



Food and Agriculture  
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Agenda Item 4

CX/AF 12/6/4 Add.4

February 2012

Original language only

## 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:

**Australia, European Union, Indonesia, Mali, Philippines**

#### AUSTRALIA

##### General comments:

Australia appreciates the efforts to simplify and shorten the document. The document is now much shorter and focused than earlier versions with less repetition.

We note that the document consistently uses the term transfer rate which we consider to be inappropriate in the context used; rather we suggest the term transfer be used with slight rearrangement of relevant sentences. This is reflected in our comments below.

The Task Force also needs to consider how this document fits into the national and international systems for standard setting.

##### Specific comments:

##### Paragraph 9 Section: Definitions

Feed definition. Suggest deletion of the text that suggests inclusion of water

**Feed:** Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food-producing animals (Code of Practice on Good Animal Feeding, CAC/RCP 054-2004). ~~In this guideline, includes water.~~

**Rationale:** Consistent with the Code of Practice on Animal feeding we do not agree that water, other than as an ingredient in feed manufacture should be considered.

Transfer definition. Suggest deletion of the text in brackets

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

**Rationale:** Suggest deletion of the text in brackets as there are many ways of expressing the transfer including through the use of sophisticated models and additionally the nomenclature for the various simple factors used is not harmonised.

Also need to ensure consistency with the definition in priority list document for any change made.

##### Section: Hazard identification

Paragraphs 25, 26, 27 seem out of place under hazard identification which is essentially a list of potential hazards that might occur which put into context through risk characterisation through the product of the hazard characterisation and exposure assessment steps. Rather these paragraphs seem to describe part of the exposure assessment steps and are possibly better placed ahead of the current paragraph 38 or 39.

Section: Exposure assessment

The paragraphs could be arranged in a more logical fashion starting with an introductory paragraph and then the preferred method of exposure assessment, see paragraph 33 and ending with the paragraph on human exposure assessment (current para 32.). These comments are expanded on below.

Paragraph 31 and Table 1

Table 1 does not reflect the text of the paragraph nor the content of the paragraphs that follow in that it does not summarise exposure assessment methods, rather it summarises one method. Suggest paragraph 31 is replaced by an introductory paragraph.

**31. The aim of exposure assessment is to estimate the level of a hazard in food of animal origin and the resulting dietary exposure of consumers to the hazard. For some hazards a maximum level will already exist for one or more foods of animal origin and in these cases the objective of an exposure assessment might be limited to estimating the level of the hazard in feed that will ensure food derived from the exposed animals will not exceed the maximum level permitted.**

~~Table 1 summarises exposure assessment methods in feed risk assessment.~~

Table 1: Exposure assessment in feed risk assessment

<b>Hazard identification in:</b>	<b>Exposure assessment method</b>	<b>Endpoint of risk assessment</b>
Feed of food-producing animal	<del>Identify all feeds which may contribute to intake of a given hazard, based on hazard identification.</del> Calculate hazard intake from all relevant feed sources, based on information from animal feeding specialists. Use toxicokinetic measurements/modelling of transfer rate to calculate relative hazard concentration in feed and edible product.	<del>Hazard concentration in edible product (e.g. mg/kg product)</del>

Paragraph 32

Suggest paragraph 32 is amended and moved to the end of this section to become paragraph 39. In this context we suggest the last sentence of current paragraph 32 be amended as follows:

~~The transfer rates~~ from feed to edible products ~~are~~ is considered in risk assessment by JECFA when evaluating veterinary drugs and by JMPR when evaluating pesticides used in food-producing animals

**Rationale:** Transfer rates is not the correct term as it implies kinetic data were evaluated.

Paragraph 34

There needs to be some linking text to introduce transfer factors. Suggest replace the existing text at paragraph 34 with:

**In the absence of monitoring data on levels in edible product it may be necessary to estimate likely hazard levels using data on levels found in feed, feeding practices and information on the transfer of the hazard from feed to food.**

**Rationale:** As the text reads it implies the information may be derived from survey data whereas this is typically not the case. There are too many complications for the statement to be useful.

