changes are:

*"This guideline should enable risk assessment of hazards in feed based upon local conditions, considering the impact, if any, **on food safety for human consumption, and for consumer health.** If any, on human". It should also enable international comparability of feed risk assessments, thereby promoting fair practices in food trade.*

### **PARAGRAPH 4**

Argentina considers that this paragraph lists a set of reference documents that are not necessarily related to "risk assessment as applied by governments". In this sense, we suggest the elimination of all references to risk management documents applied within the scope of CODEX.

On the other hand, Argentina reiterates its position of not including FAO/WHO documents that are not cited in the body of the document. As a compromise, these texts might be added at the end of the document as consulted literature.

Suggested changes are:

4. These guidelines should be read in conjunction with the:

- Code of Practice on Good Animal Feeding (CAC/RCP 54-2004).

~~—Codex Alimentarius Commission: Procedural Manual, in particular Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius; Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods; Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues; and Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods~~

- Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)

~~—Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007)~~

- Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77-2011)

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

### **Bibliographic references.**

as well as

- Food safety risk analysis: A guide for national safety authorities. FAO Food and Nutrition Paper 87. World Health Organization (WHO), Food and Agriculture Organization of the United Nations (FAO), Roma, 2006, (<ftp://ftp.fao.org/docrep/fao/010/a0822s/a0822s.pdf>)

- the WHO Principles and Methods for the Risk Assessment of Chemicals in Food. WHO IPCS Environmental Health Criteria 240. WHO, Geneva, 2009. ISBN 978 92 4 157240 8 (<http://whqlibdoc.who.int/ehc/>)

- the WHO Human Health Risk Assessment Toolkit: Chemical Hazards. IPCS Harmonization Project Document No. 8. WHO, Geneva, 2010. ISBN 978 92 4 154807 6. (<http://www.who.int/entity/ipcs/publications/methods/harmonization/toolkit.pdf>)

*and relevant sections of*

- the FAO/WHO Expert Meeting report on Animal Feed Impact on Food Safety. FAO/WHO, Rome, 2008. ISBN 978-92-5-105902-9. (<ftp://ftp.fao.org/docrep/fao/010/a1507e/a1507e00.pdf>)

- the OIE Terrestrial Animal Health Code (<http://www.oie.int/es/normas-internacionales/codigo-terrestre/acceso-en-linea/>)

- the FAO Good Practices for the Feed Industry. - the FAO Good Practices for the Feed Industry. FAO/IFIF, Rome, 2010. ISBN 978-92-5-106487-0. (<http://www.fao.org/docrep/012/i1379e/i1379e00.htm>)

## PARAGRAPH 5

Regarding the SPANISH TEXT, there are translation mistakes that should be corrected. Argentina considers that, where it reads "alimentos", it should read "piensos", as well as the elimination of "para los métodos de", to be consistent with the English text.

Correspondingly, the reference made to the Code of Practice on Good Animal Feeding is redundant considering the reference already provided in PARAGRAPH 4, and therefore we suggest its elimination. Finally, we consider that the incorporation of a reference to its implementation by governments is essential.

5. *These guidelines provide guidance for governments on risk assessment methods for feed ingredients and feed including feed additives and water. ~~as defined in the Code of Practice on Good Animal Feeding (CAC/RCP 54/2004).~~*

## PARAGRAPH 6

We suggest the following wording for a better understanding of the text, as we understand there is no need to define or clarify the interpretation of "hazard", since it is defined in the DEFINITIONS section.

6. *This guideline is applicable to all hazards in feed. "Hazard" refers to any agent which may be transferred through food of animal origin and may adversely affect human health in relation to food safety. ~~adversely affect human health.~~*

## PARAGRAPH 8

### For SPANISH version

The following correction is suggested:

8. *These guidelines consider only exposure of food-producing animals to hazards in feed. ~~Also~~ On the other hand, direct human exposure to hazards ~~risks~~ in feed, for example occupational exposure during feed production and processing, is not considered.*

## PARAGRAPH 9

### DEFINITIONS

Argentina considers that there is no need to incorporate the explanation in brackets about the source of definitions.

Argentina considers it necessary to incorporate a "HAZARD IDENTIFICATION" definition, which is mentioned in Risk Assessment, as well as a definition of "CARRY-OVER".

## PARAGRAPH 10

The SPANISH text contains a mistake, where it reads "risk assessment", it should read "Risk Analysis".

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

## PARAGRAPH 11

Argentina considers that references to paragraph 4 are repeated, and therefore suggests the total removal of this paragraph.

## PARAGRAPH 12

Argentina understands that hazard identification should consider hazards present in edible tissues **and** feed, since this document should consider the hazards eventually present in both of them. In this sense, the following editorial change is suggested:

12. *A risk assessment is commissioned by the risk manager. Preliminary risk management activities include identification of a safety problem in ~~food~~ edible tissues and feed; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; determination of a risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.*

## PARAGRAPHS 14 AND 15

Argentina considers that these paragraphs correspond to a specific scope of application of the CODEX, and not that of this document, and therefore suggests the complete elimination of the text.

## PARAGRAPH 16

Argentina considers that the paragraph is not related to the guidance to governments nor does it provide information about the procedure. In this regard, Argentina suggests its DELETION.

## PARAGRAPH 19

Argentina considers that the mandate of the Task Force and the scope of this document must be clarified before definitively adopting this paragraph.

