



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

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DRAFT GUIDELINES ON APPLICATION OF RISK ASSESSMENT FOR FEED

Comments at Step 6 (in reply to CL 2012/22-AF) of

Argentina, Canada, Chile, European Union, India, Iran, New Zealand, Philippines, United States of  
America and IFIF

**ARGENTINA**

Argentina thanks the possibility to make the following comments.

**GENERAL COMMENTS**

At a national level Argentina shares the order and contents of the present document, being the corrections presented specific.

Within the general scope adopted, we believe it would be important to highlight in a more explicit way the differentiation between feed and feed ingredients, both covered by the present document.

Being the components of feed one of the components of a feed, which reduces the level of animal exposure to the risks that may be present to them; we understand that the clarification of this approach in the document is of fundamental importance.

Finally, and in close relation to the prioritization document, we consider that the explanation of the risk analysis framework should be more explicit, understanding that changing FIGURE 1 for the one we propose below.

**SPECIFIC COMMENTS**

PARAGRAPH 5

Regarding the general comment, we understand that the text of this paragraph could be clarified in the following way:

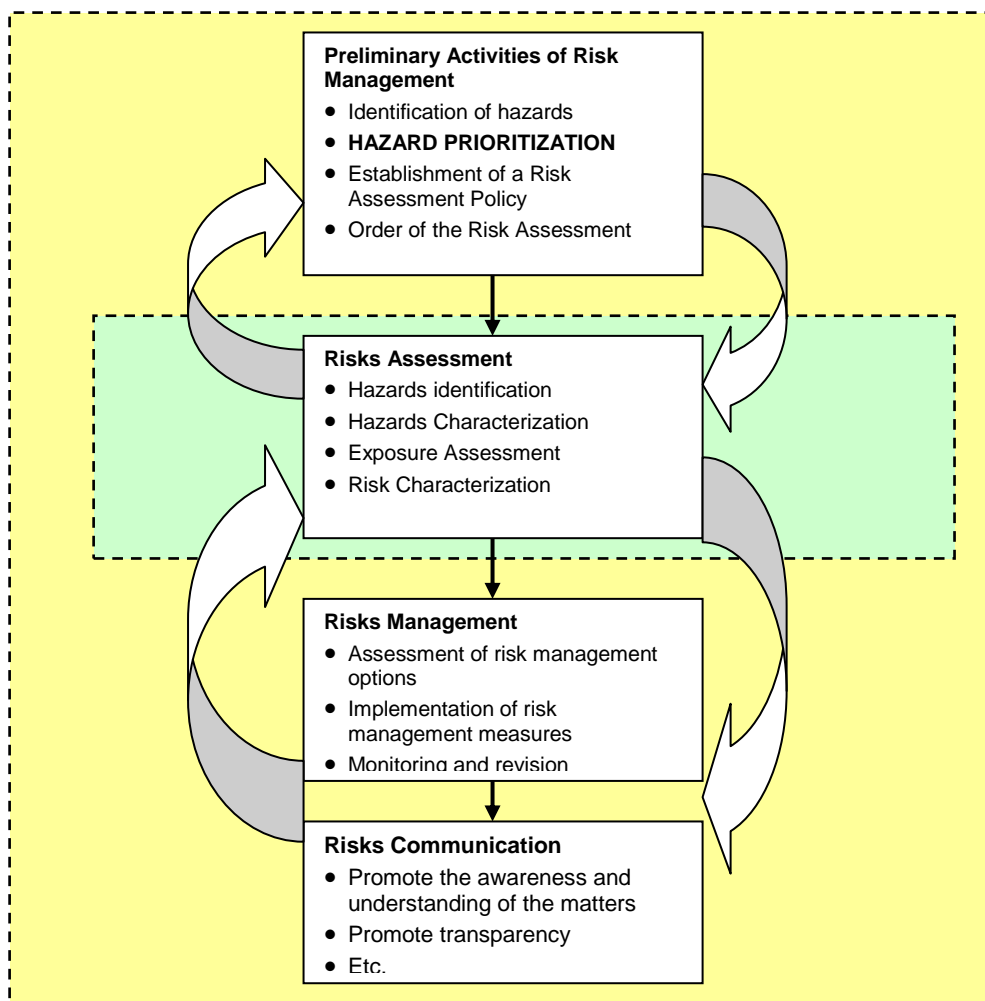
*5. These guidelines aim at providing guidance to governments on risk assessment for feed and feed*

*ingredients, recognizing that the risk assessment of the latter ones should consider the characteristics which differentiate them from complete feed.*

DEFINITIONS

We would like to highlight that it has been defined as TRANSMISSION what appears to be as TRANSFER in the text in English. We understand that we should define TRANSMISSION AS TRANSFER for a better understanding of both documents in this Task Force.

FIGURE 1 – we suggest changing for this one:



PARAGRAPH 12

Preliminary risk management activities include identification of the hazard, its prioritization, the establishment of a risk assessment policy and the assignment of an evaluation itself.

Paying attention to this we propose the following change:

12. A risk assessment is commissioned by the risk manager. Preliminary risk management activities include the identification of a food safety problem arising from feed, ~~the establishment of a~~ **and the corresponding commissioning of** risk profile, the **hazard prioritization** ~~ranking of the hazard for risk assessment and risk management priority~~, determination of a risk assessment policy for the conduct of the risk assessment, the implementation of the risk assessment, ~~and consideration of the result of the risk assessment~~

PARAGRAPH 13

We understand that the objective of a risk assessment policy should cover the evaluation that has been commissioned. According to this, we do not agree with what is described in the second sentence, and we suggest the following change:

13. The risk assessment policies should be established by the risk manager in advance of risk assessment and in consultation with risk assessors and all other interested parties. The aim ~~of this procedure~~ **of establishing the risk assessment policy is to tell the risk assessor which points should be evaluate for risk management according to the risk manager needs, and to** ~~ensures that it is carried out in a risk assessment is~~ systematic, complete, documented, transparent and unbiased **way**. The mandate given by managers to risk assessors must be as clear as possible.