Paragraph 35

Suggest the term transfer rate be replaced by transfer and a reference to chemicals be included as the text

35. Factors which influence the transfer ~~rate~~ **of chemicals** from feed to edible product include:

- The physico-chemical characteristics of the hazard, e.g.  $pK_a$  ~~or~~  $pK_b$ , 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 into edible products.

**Rationale:** text is most relevant for chemical rather than microbiological hazards.

Paragraph 36

Suggest delete rate from the text.

36. In some cases, published toxicokinetic or other models that can predict the transfer ~~rate~~ of hazard from feed to edible products, may be used or adapted for a given exposure assessment.

**Rationale:** studies often do not predict rates

Paragraph 37

There are sometimes interactions between feed components as well as different chemicals in feed that need to be taken into account. Suggest additional text:

37. If animal feeding studies are considered necessary to establish transfer rates, careful consideration should be given to factors which may affect transfer in a given species of food-producing animal, including strain, sex, and life stage **as well as the potential for other ingredients in the feed to affect the transfer from feed.**

**Rationale:** the levels of hazard in the feed as well as the presence of other ingredient in the feed can affect the degree of transfer.

**EUROPEAN UNION**English

The European Union (EU) would like to congratulate Switzerland for the excellent work with the revised document which substantially clarifies many aspects of the discussion and takes into account the different comments sent. The EU would like to submit the following comments to the revised document. The previous EU comments on the first version of the document are to be considered still valid.

**Specific comments**

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

Throughout the document it is itself referred as guideline, guidelines and guidance. It should be preferably used a single wording such as guideline.

Heading: definitions

Definition of feed. The EU would like the definition of feed to be consistent with the definition in the Codex code of Good Animal Feeding.

The additional sentence added ("in this guideline includes water") should be deleted. Water for drinking could be mentioned as such wherever in the document this is relevant.

Point 18. The guidelines are addressed to national governments and therefore the last sentence of this paragraph concerning the participation of experts from different parts of the world is not relevant and should be deleted.

Heading: Risk assessment in the Codex Risk analysis frameworkHeading: Hazard identification

Point 22. The EU would propose the following alternative wording:

*Hazards in feed can include biological agents (viruses, bacteria, endoparasites and prions), chemical substances (such as "heavy metals", dioxins, excessive levels of pesticides, veterinary drugs and additives), radionuclides and other undesirable substances.*

The definition of undesirable substances from the Code of Good Animal Feeding should be included in the list of definitions in the corresponding section.

Point 34. Besides the hazard level in feed it is necessary to know the intake of feed by the animal and the duration of the intake.

The fate of the hazard in the animal should be more clearly considered. The suggestion by Canada in Document CX/AF/12/6/4 Add 1 to consider taking elements of the relevant section of the FAO/WHO Expert meeting of 2007 may be useful in this regard.

Point 35. The references to the concepts of pKa/pKb and log Kow should be explained further if included.

Point 38. The EU would prefer to delete the reference to animal fats in brackets because there is no reason to single out animal fats as a specific example.

Point 41. The term "output" could be replaced with the term "format of the output".

**Français**

L'Union européenne (UE) tient à féliciter la Suisse pour l'excellent travail que représente la version révisée de ce document, qui précise de manière substantielle de nombreux aspects de la question examinée et tient compte des différentes observations formulées. L'Union européenne soumet les observations suivantes sur le document révisé. Il y a lieu de considérer que les observations déjà formulées par l'Union à propos de la première version du document restent valables.

**Observations particulières**

Les observations de l'Union européenne sont énumérées ci-après dans l'ordre des paragraphes et rubriques utilisés dans le projet de document du Codex.

Tout au long de l'avant-projet, il est cité en tant que «ligne directrice», «lignes directrices» ou «orientations». Il serait préférable de recourir à une formule unique, comme «ligne directrice», par exemple.