The paragraph would be appropriate, in our view, if the scope of the document is broad; otherwise, if this document is intended for the sole use of governments and only refers to the evaluation stage, this paragraph should be modified and the reference to the Codex Procedural Manual considered inappropriate, thus suggesting the following change:

*19. Risk assessment should **preferably** be conducted in accordance with the **principles established by the Codex Alimentarius Commission for application by governments** "~~Codex Alimentarius Commission Procedural Manual: Statements of Principle Relating to the Role of Food Safety Risk Assessment~~ and should incorporate the four steps of the risk assessment, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.*

## PARAGRAPH 21

Argentina would like to highlight the translation of the word "ASSUMPTIONS" from the English text, since the right translation would be "HIPÓTESIS", in consistence with the Codex Manual.

## PARAGRAPH 24

Argentina does not agree with the inclusion of all this information in the text of a document on risk evaluation. Particularly as this information is not included in other Codex documents.

In addition, the SPANISH text does not reflect that which is expressed in the ENGLISH version.

## PARAGRAPH 28

References to other Codex texts may be deleted without altering the interpretation of the text, understanding that the first one is already referred to, and the second one is not related to the text of this paragraph:

*28. Consideration should be given to the source of feed ingredients, and the potential for introduction of hazards during their manufacture. Many feed ingredients are produced as by-products from other production processes, e.g., distillers' grains from the production of biofuel, etc. ~~In accordance with the Code Of Practice on Good Animal Feeding (CAC/RCP 54 2004),~~ Feed ingredients should be obtained from safe sources and be subject to a risk analysis where the ingredients are derived from processes or technologies not hitherto evaluated from a food safety point of view. ~~The procedure used should be consistent with the Codex Alimentarius Commission Procedural Manual: Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.~~*

## PARAGRAPH 30

Argentina thinks that the management stage is dealt with in this paragraph, whereas the document refers to evaluation. In addition, we consider that a change in wording is needed:

*30. If inadequate data are available to characterize a hazard in feed, ~~it may be necessary to consider generating such data~~ the risk manager may ~~request action at national level or~~ **consider the risk prioritisation request** to the appropriate Codex Committee.*

## PARAGRAPH 31

Argentina considers that the Table contains translation errors, as described below. In addition, only the word "FEED" is left in the first column, previously defined, while in the "Exposure Assessment Method" column, the first point is deleted for being considered redundant, and a discussion of «biological models" is added, since otherwise only chemical hazards are taken into consideration. In addition, text has been added in the last column for better clarity and interpretation.

Hazard identification in:	Exposure assessment method	Endpoint Findings of risk assessment assessment
Feed of food-producing animal	<ul style="list-style-type: none"> <li>○ Identify all feeds which may contribute to intake of a given hazard, based on hazard identification.</li> <li>○ Calculate <del>hazard</del> hazardous substances intake from of all relevant feed sources, based on information from animal feeding specialists.</li> <li>○ Use toxicokinetic <u>or biological</u> measurements/modelling to calculate <u>transfer rate</u> <del>transfer rate</del> to calculate relative hazard concentration in feed and edible products.</li> </ul>	<p><b>Hazard</b> <del>hazardous substances</del> concentration in edible products (e.g. mg/kg product) <u>due to its presence in feed.</u></p>

### PARAGRAPH 32

We consider that some examples and references should be deleted, as they do not provide clarity to the text. In addition, reference to JECFA and JMPR is inappropriate in this paragraph, as they refer to food assessments, but not to feed assessments. Finally, translation mistakes have been found, for which we suggest the following changes:

*32. Human exposure assessment is done during risk assessment for foods. This requires modelling of dietary intake of relevant foods and food groups by specified human groups; see for example ~~Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (Codex Procedural Manual). The results of such assessments are considered in setting limits for hazards~~ are considered in the setting of national limits for hazards in food, such as can be maximum limits or levels and maximum residue levels, national or Codex maximum limits or levels, e.g. the Codex General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995). Details of the exposure assessments are given in published reports by the risk assessor (e.g. JECFA, <http://www.who.int/foodsafety/chem/jecfa/publications/en/>; JMPR, <http://www.who.int/foodsafety/chem/jmpr/en/>). Transfer rates Transfer rate from feed to edible products should be considered based on the specific hazard. ~~Are considered in risk assessment by JECFA when evaluating veterinary drugs and by JMPR when evaluating pesticides used in food producing animals.~~*

### PARAGRAPH 34

Argentina would like to declare its reservations concerning the text presented, as it is difficult to interpret that the knowledge of the levels in feed and edible products could allow one to derive, on a scientific basis, that there is a direct correlation that allows the transfer rate to be defined.

In this sense, uncertainties associated with the true causality which could be ascribed to levels in a particular edible product give rise to questions on the presence of a specific risk level in a feed or feed group.

Argentina suggests deleting the whole paragraph.

### NEW PARAGRAPH 34

Argentina would like to propose for consideration the addition of a new paragraph 34 which would take into account the difference between assessing a "feed" and assessing a "feed ingredient". Regarding this, Argentina suggests the following text:

**34. When performing an Exposure Assessment, differences in specific hazard exposure levels between its presence in feed and its presence in a specific feed ingredient should be taken into account.**

### PARAGRAPH 35

Argentina considers that there are other questions to be considered in relation to TRANSFER RATE, when CHEMICAL and BIOLOGICAL hazards are considered. In this sense, we suggest that, if applicable, Production Practices (farming, animal, industrial, etc.) and biology of micro-organism involved, amongst others, should be taken into consideration. Specifically:

35. ~~Factors~~ Questions which will influence the transfer rate from feed to edible product include:

- The physical-chemical characteristics of the hazard, e.g. pKa/pKb, log Kow, water solubility, and chemical and thermal stability.