PARAGRAPH 15

We believe that expertise is given by theoretical and/or practical knowledge therefore we suggest the following correction:

15. Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise and / or practical experience their independence with regard to the interests involved.

#### PARAGRAPH 17

We do not understand the meaning of QUALITATIVE data consideration in the second sentence of this paragraph. Data for risks assessment are QUANTITATIVE; in case of not being sufficient the RISK ASSESSMENT must be QUALITATIVE. In this sense we understand that the sentence is misleading and should be eliminated.

17. Risk assessment should be based on all relevant available scientific data. It should use available quantitative information to the greatest extent possible

~~. Risk assessment may also take into account qualitative information.~~

#### PARAGRAPH 18

Argentina requests clarification on the meaning of the second sentence in the paragraph, regarding its meaning and interpretation.

#### PARAGRAPH 22

The first part of the paragraph has been mistranslated and it is misleading. We suggest the following correction:

22. ~~Regulatory surveillance samples and investigative work,~~ **Useful information on the presence of hazards in feed may be obtained from regulatory surveillance samples and research work,** published data from government agencies, and from international programs such as the WHO Global Environment Monitoring System (GEMS/Food)<sup>3</sup>; the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN)<sup>4</sup>; and other reliable rapid alert systems on the presence of hazards in feed.

#### PARAGRAPH 24

In the first sentence, we suggest the incorporation of transport as a step where a hazard can be introduced in feed or ingredient.

On the other hand, the third and fourth sentence of the same paragraph do not refer to the identification of risks, therefore we suggest their elimination to maintain coherence and consistency with the text.

Specifically, the changes are:

24. Consideration should be given to the source of feed ingredients, and the potential for introduction of hazards during their manufacture, preparation, **transport** and storage. Many feed ingredients are produced as byproducts from other production processes, including but not limited to distillers grains from the production of biofuel, agriculture and food processing minerals from industrial processes, etc . ~~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 28

We believe that the reference to the characterization of hazard in feed is a mistake, since characterization has to do with the harmful effect on the health of the consumer, and not with the pathway through which the hazard is introduced. In this sense, we suggest removing this reference.

28. ~~If the available data are inadequate to characterize a hazard in feed, it may be necessary to consider generating such data. [...]~~

#### PARAGRAPH 29

According to the coherence along the text we suggest modifying food by edible product.

29. Exposure assessment is the qualitative and/or quantitative evaluation of the likely intake of the hazard(s) via **feed edible product**.

#### PARAGRAPH 34

We suggest clarifying the origin of the feed of risk as follows:

34. Exposure assessment of exposure for a hazard arising from feed is a two-step process The first step concerns the exposure of food producing animals to hazards through feed. The second step is to evaluate

*the transfer/transmission of the hazard(s) to edible products through food producing animal. The aim of exposure assessment in feed risk assessment is to estimate the level of prevalence of hazard(s) in edible product **whose origin was feed.***

#### PARAGRAPH 35

There has been a mistake in translation. Where it reads “figura” it should be read “es considerada”.

#### PARAGRAPH 39

In order to unify criterion along the document, where it says TRANSFER it should say TRANSFER/TRANSMISSION.

#### PARAGRAPH 40, bullet 2

We understand that the reference to STRAIN in wrong in this bullet, because it makes reference to ANIMAL issues and not to the pathogen. Therefore we suggest removing the word STRAIN.

#### PARAGRAPH 42

We suggest unfolding the paragraph and removing the sentence that corresponds to exposure assessment and a minor correction according to the following:

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

~~*[Food exposure assessment considers hazards in edible products. XX. Human exposure assessment is conducted during **this stage** risk assessment for foods. This may require modelling of dietary intake of relevant foods and food groups in specified human groups. The results of such assessments are considered in setting limits for hazards in food, such as national or Codex maximum limits or levels.]*~~

#### PARAGRAPH 43

We consider the paragraph repetitive and it does not provide any content, therefore we suggest its removal.

#### PARAGRAPH 44

Due to the importance of the last sentence we suggest presenting it as a separate paragraph.

#### PARAGRAPH 47

We request clarification on what “minority opinions” means. If it refers to the opinion of experts, we ask for its clarification in the text.

#### PARAGRAPH 48

We consider that the clarification between commas is unnecessary and leads to misinterpretation. Risk Estimate is the basis of the evaluation, so that it should not be left aside as part of the result. In this respect we suggest deleting the referenced text.

*48. The conclusion of the risk assessment (~~including a risk estimate, if appropriate~~) should be presented in a readily understandable and useful form to the risk manager and made available to other risk assessors and interested parties so that they can review the assessment.*

## CANADA

### General Comments

Canada continues to support the further development of this document, as it will serve as a useful tool in guiding governments in the risk assessment processes that are unique to feed, for both feed contamination events and the assessment of new feed ingredients.

### Specific Comments

#### Section Definitions, Paragraph 9

##### Exposure assessment

We are of the view that the definition of exposure assessment does not clearly align with a feed risk assessment. In order to be consistent with using established Codex definitions, Canada would suggest maintaining the Codex definition as per the Procedural Manual as noted, however suggestions are made below to the clarifying sentence to fully cover the intent for feed.

The qualitative and/or quantitative evaluation of the likely human intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant (Codex Alimentarius Commission: Procedural Manual). In these guidelines, it may also refer to **the consideration of the exposure of a hazard to a food producing animal and to an** evaluation of the likely **amount of a hazard in feed** amount of a biological or chemical agent **that can transfer to an** edible product. of animal origin. given the presence of that agent in feed.

#### **Feed:**

We note a discrepancy in the definition of feed as referenced from the *Code of Practice on Good Animal Feeding, CAC/RCP 054-2004*, which includes Feedingstuffs. Canada would suggest inserting this back in the definition as noted here for consistency.