- Kinetics of the hazard in the food-producing animal, including systemic absorption, metabolism (including generation of hazardous metabolites), distribution and accumulation potential of hazard in body compartments, and extent of transfer of hazard to edible products.

**- Production Practices (farming, animal, industrial) and feed handling; and**

**- Biology of micro-organism involved.**

**PARAGRAPH 38**

Argentina considers that the text does not allow a clear interpretation, and we suggest the following correction:

38. The edible product **involved in exposure assessment** should be defined as precisely as possible (e.g. ~~for~~ **bovine animal fats**).

**PARAGRAPH 39**

Argentina considers that sampling and analysis issues lie within the area of risk management, which is beyond the scope of this text, and therefore we suggest the deletion of the whole text.

**PARAGRAPH 45**

As in PARAGRAPH 21, Argentina would highlight the word "assumptions" in the English text and propose it to be translated in the Spanish version as "HIPÓTESIS", term also coined in the Codex Procedural Manual.

**CANADA****General Comments**

Canada would like to thank the Secretariat for the revision to the draft document. The new version reflects to a large extent the comments received, and hence results in an improved document.

The revised text, while being more concise, has lost some important information for a feed risk assessment perspective. Namely, Canada believes that some information regarding a semi-quantitative or qualitative approach should be re-incorporated in the document. During a feed risk assessment process, there is often insufficient scientific data to conduct a full quantitative risk assessment. A form of a semi-quantitative or qualitative risk assessment may be necessary in these circumstances.

**Specific Comments****Section - Introduction****Paragraph 4:**

Canada notes that the listing of the reference documents in this paragraph is to a large extent a duplication of the enumeration of the same texts as outlined further in the document (e.g. in paragraphs 11, 16). A discussion should be held as to the most appropriate location for the enumeration of these reference texts, while avoiding duplication.

**Section - Hazard Characterization****Paragraph 29**

“... and/or in the scientific literature.”

We suggest this latter statement be modified as follows: “... **and/or in the peer-reviewed scientific literature.**”

***Justification:***

The use of peer-reviewed data provides more valid scientific support to the assessment.

**Section - Exposure Assessment****Paragraph 31**

Canada questions the appropriateness of this information to be contained in a table format, while other related paragraphs are not. Hence, we would suggest providing a text version of the content broken down into the 3 steps.

In addition, for the third endpoint in the table “Endpoint of risk assessment”, we suggest it be changed to “Endpoint of feed exposure”

**Paragraph 32**

Canada suggests moving this paragraph to the end of this section as it relates to the human exposure assessment which should follow the feed exposure assessment step.

In addition, we suggest the following modification to the last line of this section:

“Transfer rates from feed to edible products are **usually** considered ... in food producing animals **at approved use rates and for approved species only.**”

***Justification:*** This may not be applicable for non-target species or for low-dose extrapolation exposures in contamination situations.

**Paragraph 33**

We suggest the following changes to the paragraph as follows:

“Feed exposure assessment is ~~best carried out~~ **most accurate when** using monitoring data of hazard levels in feed and edible product **as available.**”

**Paragraph 34**

The numbering system for the second paragraph is off and should be renumbered as a new paragraph.

7. Paragraph - - Factors which .....

**Paragraph 35**

The numbering system for the second paragraph is off and should be renumbered as a new paragraph.

“8. Paragraph -. If animal feeding studies are considered ...”

**Paragraph 36 (bis)**

Consistent with our previous remark under General comments, Canada is of the view that a new paragraph should be added in this section to consider when transfer data is not available. Hence, the following insertion is proposed:

**Paragraph 36 (bis)**

**In the event that the transfer rates from feed to food are unavailable, a semi-quantitative or qualitative risk assessment approach may be useful in assessing the potential food safety risk. A determination of negligible risk would reduce the need to generate further quantitative data.**

Section - Risk Characterization

**Paragraph 40**

Canada suggests the insertion of a new paragraph to follow paragraph 40 to discuss the options to be considered when there is no established international or national standard for the hazard under consideration in food. At this point, we are of the view that a food risk assessment should be undertaken to determine the safety of this hazard to human health. Hence, we suggest the following paragraph be added:

**Paragraph 40 (bis)**

**In the event when there is no international or national standard in food for a feed-derived residue in foodstuff of animal origin under consideration, a food risk assessment would be required to determine the acceptability of the edible products for human consumption.**

**CHILE****a) General comments**

In general terms, the document is endorsed, with some specific observations that will be indicated.

**b) Specific Comments****Comment 1.****SCOPE**

It is understood that bee feed and its sub-products are included in these guidelines.

**Comment 2.****INTRODUCTION**

Paragraph 4 This guideline should be read in conjunction with the:

- **Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)**

Rationale: These Guidelines should be referred to at the end of the Codex texts, taking into account that one of the objectives of the Proposed Draft is to provide Governments with guidelines to perform the assessments of feed risks, and therefore it is suggested to add them in Paragraph 4.

**Comment 3.****FOOD RISK ASSESSMENT PROCEDURE**

Paragraph 16 Add after "*Codex Alimentarius Commission Procedural Manual: Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*" and **Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)**.

Rationale: The aim is to provide Governments with guidelines.

**Comment 4.**

Paragraph 18 A sentence not relevant for each Government procedure in performing a risk evaluation is included at the end of Paragraph 18. Therefore, its deletion is proposed, leaving the text as follows:

"Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise, experience, and independence with regard to the interests involved. The procedures used to select these experts should be documented including a public declaration of any potential conflict of interest. This declaration should also identify and detail their individual expertise, experience and independence. ~~Expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from developing countries.~~"

Rationale: It is not applicable to Government procedures.

**IRAN****General comments:****Iran supports this document****Comments on paragraphs:**

Paragraph 9-contaminants

Storage is missing but It is expressed in other parts such as parag 27. We suggest to add **storage** to definition of contaminant: ,.....preparation, treatment, **storage**,.....

Paragraph 20

Omit **'may'** in the 2nd line because both quantitative and qualitative info should take into account. Also, qualitative info is discussed in para. 21.

Paragraph 27, line2

Spelling of **local** should be edited.

Paragraph 27, line 3

Add **Planting** : ....during **planting**, growth,.....

Paragraph 30

We are object to this para. We suggest to change it as: **30- To characterize a hazard in feed, It is necessary to have adequate data. The risk manager may....**

**JAPAN****General Comments**

Japan appreciates Switzerland's efforts in preparing the revised version of draft and opportunity to comment on this draft. We are supportive of this well-drafted document ensuring consistency with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius and taking the provision of "risk assessment should use available quantitative information to the greatest extent possible" into account.

We would like to provide specific comments as follows:

**Specific Comments****(p 4) DEFINITIONS**

Contaminant

Japan notices that the definition of "Contaminant" is currently under discussion in the electronic working group on Risk Analysis Principles of the CCCF and it would be considered in the forthcoming CCCF. We suggest that the definition should be consistent with the result of the discussion in the CCCF.



## NORWAY

Norwegian response to Proposed Draft Guidelines on application of Risk Assessment for feed CX/AF 12/6/4 Add. 2 and Proposed Draft Prioritised list of Hazards CX/AF 12/6/5 Add.2.

We appreciate this opportunity to comment upon the two proposed drafts. We would like to thank Switzerland, and congratulate the working group for the good work on both the revised drafts.

Norway is of the opinion that a whole food chain approach (from farm/fiord to fork) is of great importance.

The Guidelines on application of risk assessment for feed provides a framework for governments to address the risks to human health associated with the presence in animal feed. The guidelines as presented in the revised draft document are improved. The revised document is more clear and consistent compared to the first version of the guidelines.

Regarding the revised Prioritized list of hazards, this version is also an improved document compared to the first proposed draft. This document appears more consistent and simplified.

We think that the two proposed draft documents will form a good basis for the discussions at the meeting in Berne in February.

## THAILAND

Thailand appreciated the opportunity to provide the following comments on CX/AF 12/6/4-Add.2

Definition; The term “Feed”

The inclusion of water in the definition of feed in the last sentence (“In this guideline, includes water”) can cause problem in implementation since risk assessment of feed is different from risk assessment of water. Furthermore, risk assessment of water was not detailed in the section of exposure assessment of this draft guideline. Therefore, we proposed that the last sentence on the inclusion of water should be deleted. However, if the last sentence is retained, the content of risk assessment of water should be added in the separated sub section.

### Hazard Identification

- Para 25 and 26 addressed sampling protocols and analytical laboratory methods respectively by using scientifically recognized principles and procedure accordance with the Codex Procedure Manual. As data used in hazard identification step can be collected from multiple sources, para 25 and 26 should be deleted or moved to other appropriate step. We suggest, for this step, a more general text such as “Risk assessor should review scientific literature and information e.g. from surveillance programs to identify specific hazard that may pose risk in feed to edible product.”

### Hazard characterization

We are of the opinion that the hazard characterization step should be rewritten to be clearly detail on how to characterize a hazard in feed and what is hazard characterization in feed.

### Exposure assessment and Risk characterization

We recognized that both Exposure assessment and Risk characterization steps are important particularly for feed risk assessment.

We are of the opinion that the contents should be revised to addressed on a step-by-step basis which is easier to follow for users of the document.

Para 32: The transfer rates from feed to edible products related to veterinary drugs and pesticide have been mentioned. We are of the opinion that transfer rates related to contaminant which are also important is missing. Therefore we would like to propose the following addition to the end of the sentence as follows:

“Transfer rates related to contaminants are considered by JECFA when evaluating contaminants in feed for food producing animals”

Para 41: We would like to modify the sentence as follows;

“the output of a feed risk characterization and, it appropriate a risk estimate, are defined by the risk manager in advance during establishing risk assessment policy”

Para 42: The sentence with the word “for example” at the beginning of the sentence can be misinterpreted by the users of the document. The paragraph should start by explaining in general what the outcome of the risk estimate should be then followed by some examples (can be more than one) of the risk estimates.

## UNITED STATES OF AMERICA

The United States appreciates the consideration of the previous comments submitted on the Proposed Draft Guidelines on Application of Risk Assessment for Feed, as well as the continued open, transparent and constructive manner in which this process has been conducted.