Feed (**Feedingstuff**)

#### **Feedingstuffs:**

Given the above rationale for Feed, we would suggest deleting this definition from the list as it can be considered part of the definition of Feed, and, hence, becomes redundant.

~~Feedingstuffs: In this guideline, means Feed.~~

### **Section – Risk Assessment Procedure**

#### **Paragraph 13**

We note a small editorial addition is required in the first line, as follows:

“..... should be clearly stated and **be** in accordance with risk assessment policy.”

### **Section - Hazard Identification**

#### **Paragraph 19**

We support the inclusion of pesticides in this section as being very relevant. Feed-through pesticides, such as de-wormers for action in manure, have been approved in various jurisdictions to enable a more efficient mode of administration via feed, much like exists for veterinary drugs, and hence, Canada would support the removal of the square brackets which are currently related to “pesticides”.

#### **Paragraph 20**

We are of the view that the wording in this section should more clearly relate the physical hazard to an adverse human health effect via food safety. Canada suggests clarifying the statement as follows:

Physical agents in feed are not known to be hazards ~~reasonably~~ likely to cause **food safety risks** ~~adverse health effects in humans~~; but rather may cause a risk to animal health, which is outside the scope of these guidelines.

#### **Paragraph 22**

Canada suggests that the information contained in this paragraph is germane to the discussion and considerations of hazard identification, and hence we support the removal of the square brackets.

#### **Paragraph 23**

Canada suggests the separation of the current Paragraph 23 into two distinct paragraphs as this applies to all feed ingredients. After the discussion of the processing by-products, the paragraph could continue on to a more generalized discussion of any feed ingredient. The following text could be considered a separate new paragraph 23 (bis).

We also note a small editorial addition is required in the second sentence to separate food processing from mineral production; a comma has been added after food processing. Therefore, the new paragraphs are as follows:

#### **New para 23 (with the comma added):**

- Many feed ingredients are produced as by-products from other production processes, including but not limited to distillers grains from the production of biofuel, agriculture and food processing, minerals from industrial processes, etc.

**Paragraph 23 (bis)**

- 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.

**Section - Hazard Characterization****Paragraph 26**

We note a small editorial addition is required in the first sentence, as follows:

For the hazard characterization of chemicals, the relevant reference values especially for an oral route of exposure are identified (e.g. LD50, ADI).

**Section - Exposure Assessment****Paragraphs 28-40**

Canada would like to suggest the following reorganization of this section to better reflect the flow of a feed exposure assessment. This section was discussed briefly by the informal working group session at the Task Force meeting and upon reflection, the relevance of how a feed exposure assessment relates to a food exposure assessment was lost. The substance of the original text has not been changed, only some paragraphs have been rearranged. There are minimal modifications as edits and suggestions for clarity; these have been tracked as noted below in bold and underline. An explanatory statement is added to preface paragraph 31 as there was no linkage to the rest of the section.

***Exposure assessment***

28. Exposure assessment is the qualitative and/or quantitative evaluation of the likely intake of the hazard(s) via food. **The aim of the exposure assessment in feed risk assessment is to estimate the level or prevalence of hazard(s) in edible products through feed.**

29. The **final** edible product(s) in **the** exposure assessment should be defined as precisely as necessary.

31. **Data obtained from sampling of feed and edible products may be useful for quantifying the exposure.** Sampling plans for **both feed and edible products** should use scientifically recognized principles and procedures in accordance with the *General Guidelines on Sampling* (CAC/GL 50-2004). The sampling plan should take into consideration possible non homogeneous distribution of the hazard.

33. Exposure assessment for a hazard arising from feed is a two-step process. The first step concerns the exposure of food-producing animals to hazard(s) through feed **and** the second step is to evaluate the transfer/transmission of hazards to edible products through food-producing animals. ~~The aim of exposure assessment in feed risk assessment is to estimate the level of prevalence of hazard(s) in edible products.~~ **(added to para 28 above).**

34. ~~Human exposure is considered under Risk characterization.~~ **(move this para at the end, see para 40 below)**

***First Step: Animal exposure assessment***

34. (old para 35) The first step involves:

- (a) Identification of feeds, which may contribute to intake of a given hazard;
- (b) Determination of **the** concentration of the hazard in feed;
- (c) Calculation of hazard intake by the food-producing animal from relevant feed sources, based on information on feeding practices (quantity, frequency and duration of feed intake), as appropriate.

35. (old para 36) Animal exposure will differ as a result of the formulation of the feed, the use patterns for the animal, and the exposure scenarios.

***Second Step: Transfer/Transmission***

36. (old para 37) ~~The second step uses~~ Modelling and measurements **are used** to calculate transfer through food-producing animals and the resulting hazard level and/or prevalence in edible products.

37. (old para 38) Transfer of a hazard from feed to edible products depends on its kinetics in the food-producing animal; including absorption, hazard [bio-] transformation, distribution, **excretion**, and **the**

potential for accumulation or proliferation in tissues.

38. (old para 39) The kinetics may be influenced, in particular, by:

- biological or chemical properties of the hazard;
- species, strain, gender, and life stage of the food-producing animal, **and its health status**;
- potential interaction between the hazard and feed components.

39. (old para 40). Published, preferably peer-reviewed, toxicokinetic or other models that can predict the transfer of hazard from feed to edible products, may be used or adapted for a given exposure assessment.

**40. (old para 34, moved here).** Human exposure is considered under Risk characterization.

## **Section – Risk Characterization**

### **Paragraph 41**

We suggest this paragraph be the link to the purpose of the risk assessment, and the conclusions which may be drawn. Canada suggests the following edits to this paragraph, which also serve to relate the current wording within the square brackets to the intent of this paragraph.