### I. SPECIFIC COMMENTS

The United States proposes the following revisions for the Task Force consideration:

#### DEFINITIONS

**Feed Additive:** (Micro-organism, enzymes, acidity, regulators, trace elements, vitamins, and other products **excluding veterinary drugs**....)

Rationale: Veterinary drugs are not included within the definition of feed additives. In addition, all actions related to veterinary drugs are the responsibility of the Codex Committee on Residues of Veterinary Drugs in Food.

**Feed ingredient:** Ingredients are of plant or animal ~~or aquatic origin~~....

Rationale: This is redundant since an ingredient of aquatic origin is either a plant or animal.

#### RISK ANALYSIS IN THE FRAMEWORK OF A CODEX RISK ANALYSIS

#### RISK ASSESSMENT PROCEDURE

##### Paragraph 13

Add to second sentence as follows:

This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased, **and transparent and documented**.

Rationale: This is an appropriate step that should be added.

**Paragraph 19:** Please consider the following addition:

... Food Safety Risk Assessment and should **follow a structured approach incorporating** the four steps of the risk assessment, ....

Rationale: This addition further ensures that the proper procedure is performed.

**Paragraph 21:** Please add to second sentence:

... but should be qualified **and documented** to the extent that is scientifically achievable.

Rationale: This is an appropriate and necessary step for conducting a risk assessment. It is also consistent with the previous statement of the same paragraph.

#### Hazard identification

**Paragraph 22:** 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, and **chemical agents (dioxins and PCBs, and excessive levels of pesticides, veterinary drugs)** and additives (as well as certain of their residues). “

Rationale: This suggested change is editorial and improves the parallelism of this sentence.

#### Exposure Assessment

**Paragraph 32:** We suggest the following revision.

This guideline provides general principles and guidance for feed risk assessment by governments in accordance with Codex principles. **The assessments would form the basis for controlling hazards in feeds so as to assure that the hazards that may be transferred to edible products of animals are within levels that are protective of human health, such as Codex Maximum Limits, or national standards in the absence of Codex standards.** ~~It addresses the potential risks to human health associated with the presence of hazards in the feed of food-producing animals, and the transfer of hazard to edible products.~~

Rationale: The original statement says that JECFA would use the transfer rates whereas paragraph 1 states that these are for use by governments as opposed to JECFA. Our proposed language makes it clearer who is the intended user of these feed evaluations.

**Paragraph 33:** Please change as noted and move to Paragraph 31 (thus renumbering the balance of document, making the focus and direction of this document much stronger).

Feed e **Exposure** assessment should best carried out using use quantitative and surveillance data of hazard levels in feed and edible products.

**Rationale:** this suggested change is more precise.

**Paragraph 7:** pkA, pKB and Kow should be defined.

**Rationale:** Definitions are necessary for further understanding.

**Paragraphs 7 & 8:** the numbering should be corrected in sequence between present paragraphs 34 and 36

**Rationale:** this is an editorial change.

Thank you for the opportunity to provide these comments.

## FAO

### (i) General comments

The value of having guidance for risk assessment in animal feed is recognized and it is good to now have a base document from which to develop this work. In this regard the work of Switzerland to date is to be commended.

The document recognized the numerous sources of information on risk assessment which already exist although the way in which references are included in the section on Risk Assessment in the Codex Alimentarius Framework makes reading of the document a bit heavy. Perhaps the title could be retained in the text and the more detailed information regarding the publication place, date, where to find the document etc be included in a footnote or a list at the end. While some of the elements specific to risk assessment of feed have been addressed such as transfer rate there is probably a need to highlight other specificities in relation to feed. Also perhaps it should be noted that assessment of hazards in feed may not be undertaken in isolation but could be a component of a broader risk assessment and reminding countries not to forget this important aspect of the pathway when undertaking Risk Assessments.

The section on exposure assessment focuses primarily on chemical hazards and the guidance provided specifically relates to chemical hazards. This may or may not be relevant to microbiological hazards and therefore some effort should be made to ensure that it is clear for governments which parts are relevant when assessing biological vs chemical hazards. At the same time, it should be noted that adequate attention should also be given to biological and physical hazards, including radionuclides.

Table 3.1 is very much focused on chemical hazards rather than biological hazards. As the nature of the hazards means that there are some differences in approaches used for biological hazards compared to chemical hazards then this should be reflected in any table which is included or the table only included as an example of the approach that can be taken for some of the hazards found in animal feed. As per the general comment, it should be noted that adequate attention should also be given to biological and physical hazards, including radionuclides.

### (ii) Specific comments

Section	Para	Proposed Amendment	Rationale
Introduction	1	It addresses the potential risks to human health associated with the presence of hazards in the feed of food-producing animals, and the transfer of <u>such</u> hazards to edible products.	Clarity of language
	4 – bullet 7	the <del>WHO/FAO/WHO</del> food safety risk analysis guide for national authorities (Food safety risk analysis: A guide for national safety authorities. FAO Food and Nutrition Paper 87. <del>WHO/FAO/WHO</del> , Rome 2006.	Organizations are listed in alphabetical order in joint publications
	4 – after bullet 7	FAO/WHO. Hazard characterization for pathogens in food and water: Guidelines. Microbiological risk Assessment Series 3. 2003. Available at <a href="ftp://ftp.fao.org/docrep/fao/006/y4666E/y4666E00.pdf">ftp://ftp.fao.org/docrep/fao/006/y4666E/y4666E00.pdf</a> FAO/WHO. Exposure assessment of microbiological hazards in food: Guidelines. Microbiological risk Assessment Series 7. 2008. Available at <a href="http://www.fao.org/docrep/010/a0251e/a0251e00.htm">http://www.fao.org/docrep/010/a0251e/a0251e00.htm</a> FAO/WHO. Risk characterization of microbiological hazards in food: Guidelines. Microbiological risk Assessment Series 17. 2009. Available at <a href="http://www.fao.org/docrep/012/i1134e/i1134e00.pdf">http://www.fao.org/docrep/012/i1134e/i1134e00.pdf</a>	As these guidelines also refer to microbiological hazards in feed we would also like to suggest the inclusion of three FAO/WHO publications which provide more detailed guidance to countries when undertaking microbiological risk assessment.

Section	Para	Proposed Amendment	Rationale
	9 -	It should be noted that the definition of “transfer”, does not apply for microorganisms	
Scope	7	Agents which may adversely affect animal health <u>and welfare</u> but ...	
Risk Assessment in the Codex Risk analysis framework	11 after bullet 4	the <del>WHO/FAO/WHO</del> food safety risk analysis guide for national authorities (Food safety risk analysis: A guide for national safety authorities. FAO Food and Nutrition Paper 87. <del>WHO/FAO/WHO</del> , Rome 2006.	Organizations are listed in alphabetical order in joint publications
	12	A risk assessment is commissioned by the risk manager. Preliminary risk management activities include identification of a safety problem in food or feed; establishment of a risk profile; developing a specific question(s) and/or charge for the risk assessment team, ranking of the ....	This addition is a critical piece in the whole risk assessment process and should be added in somewhere. Also, the way the text is written implies that all these activities need to be done. A risk profile, for example, is not necessarily needed in all situations.
Risk assessment guidance	14	As described in the FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition ( <del>World Health Organization</del> —FAO/WHO, Rome, 2007. ISBN 978-92-5-105807-7; <a href="ftp://ftp.fao.org/docrep/fao/010/a1296e/a1296e00.pdf">ftp://ftp.fao.org/docrep/fao/010/a1296e/a1296e00.pdf</a> ),	Correction of reference
	14	....governments and industry by the Joint FAO/WHO Expert Committee on Food Additives, <del>Contaminants and Veterinary Drugs</del> (JECFA), the ....	While JECFA covers contaminants and veterinary drugs these are not included in the title.
	14	<del>JECFA and JMPR These expert groups assess hazard and exposure to hazards and use this together with a characterization of the hazard or dose -response</del> to establish the amount of a given hazard which may safely be present in a given food. Risk assessments undertaken by JEMRA assess the risk associated with particular hazards in specified commodities and can provide relative estimates of risk for a range of scenarios.	The outputs of JEMRA are somewhat different to JECFA and JMPR as MRLs or ADIs are not established although a dose-response is developed. The presence of one organism may be considered adequate to cause infection and or illness. While MC, PC, POs, FSOs their objective is to minimize risk rather than act a bright line below which one can say there is no risk.
	15	<u>Overarching Guidance on microbiological risk assessment is given in the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999); while more detailed guidance can be found in volumes 3, 7 and 17 of the FAO/WHO Microbiological Risk Assessment Series. These guidelines were developed to provide guidance to JEMRA and FAO/WHO member countries on undertaking microbiological</u>	

Section	Para	Proposed Amendment	Rationale
		<u>risk assessment.</u>	
	18	Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise, experience, and their independence with regard to the interests involved. The procedures used to select these experts should be documented including a public declaration of any potential conflict of interest. This declaration should also identify and detail their individual expertise, experience and independence. <del>Expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from developing countries.</del>	While this last sentence is very relevant for international risk assessment work it might be too restrictive and may not always be necessary (e.g. if feed is produced domestically) for national governments for whom these guidelines are intended
	20	Risk assessments should be based on all available scientific data, whether qualitative or quantitative. When both are available, quantitative data should be used preferentially.	Clarity of language
	21	Hazards in feed can include biological agents (viruses, bacteria, endoparasites and prions), chemical agents (such as heavy metals, aflatoxins, dioxins, pesticides and veterinary drugs residues beyond their MRLs) and physical agents, including radionuclides.	Clarity of language and definitions. See DEFINITIONS
	25	<del>i) It should be ensured that</del> It is recommended that feed sampling protocols ..... ii) The sampling plan for hazard identification should take into consideration possible <del>inhomogeneous</del> <u>heterogenous</u> distribution of the hazard, based on all relevant factors. OR The sampling plan for hazard identification should take into consideration possible <del>inhomogeneous</del> random distribution of the hazard, based on all relevant factors.	Clarity of language
	26	Please note that the Codex Alimentarius Commission Procedural Manual: General Criteria for the Selection of Methods of Analysis Using the Criteria Approach, is rarely, if ever, used by microbiologists.	General Comment.
	29	Information on characterization of specific hazards may be obtained in international reports and monographs from bodies including JECFA (Joint FAO/WHO Expert Committee on Food Additives; <a href="http://www.who.int/foodsafety/chem/jecfa/publications/en/">http://www.who.int/foodsafety/chem/jecfa/publications/en/</a> and <a href="http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/">http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/</a> ), JMPR (Joint FAO/WHO Meeting on Pesticide Residues; <a href="http://www.who.int/foodsafety/chem/jmpr/en/">http://www.who.int/foodsafety/chem/jmpr/en/</a> and <a href="http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/en/">http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/en/</a> ), JEMRA (Joint FAO/WHO expert meetings on microbiological risk assessment; <a href="http://www.who.int/foodsafety/micro/jemra/en/">http://www.who.int/foodsafety/micro/jemra/en/</a> and <a href="http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/">http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/</a> ), the WHO International Programme on Chemical Safety (IPCS, <a href="http://www.inchem.org/">http://www.inchem.org/</a> ), WHO Concise International Chemical Assessment Documents (CICAD; <a href="http://www.who.int/ipcs/publications/cicad/">http://www.who.int/ipcs/publications/cicad/</a> ), and/or in the scientific literature.	JECFA, JEMRA and JMPR have websites at FAO as well as WHO. These have been added here as sometimes the distribution of tasks may mean that the there is some additional information on these sites not covered by the WHO one and vice versa
	31	Under Exposure assessment method, add the following text: Use the latest microbiological methods to determine the	