Risk characterization, **in a feed risk assessment, considers** the key findings from **the** hazard characterization and **the** exposure assessment to estimate the risk for **food safety**. ~~a given population.~~ Establishing the probability of occurrence and severity of an identified adverse effect is the expected result of risk characterization. ~~[The feed~~ Feed exposure assessment ~~considers hazards in edible products~~ **should result in a determination of whether an unacceptable risk of a hazard in edible products exists. This endpoint is then incorporated into the human exposure assessment for food.** ~~Human exposure assessment is conducted during risk assessment for foods.~~ This may require modelling of dietary intake of relevant foods and food groups in specified human groups **to account for the new contribution in edible products**. The results of such assessments are considered in ~~setting~~ **adjusting existing limits, or setting new** limits for hazards in food, such as national or Codex maximum limits or levels. ~~]~~

### **Paragraph 43**

To be consistent with the terminology already found in the definition of hazard, Canada would suggest replacing the term in (b) of biological level to biological agent.

“... Or (b) a certain prevalence of a biological **level agent** in feed may result...”

## **CHILE**

### **General Comments**

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

### **Specific Comments**

**Comment 1.** The correction of a paragraph in the Spanish version is suggested and indicated below:

#### **INTRODUCTION**

1. These guidelines aim at providing guidance for feed risk assessment by governments in accordance with Codex principles. They address the potential risks to human health associated with the presence of hazards in the feed of **food-producing animals** ~~intended for human consumption~~, and the transfer of hazards to edible products.

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

**Comment 2.** The correction of a paragraph in the Spanish version is suggested and indicated below:

#### **SCOPE**

6. These guidelines are applicable to all hazards in feed **for food-producing animals** ~~for animals intended for human consumption~~.

**Reasoning:** The proposal reflects the proposed draft's scope and what was expressed in the English version.

**Comment 3.** The correction of the paragraph in the Spanish version is suggested and indicated below:

## DEFINITIONS (for subsequent debate)

Feed: 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 scope and what was expressed in the English version.

**Comment 4.** The correction of the paragraph in the Spanish version is suggested and indicated below:

## DEFINITIONS (for subsequent debate)

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 these guidelines, it may also refer to the probability that a hazard present in feed eaten by a food-producing animal ~~animals intended for human consumption~~ will transfer to an edible product at a level, which may cause an adverse health effect in humans..

**Reasoning:** The proposal reflects the proposed draft's scope and what was expressed in the English version.

**Comment 5.** It is suggested the addition of a definition of food

## DEFINITIONS (for subsequent debate)

**Food: Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drinks, 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 above mentioned in documentation that does not refer to animal food/feed.

**Comment 6.** It is suggested that the following sentence, at the end of the paragraph corresponding to the definition of Contaminant, be deleted:

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

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

**Comment 7.**

**Paragraph 19.** It is suggested that the concept "bio-transformation" be included in the definitions as it is used in many occasions throughout this document.

**Reasoning:** It is suggested that the definition must be specified in order to clarify when and how this concept is applicable.

**Comment 8.** It is considered that paragraph 24 already has the information being proposed in paragraph 23.

~~23. Factors to be considered which can markedly influence the occurrence of a given hazard in feed and which may be specific to a locale, country, or region, such as environmental conditions and interactions with other materials during growth, harvesting, drying, storage, handling and transport.~~

**Comment 9.** It is suggested that paragraph 24 should be completed as indicated below:

24. Consideration should be given to the source of feed ingredients, conditions and environmental interaction, as well as the possibility of hazards being introduced throughout the various stages of production; storage, handling, transport and distribution. Many feed ingredients are produced as by-products from other production processes, including but not limited to distillers grains from the production of bio-fuel, agriculture and food processing minerals from industrial processes, etc. 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..

#### Comment 10.

Paragraph 27. For the hazard characterization of chemicals the relevant reference value especially for an oral route exposure are identified (e.g. LD50, ADI). For ~~microbiological~~ **biologic hazards**, the nature and severity of the adverse health effects are characterized and where possible a dose-response relationship established.

**Reasoning:** The modification is suggested in order to harmonize the definitions with the Proposed Draft on Feed Hazard Prioritization.

#### Comment 11.

Paragraph 28. If available data are inadequate to characterize a hazard in feed, it may be necessary to consider generating such data. The risk manager may request action to resolve the data gaps **from those in charge of risk assessment. This action must be based on relevant scientific principles and procedures.**

**Reasoning:** It is suggested a final sentence be added in order to explain the responsibilities undertaken in the delivery of information and its characteristics.

#### Comment 12.

It is suggested that the Spanish version should be revised and the word "cepa" (strain) be changed to "raza" (breed).

Paragraph 40. The kinetics might be influenced, in particular, by:

- biological or chemical properties of the hazard;
- species, ~~strain~~ **breed**, gender, and life stage of the food-producing animal;
- potential interaction between the hazard and feed components.

**Reasoning:** The term proposed is more adequate within the classification of animals.

### EUROPEAN UNION

The European Union (EU) would like to congratulate Switzerland for the continuous effort in supporting very well the work of the Task Force.

Please find attached the EU comments as requested by Circular Letter CL 2012/22-AF.

In general, it is desirable that both this document and the "Proposed draft guidance for governments on prioritizing hazards in feed" use the same definitions and terminology. We have included in the specific comments some points to this effect.

#### Specific comments

#### DEFINITIONS

Definitions should be identical in this document and in the "Proposed draft guidance for governments on prioritizing hazards in feed".

The EU would like to propose the 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."***

The **definition of carry over** should be taken from the document: "Proposed draft guidance for governments on prioritizing hazards in feed".

**Definition of contaminants:** The EU proposes to use the revised definition of contaminant as endorsed by CAC35: *"Contaminant means any substance not intentionally added to food or feed for food producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter."*

The **definitions of feed and feedingstuffs** should also be harmonized with the same wording as in CAC/RCP 54-2004 and in the document "Proposed draft guidance for governments on prioritizing hazards in feed".

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 questions 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).

## **RISK ASSESSMENT IN THE CODEX RISK ANALYSIS FRAMEWORK**

### **Paragraph 9**

It requires a sentence introducing the figure. The EU proposes the following: "Risk assessment is one of the three components of the risk analysis framework together with risk management and risk communication. **This is illustrated in figure 1.**"

### **Figure 1**

The EU suggests to keep figure 1 and complete it with arrows, illustrating the links between the different elements of the figure, as suggested by some delegations (Argentina, Netherlands, others) in the electronic Working Group.

### **Paragraph 11**

The reference to the "Proposed draft guidance for governments on prioritizing hazards in feed" should be put in a new separate paragraph with the following text:

***"Risk management priority can be carried out following the "Proposed draft guidance for governments on prioritizing hazards in feed".***

### **Paragraph 12**

The term "*risk assessment policy*" is not clear. The EU would propose to change the paragraph to:

***This risk analysis procedure aims at ensuring that the risk assessment is systematic, complete, documented, unbiased and transparent. The mandate given by risk managers to risk assessors should be as clear as possible. Risk managers should consult risk assessors and interested parties in advance of the risk assessment.***

## **RISK ASSESSMENT PROCEDURE**

### ***Hazard identification***

### **Paragraph 18**

The EU proposes to replace the square bracket [ **bio-**] with normal parenthesis. Therefore the EU is proposing to add the definition of the term **bio-transformation** under the Section "Definitions".

### **Paragraph 19**

The EU proposes to drop the square brackets in this sentence to read: "*Feed additives, veterinary drugs and pesticides used in feed, which have been assessed for safety and which have been used under stated conditions of use as pre-approved by the competent authorities should not be ~~prima-facie~~ considered in principle as a hazard.*"

The following sentence should be **added to Paragraph 19**:

***"However, in the case of carry over, the presence of such substances (such as veterinary drugs) should be assessed as a potential hazard."***

### ***Hazard characterization***

### **Paragraph 21**

It is proposed to include at the end of the paragraph: '**and industry self monitoring programmes**' as follows:

***"Useful information on the presence of the hazard in feed may be obtained from regulatory surveillance samples, and investigative work, published data from government agencies, from international programmes such as the WHO Global Environment Monitoring System (GEMS/Food)<sup>(3)</sup> the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN)<sup>(4)</sup>, other reliable rapid alert systems, and industry self monitoring programmes."***

**Paragraph 22**

The EU proposes to remove the square brackets and add the term '**processing**' as follows:

"... during growth, harvesting, drying, **processing**, storage, handling and transport."

**Paragraph 23**

This paragraph draws to attention the need to consider, in the risk analysis, the origin of the feed ingredients and in particular that many feed ingredients are co- or by-products of other industrial processes. An example regarding by-products of the food industry are the ones from the sugar industry whose origin requires particular consideration to take into account residues of processing aids and chemical impurities associated with this industry. The paragraph also lists a number of examples of other by-products from non-food processes whose use in feed are likely to increase in the coming years.

The EU would therefore like to amend the paragraph as follows:

*In order to evaluate which feed ingredients may contain a given hazard, consideration should be given to ~~their the source of feed ingredients~~, and the potential for introduction of hazards during their manufacture, preparation, **transport** and storage. **Many feed ingredients are produced as by-products from food production processes, e.g. by-products from agriculture, food processing minerals from industrial processes, by-products of the sugar industry etc. But also the non-food industry delivers by-products for feed purposes, e.g. by-products from the production of biofuel, the pharmaceutical industry and the oleo-chemical industry.** ~~Many feed ingredients are produced as by-products from other production processes, including but not limited to distillers grains from the production of biofuel, agriculture and food processing minerals from industrial processes, etc.~~ Feed ingredients should be obtained from safe sources and be subject to a risk analysis **when these products** 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 24**

The EU proposes to amend this paragraph as follows: "*Hazard characterization refers to the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with hazards **in feed**, which may be present in edible products **as a result of transfer**. For any hazard identified, including (bio-) transformation products in edible products, a hazard characterization should be conducted.*"

**Paragraph 25**

Replace "*from bodies*" with "*from risk assessment bodies*".

**Paragraph 26**

Change the order and complete the information in the brackets as follows:

"..(ADI, TDI, ARfD, LD<sub>50</sub>) ...".

Reasoning: ADI and TDI are intended for long term effects, ARfD, LD<sub>50</sub> is intended for acute, short term effects.

**Paragraph 29**

The sentence should be completed at the end with "**and possible**".

**Exposure assessment****Paragraph 35**

In letter (a) the comma after identification of feeds could be deleted.

A **new letter (d) should be added** to address the exposure from other sources than feed to the hazard. The EU proposes the following wording:

**(d) Identification, and if possible quantification, of other sources of the hazard which may contribute to the animal exposure or to the accumulation of the hazard in the animal (soil, water, air, medicinal products, biocides or others).**

**Paragraph 39**

The EU proposes the following wording:

*The kinetics may be influenced, in particular, by:*

- biological or chemical properties of the hazard;
- species, ~~strain~~, gender, ~~and~~ life stage **and health status** of the food-producing animal;
- **frequency and duration of feed intake**;
- **formulation of the feed and** potential interaction between the hazard and feed components.

### **Risk characterization**

#### **Paragraph 41**

The EU proposes to **delete** the sentences currently between square brackets and proposes to **replace** them by the following wording:

~~"[ Feed exposure assessment considers hazards in edible products. Human exposure assessment is conducted during risk assessment for foods. This may require modelling of dietary intake of relevant foods and food groups in specified human groups. The results of such assessments are considered in setting limits for hazards in food, such as national or Codex maximum limits or levels. ]~~ **For the purposes of this document feed exposure assessment considers occurrences of hazards in edible products as a result of their presence in feed."**

(New paragraph 41 bis):

**"In most cases, when the hazard may also be present in foods of non-animal origin, a human exposure assessment has already been conducted during risk assessment for foods in general. This may include or require modelling of dietary intake of relevant foods and food groups in specified human groups. Results of such assessments are considered in setting limits for hazards in food, such as national or Codex maximum limits or levels. These assessments and limits may also need to be taken into consideration for the risk characterization of the hazard when arising from feed."**

### **ANNEX I**

The EU would prefer to keep this Annex.