Section	Para	Proposed Amendment	Rationale
		prevalence and/or levels of the microbial hazard in feed and edible product.  Under Endpoint of risk assessment, add the following text:  Microbial hazard in edible product (cfu/g or ml).	
	34	If the amount of a given chemical hazard in feed and edible product is known, then it is possible to derive the transfer rate for the given hazard. In general, if any two of these three variables (hazard level in feed, transfer rate, and hazard level in edible product) is known, the third can be derived.	To clarify that this does not apply to microbial hazards.
	42	A risk estimate could be, for example, that a certain prevalence of a microorganism in a feed will result in an infected animal, which will then lead to a contaminated foodstuff, or an estimate of the probability that a given concentration of hazard in feed will result in a concentration in edible products which, for example, exceeds the Codex Maximum Level for a contaminant or a Codex Maximum Limit for residues of pesticides or veterinary drugs (MRL), or a similar national standard.	To try and add more microbiological examples to the Guidelines.

## IDF

### General:

We note that the two guidelines overlap to a great extent.

The proposed draft prioritized list of hazards in feed appears to attempt to give detailed information on specific hazards rather than providing general principles and guidance as indicated in the Introduction and Scope. It would be more appropriate to take a higher level category approach than attempt to provide an exhaustive list which is incomplete and where the hazard in feed may have different significance both epidemiologically and internationally. A detailed approach may be difficult to keep up to date and maintain relevance.

### Specific comments on CX/AF 12/6/4 Add.2

#### Para 9 - definition of "contaminants"

The definition of contaminants should include "agents"

**Contaminant:** Contaminant means any substance **or agent** not intentionally added to food

#### Para 9 - definition of "risk"

The statement added to the established definition does not seem to be correct and should be deleted. Risk does not refer to the probability of transfer to food. The addition makes the understanding ambiguous. Probability of transfer is related to prevalence (likelihood/frequency of occurrence), but is not the same as likelihood of adverse health effect.

**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 guideline, 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.~~

#### Para 24 - hazard identification

The use of the word "identification" in this paragraph is not meaningful. Use "occurrence" or "prevalence" instead.

24. Useful information on hazard **occurrence** ~~identification~~ may be obtained from regulatory surveillance samples and investigative work, published data from government agencies, and from international programs such as the WHO Global Environment Monitoring System (GEMS/Food ;<http://www.who.int/foodsafety/chem/gems/en/>), and the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN; [http://www.who.int/foodsafety/fs\\_management/infosan/en/](http://www.who.int/foodsafety/fs_management/infosan/en/)).

#### Para. 38 – risk characterization

Since both feed exposure assessment and human exposure assessment are used in this document, the assessment mentioned here should be qualified as "human".

38. Risk characterization considers the key findings from hazard characterization and human exposure assessment to estimate the risk.

## **IFIF**

### **I. General Comments:**

The International Feed Industry Federation (IFIF) appreciates the consideration of previous comments submitted, as well as the continued open, transparent and constructive manner in which this process has been conducted. We believe the overall presentation of the documents has improved and the core part of the working documents has been well written and thought through.

As we prepare to convene the Task Force meeting, we believe there is an opportunity to improve the introduction section and the preamble by setting out more clearly the main objectives of the two working documents with regard to responding to the terms of reference.

The draft guidance documents could become more user-friendly by introducing further specific guidance notes to feed safety risk assessors and risk managers. The bibliographic references to existing CODEX standards are useful but not always practical, as they are not necessarily familiar references for feed safety risk assessors and do not include feed safety specific references important to feed safety risk assessors. We would in particular recommend considering using the guidance approach set out in the WHO/FAO food safety risk analysis guide for national safety authorities (Food safety risk analysis: a guide for national authorities) as a highly useful “template” to introduce more specific guidance notes into the present draft working documents.

As a concrete example illustrating the need for further specific feed safety guidance, IFIF draws particular attention that the current guideline on prioritized feed hazards is focused on a consumer safety assessment related to the presence of a hazard in feed or feed ingredients. As such, the identification of hazards should not be restricted to their presence in feed, but also should consider the different routes of transfer of the hazard and its derivatives to animal food products and their subsequent impact on human health. The routes of transfer may depend upon the type of hazard (a chemical hazard may transfer into edible animal tissues by biotransformation, while a biological hazard may be transferred to such tissue during slaughter). The biotransformation route may vary from one animal species to another. This evaluation should be part of the hazard identification in the risk assessment, and not be addressed in the exposure assessment as proposed in the current draft. By doing so, all identified hazards potentially exposable to consumers could be characterized in the hazard-characterization phase.