### **INDIA**

#### **DEFINITIONS**

The definition of "**Contaminant**" should be replaced as below:

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

#### **RISK ASSESSMENT IN THE CODEX RISK ANALYSIS FRAMEWORK**

**Paragraph 11:** The text should be modified as below:

A risk assessment is commissioned by the risk manager. Preliminary risk management activities include identification of a food safety problem arising from 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. ~~[Reference is made to the Proposed draft prioritised list of hazards in feed (ad hoc Intergovernmental Task Force on Animal Feeding)].~~

**Rationale:** The text refers to the prioritized list of hazards in feed which is a dynamic list and need not be referred in this document.

**Paragraph 14:** The text should be modified as below:

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 and ~~may~~ include a public declaration of any potential conflict of interest. This declaration could also identify and detail their individual expertise, experience and independence.

**Rationale:** The procedures used to select the experts should include declaration of potential conflict of interest.

**Paragraph 19:** The text should be modified as below:

Feed additives and veterinary drugs [ ~~and pesticides~~ ] used in feed, which have been assessed for safety and which have been used under stated conditions of use as pre-approved by the competent authorities should not be prima facie considered as a hazard.

**Rationale:** Pesticides are not used in feeds.

**Paragraph 22:** The text should be modified as below:

~~[Factors to be considered which can markedly influence the occurrence of a given hazard in feed and which may be specific to a locale, country, or region, include environmental conditions and interactions with other materials during growth, harvesting, drying, storage, handling and transport.]~~

**Rationale:** The guidance in the paragraph, on factors to be considered which can markedly influence the occurrence of a given hazard, is useful and acceptable.

**Paragraph 32:** The text should be modified as below:

Analytical laboratory methods should be validated using scientifically recognized principles and procedures in accordance with the [ ~~General Criteria for the Selection of Methods of Analysis Using the Criteria Approach (Codex Alimentarius Commission, Procedural Manual)~~ ].

**Rationale:** The reference to the 'General Criteria for the Selection of Methods of Analysis Using the Criteria Approach' in the Codex Procedural Manual is useful and acceptable.

**Paragraph 34:** The text should be amended as follows:-

*'Human exposure is considered under Risk characterization. **In respect of feed, the human exposure is estimated through animal exposure and transfer/transmission of contaminant from animal to edible product. This may require modeling of intake of relevant feed in animals and of foods and food groups in specified human groups.***

**Rationale:** To increase clarity and include relevant guidance related to estimation of human exposure.

**Paragraph 41:**

Risk characterization considers the key findings from hazard characterization and exposure assessment to estimate the risk for a given population. Establishing the probability of occurrence and severity of an identified adverse effect is the expected result of risk characterization. {Feed exposure assessment considers hazards in edible products. Human exposure assessment is conducted during risk assessment for foods. ~~This may require modelling of dietary intake of relevant foods and food groups in specified human groups.~~ The results of such assessments are considered in setting limits for hazards in food, such as national or Codex maximum limits or levels. }

**Rationale:** The deleted sentence is proposed to be included in the paragraph 35 where it is more appropriate. Please see also the comment on Paragraph 35 above.

## IRAN

**General comments:** Iran supports this document and would like to thank Switzerland for preparing the draft of the standard

### Specific Comments on paragraph

9-control

Adding **in feed** in the end of the sentence .

27-line 3

We suggest to change **dose response** to **infection dose**.

## NEW ZEALAND

We found that in paragraphs 15 – 47 of the Report of the 12<sup>th</sup> Session of the Task Force on Animal Feeding (REP12/AF, the references to the paragraphs in the proposed Guidelines detailed in Annex II were confusing, and seemed to be out of step with the actual paragraph numbers. Consequently, to be quite clear, in these comments, we have assumed that the numbering of the paragraphs in the proposed Guidelines is as in Annex II (pages 21 – 28) of REP 12/AF.

The explanations detailed in REP 12/AF paragraphs 15 – 47 were taken into account in these comments.

Specific comments on the Proposed Guidelines:

- Paragraph 1 – suggest the ending read “....and the **subsequent** transfer of hazards to edible products.”
- Paragraph 18 – transformation of hazards can take place by both biological and non-biological means (see details influences listed in paragraph 39)and both forms of transformation need to be taken into account. Thus, we suggest the second sentence should read “**Products of both biological and non-biological transformations of the hazard present in edible products need to be considered.**” Subsequent references to transformation only need to be stated as “transformation(s)” and not specify either form of transformation.
- Paragraph 22 – This square-bracketed paragraph does not make sense as drafted because as it stands, it is unfinished. It would make sense if it read “Factors to be considered **include those** which can markedly influence....”
- We believe it would not hurt to state that models used need to be clearly described and their inherent uncertainties in the context of their use discussed even though this concept is stated elsewhere in the proposed Guidelines.
- Paragraph 41 – We find the words in square brackets “Feed exposure assessment ..... Codex maximum limits or levels” to be confusing and they do not add anything useful to the proposed Guidelines. We suggest they be deleted.
- Paragraph 43 – currently part (b) of this paragraph is incorrect in that a risk estimate is a probability and currently part (b) does not state anything about probability. The wording of this part should be similar to that of part (a), and accordingly we suggest this should read “(b) **an estimate of the probability that** a certain prevalence of **an infectious agent** in feed....”
- Also in paragraph 43 – in the last sentence “If there is no international or national standard ....., consideration may bi given...”, we believe the word “may” is not strong enough and the word “should” would better reflect the situation.

We agree that there has been excellent progress in the drafting of this document and look forward to progressing the document.

## PHILIPPINES

### General comments:

The Philippines appreciates the work led by Switzerland in the Proposal Draft Guidelines on Application of Risk Assessment for Feed.

(i) The Philippines supports the Proposed Draft Guidelines at Step 6.

### (ii) Comments on paragraphs:

Definitions

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

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

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

Para 12

and consideration of the result of the risk assessment. [~~Reference is made to the Proposed draft prioritized list of hazards in feed (ad hoc Intergovernmental Task Force on Animal Feeding)~~]

Rationale: There is no need to include this to make it consistent with the format of the other paragraphs presented in the draft. (Editorial)

## UNITED STATES OF AMERICA

### SPECIFIC COMMENTS:

#### Introduction

**Paragraph 1:** suggested editorial change

1. These guidelines ~~provide aim at providing~~ guidance...

Rationale: This is a suggested editorial revision.

**Paragraph 2:** Suggested revision to insert underlined text:

2. These guidelines should enable risk assessment of hazards reasonably likely to occur in feed based upon local conditions and considering the impact on food safety and human health.

Rationale: This is consistent with the language used in the *Guidance for Governments on Prioritizing Hazards in Feed*.

**Paragraph 5:** suggested editorial change

5. These guidelines ~~provide aim at providing~~ guidance...

Rationale: This is a suggested editorial revision.

### Scope

**Paragraph 7: suggested text insertion (underlined)**

7. Direct human exposure to hazards in feed, for example occupational exposure during feed production and processing, is not considered, as it is not considered within the scope of Codex Alimentarius.

Rationale: This is consistent with the previous paragraph.

**Definitions:** Include a definition for bio-transformation.

Rationale: This appears in the document in a number of instances and it needs to be defined. Given that bio-transformation is already considered in determining the Codex maximum limits for pesticides and veterinary drugs and codex maximum level for contaminants, it is unclear why bio-transformation needs to be specifically mentioned in the text. A clear definition of bio- transformation would help explain the purpose and significance of including this term.

### Risk Assessment in the Codex Risk Analysis Framework

**Paragraph 11:** remove brackets and include suggested revision

11.:.... Reference is made to the Proposed draft Guidance for Governments on Prioritizing Hazards in Feed ~~list of hazards in feed~~ (ad hoc Intergovernmental Task Force on Animal Feeding.)

Rationale: This revision is consistent the current title of the guidance document.

**Paragraph 13:** suggested revision for clarity

13. The scope and purpose of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. ~~The output form and possible alternative outputs of the risk assessment should be defined. The output should be relevant to risk management questions and provide scientifically supported options for risk managers to consider.~~

Rationale: This addition provides further clarity and elaboration.

**Paragraph 18:** retain brackets

[bio]- transformation

Rationale: Products of biotransformation needs to be articulated to understand their relevancy and purpose in this document.

**Paragraph 19:** remove brackets and suggested revision

Feed additives and residues of veterinary drugs and { pesticides } used in feed, which have been approved for use and assessed for safety and which have been applied used under stated conditions of use ~~as pre-approved as determined~~ by the competent authorities should not be *prima facie* considered ~~as~~ to be a hazard.

Rationale: These revisions make the text more precise.

**Paragraph 22:** Remove brackets and move paragraph 22 before paragraph 21(current version).

Rationale: This paragraph is relevant and should be placed before paragraph 21 since it introduces the discussion on factors for consideration on hazard identification.

**Paragraph 23:** Suggested revisions

Consideration should be given to the source of feed ingredients, and the potential for introduction of hazards during their manufacture, preparation, transportation, handling and storage. Many feed ingredients are produced as by-products from other production processes, and an evaluation may be needed to be made of these processes and their potential for introducing hazards in feed including but not limited to distillers grains from the production of biofuel, agriculture and food processing minerals from industrial processes, etc.

Rationale: This suggested text covers the need for evaluation and review of processes for a broader range of products.

**Paragraph 24:** Retain brackets

[bio]- transformation

Rationale: Bio transformation needs to be defined to understand its relevancy and purpose in this document.

**Paragraph 25:** include the following revision

25. Information characterization of specific hazards may be obtained in international reports and monographs from bodies and/or preferably in peer-reviewed scientific literature (relevant references are included in Annex1). Sources of information should be documented.

Rationale: suggested revision

**Paragraph 30:**

If quantitative data are not available, a semi-quantitative or qualitative risk assessment approach may be useful in assessing the potential food safety risk. If necessary, the assessment may be reconsidered when scientific quantitative data is obtained.

Rationale: This provides further clarification. Depending on the risk management question(s) and if practicable, a full quantitative assessment may be conducted once data becomes available.

**Paragraph 37:** remove the term 'transmission.'

*Transfer/transmission*

Rationale: "Transmission" is not included in the current definition of transfer.

**Paragraph 33:** Move paragraph 33 after paragraph 28 and delete the 'term transmission and add text.

~~33...~~29... ... Exposure assessment for a hazard arising from feed is a two-step process. The first step is to determine if food-producing animal(s) are exposed to hazard(s) through feed. If such exposure is present, the second step is to evaluate the transfer/~~transmission~~ of hazard(s) to edible products through food producing animals. The aim of exposure assessment in feed risk assessment is to estimate the level of prevalence of hazard(s) in edible product.

Rationale: This reorganization makes this section flow more easily.

## INTERNATIONAL FEED INDUSTRY FEDERTATION (IFIF)

### INTRODUCTION

1. These guidelines should enable risk assessment of hazards reasonably likely to occur in feed based upon local conditions, considering the impact on food safety and human health. The application of these guidelines should also enable international comparability of feed risk assessments and thereby promote fair practices in food and feed trade.