The clarification of the scope of the hazard characterization phase is of particular relevance when considering the scope for guidance for the application of risk assessment for feed: in practice most feed safety risk assessors perform their tasks either on feed products subject to an official pre-market authorization or on feed contaminants and/or undesirable substances present in certain feedstuffs. It is therefore necessary to address all feed – related hazards, which may impact food safety adversely, including their metabolites in edible tissues.

### **II. Proposed Draft Guidelines on Application of Risk Assessment for Feed:**

**Paragraph 2** Please add as follows:

This guideline should enable risk assessment of hazards in feed based upon local conditions, considering the impact, if any, on human health. It should also enable international comparability of feed risk assessments, thereby promoting fair practices in food trade **and consistent use of risk assessment at international level.**

**Paragraphs 5-8 on SCOPE** Please add new additional paragraph under Scope, which emphasises that Physical Agents are outside the scope of this guideline:

Physical agents in feed are not known to be hazards reasonably likely to cause adverse health effects in humans; but rather may cause a risk to animal health, which is outside the scope of this guideline.

**Paragraph 9** Definitions – we recommend the following changes/additions:

**Exposure Assessment:** We recommend amending second sentence as follows:

In this guideline, it may also refer to evaluation of the likely **level or** amount of a biological ...

**Risk Estimate:** We recommend the following addition:

the quantitative estimation of risk resulting from risk characterization (Codex Alimentarius Commission: Procedural Manual), **including 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.**

**Paragraph 12** We recommend the following addition to the end of this paragraph:

**These activities should include risk communication with interested parties.**

**Paragraph 12 & 13** As the term Risk Profile was not defined in this document, we recommend that the reference also be made to the references listed in paragraph 11 for guidance in establishment of a risk profile.

**Paragraph 13** We request the following addition to the second sentence:

This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased, ~~and~~ transparent **and documented.**

**Paragraph 18** We propose deleting the following words in the last sentence, as this document is for all countries use and this wording is inconsistent, and adding the following:

Different parts of the world, ~~including experts from developing countries,~~ **including animal feeding experts.**

**Paragraph 19** We request the following changes:

... Food Safety Risk Assessment and should **follow a structured approach** incorporating ~~the~~ the four steps of the risk assessment, ....

**Paragraph 20** We request the following changes to the second sentence:

**When the scientific data is not complete or sufficient,** Risk assessment may also take into account **relevant** qualitative **data or** information.

**Paragraph 21** We request the following addition to the second sentence:

... Expression of **possibility uncertainty** or variability in risk estimates may be quantitative or qualitative, but should be quantified **and documented** to the extent that is scientifically achievable.

**Paragraph 24** We request the following addition to the final sentence:

...(INFOSAN; [http://www.who.int/foodsafety/fs\\_management/infosan/en/](http://www.who.int/foodsafety/fs_management/infosan/en/)), **Or other reliable, functioning rapid alert feed safety systems.**

**Paragraph 33** We request the following change (and move to place of Paragraph 31, thus renumbering balance of document), making the focus and direction of this document much stronger.

~~Feed~~ Exposure assessment is ~~best carried out using monitoring~~ **should use quantitative and surveillance** data of hazard levels in feed and edible products.

**Paragraph 34** We request the following addition because the calculation would be impossible without the amount of feed intake:

In general, if any two of these three variables (hazard level in feed **and the feed intake by animal,** transfer rate, and hazard level in edible product) is known, the third can be derived.

**Paragraphs 7 & 8** should be corrected in sequence between present paragraphs 34 and 36

**Paragraph 35 (old 7)** We request the following correction in the second paragraph:

- Kinetics of the ~~hazard~~ **compound** in the food-producing animal, including systemic absorption, metabolism (including generation of ~~hazardous~~ metabolites), distribution and accumulation potential of ~~hazard~~ **compound** in body compartments, and extent of transfer of ~~hazard~~ **compound** into edible products.

**Paragraph 37 (old 8)** We request the following addition to the end of the paragraph because these factors influence transfer rates:

...including strain, sex, ~~and~~ life stage, **Nutrients level of the feed, and nature and type of feed ingredients used.**

**Paragraph 40 (old 38)** We request the following, which is consistent with the definitions:

Risk characterization considers the key findings from hazard characterization and exposure assessment to estimate the risk **for a given population. Establishing the probability of an identified adverse effect is the expected result of risk characterisation.**



**OIE**

(i) Specific comments

Paragraph 4.

[...]

And relevant sections of

- The OIE Terrestrial Animal Health Code (~~[http://www.oie.int/eng/normes/mcode/en\\_sommaire.htm](http://www.oie.int/eng/normes/mcode/en_sommaire.htm)~~  
<http://www.oie.int/en/international-standard-setting/terrestrial-code/access-online/>)
- The OIE Aquatic Animal Health Code (<http://www.oie.int/en/international-standard-setting/aquatic-code/access-online/>)

Rationale:

Provided updated link to OIE website.

Added the OIE Aquatic Animal Health Code as it includes chapters relevant to the topic.