Rationale: Consistent with Guidance for Governments on Prioritizing Hazards in Feed document

### SCOPE

7. Direct human exposure to hazards in feed, for example occupational exposure during feed production and processing, is not considered, as it is not within the scope of the Codex Alimentarius.

Rationale: Consistent with previous paragraph

### DEFINITIONS (for further discussion)

Bio-Transformation (this term is used in a number of places in the document and should be precisely defined)

**Transparent:** Characteristics of a process where the rationale, the logic of development, constraints,



assumptions, value **judgments**, decisions, limitations and uncertainties of the expressed determination are fully and systematically stated, documented, and accessible for review (*Principles and Guidelines for the Conduct of Microbiological Risk Assessment*, CAC/GL 30-1999).

## RISK ASSESSMENT IN THE CODEX RISK ANALYSIS FRAMEWORK

11. A risk assessment is commissioned by the risk manager. Preliminary risk management activities include identification of a food safety problem arising from 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. [ Reference is made to the Proposed draft **Guidance for Governments on Prioritizing Hazards in Feed** (*ad hoc* Intergovernmental Task Force on Animal Feeding) ].

Rationale: Changed to be consistent with the actual title of the guidance document currently under review, reflecting AF Task Force's decision not to develop a "prioritized list" as implied in this phrase.

12. The risk assessment policy should be established by the risk manager in advance of risk assessment in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, documented, unbiased and transparent. The mandate given by risk managers to risk assessors should be as clear as possible.

## RISK ASSESSMENT PROCEDURE

13. The scope and purpose of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output **from** and possible alternative outputs of the risk assessment should be defined.

16. Risk assessment should be based on all relevant available scientific data. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information, **when scientific quantitative data is not available, until such data can be obtained.**

Rationale: Quantitative risk assessment is the gold standard and should always be the end objective.

### ***Hazard identification***

18. Hazards in feed can include biological agents, chemical substances (such as "heavy metals", dioxins, excessive levels of pesticides, veterinary drugs and additives), radionuclides and other undesirable substances. Products of [bio-] transformation of the hazard present in edible products also need to be considered.

Rationale: Products of bio-transformation needs to be defined and further discussion on this point.

19. Feed additives and **residues of** veterinary drugs and pesticides, used in feed, which have been **approved for use and** have been **applied** under stated conditions of use by the competent authorities should not be *prima facie* considered **to be** a hazard.

**21. Factors to be considered which can markedly influence the occurrence of a given hazard in feed and which may be specific to a locale, country, or region, include environmental conditions and interactions with other materials during growth, harvesting, drying, storage, handling and transport.**

Rationale: Moving this paragraph provides better consistency and flow of the guidance

23. Consideration should be given to the source of feed ingredients, and the potential for introduction of hazards during their manufacture, preparation, **transportation, handling** and storage. Many feed ingredients are produced as by-products from other production processes, **and an evaluation may be needed to be made of these processes and their potential for introducing hazards in feed** . 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.

Rationale: This better defines the need for evaluation and review of processes for the broader group of present and future by-products used as feed ingredients.

### ***Hazard characterization***

24. Hazard characterization refers to the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with hazards, which may be present in edible products. For any hazard identified, including [bio-] transformation products in edible products, a hazard characterization should be

conducted.

Rationale: Products of bio-transformation needs to be defined and further discussion on this point.

25. Information on characterization of specific hazards may be obtained in international reports and monographs from bodies and/or peer-reviewed scientific literature (relevant references are included in Annex 1). **Sources of information should be documented.**

**Rationale:** Peer-reviewed data is a critical standard that should not be compromised

26. For the hazard characterization of chemicals the relevant reference value especially for an oral route exposure are identified (e.g. LD50, ADI). For microbiological hazards, the nature and severity of the adverse health effects are characterized and where possible a dose-response relationship **is** established.

27. If available **scientific** data are inadequate to characterize a hazard in feed, it may be necessary to consider generating such data. The risk manager may request action to resolve the data gaps.

### ***Exposure assessment***

29. **Exposure assessment for a hazard arising from feed is a two-step process. The first step is to determine if food-producing animal(s) are exposed to hazard(s) through feed. If no exposure is present, the assessment is concluded at this point. If such exposure is present, the second step is to evaluate the transfer of hazard(s) to edible products through food-producing animals. The aim of exposure assessment in feed risk assessment is to estimate the level or prevalence of hazard(s) in edible product.**

Rationale: This paragraph is more appropriate flow of guidance in this position. The other changes for clear guidance. Eliminated the “/transmission” as this is not included in the definition of the term transfer in this document.

30. Exposure assessment should use quantitative data on the level of hazard(s) or prevalence in feed and/or edible product. If quantitative data are not available, a semi-quantitative or qualitative risk assessment approach may be useful in assessing the potential food safety risk, **until scientific quantitative data is obtained.**

*Transfer /Transmission:*

Rationale: Eliminated the “/transmission” as this is not included in the definition of the term transfer in this document.

38. Transfer of a hazard from feed to edible product depends on its kinetics in the food-producing animal, including absorption, hazard [bio-] transformation, distribution, and potential for accumulation or proliferation in tissues.

Rationale: Products of bio-transformation needs to be defined and further discussion on this point.

40. Published, peer-reviewed, toxicokinetic or other models that can predict the transfer of hazard from feed to edible products, may be used or adapted for a given exposure assessment. **Sources of information should be documented.**

41. Risk characterization considers the key findings from hazard characterization and exposure assessment to estimate the risk for a given population. Establishing the probability of occurrence and severity of an identified adverse effect is the expected result of risk characterization. Feed exposure assessment considers **potential feed** hazards in edible products. Human exposure assessment is conducted during risk assessment for foods. This may require modeling of dietary intake of relevant foods and food groups in specified human groups. The results of such assessments are considered in setting limits for hazards in food, such as national or Codex maximum limits or levels.-