**Rubrique: définitions**

Définition du terme «aliments pour animaux». L'Union européenne aimerait que la définition du terme «aliments pour animaux» corresponde à celle figurant dans le *Code d'usages pour une bonne alimentation animale* du Codex.

Il y aurait lieu de supprimer la phrase supplémentaire qui a été ajoutée («Dans la présente ligne directrice, cela inclut l'eau»). L'eau potable pourrait être mentionnée en tant que telle dans le document chaque fois que cela est pertinent.

Point 18. Les gouvernements nationaux étant destinataires des lignes directrices, il conviendrait de supprimer la dernière phrase de ce paragraphe, relative à la participation d'experts de différentes parties du monde, sans objet en l'occurrence.

**Rubrique: l'évaluation du risque dans le cadre de l'analyse de risque Codex****Rubrique: identification du danger**

Point 22. L'Union européenne propose de modifier le libellé comme suit:

*Dans les aliments pour animaux, les dangers peuvent se présenter sous la forme d'agents biologiques (virus, bactéries, endoparasites ou prions), de substances chimiques (telles que les «métaux lourds», les dioxines, des teneurs excessives en pesticides, en médicaments vétérinaires ou en additifs), de radionucléides ou d'autres substances indésirables.*

Il y aurait lieu d'insérer dans la liste des définitions, dans la section appropriée, la définition du terme «substances indésirables» figurant dans le *Code d'usages pour une bonne alimentation animale*.

Point 34. Outre le niveau de danger dans les aliments pour animaux, il est nécessaire de connaître la quantité d'aliments pour animaux ingérée par l'animal et le délai d'ingestion.

Le devenir du danger dans l'animal devrait être envisagé plus clairement. La suggestion formulée par le Canada dans le document CX/AF/12/6/4 Add. 1, à savoir d'envisager de reprendre certains éléments de la section pertinente du rapport de la réunion d'experts de la FAO/OMS de 2007, pourrait être utile à cet égard.

Point 35. Si les références aux notions de «pKa/pKb» et de «log Kow» sont retenues, il y aurait lieu d'expliquer ces références.

Point 38. L'Union européenne préférerait que la référence aux graisses animales figurant entre parenthèses soit supprimée, vu qu'il n'existe aucune raison justifiant de mettre en évidence, en guise d'exemple spécifique, les matières grasses animales.

Point 41. Le terme «résultat» pourrait être remplacé par le terme «format des résultats».

**Español**

La Unión Europea (UE) desea felicitar a Suiza por el excelente trabajo realizado con el documento revisado, que aclara sustancialmente muchos aspectos del debate y toma en consideración las observaciones que se le enviaron. La UE desea presentar las siguientes observaciones al texto del documento revisado. (Los comentarios anteriores de la UE sobre la primera versión del documento siguen siendo válidos).

**Observaciones específicas**

He aquí los comentarios de la UE siguiendo los apartados y las rúbricas del proyecto de documento del Codex.

En el texto se denomina el documento *guideline* (directriz), *guidelines* (directrices) y *guidance* (orientación). Convendría utilizar un único término, como *guideline* (directriz).

Epígrafe: Definiciones

Definición de piensos. La UE considera que la definición de «piensos» debe ser coherente con la definición del Código del Codex sobre Buena Alimentación Animal.

Debe suprimirse la frase añadida («Para los fines de estas directrices, se incluye el contenido de agua en el pienso»). El agua para beber puede mencionarse como tal cuando sea pertinente para el documento.

Punto 18. Las directrices van dirigidas a los gobiernos nacionales, por lo que la última frase de este apartado (sobre la participación de expertos de diferentes partes del mundo) no es pertinente y debe suprimirse.

Epígrafe: Evaluación de riesgos dentro del marco del análisis de riesgos del CodexEpígrafe: Identificación del peligro

Punto 22. La UE propone el siguiente texto alternativo:

*Entre los peligros presentes en el pienso se pueden incluir los agentes biológicos (virus, bacterias, endoparásitos y priones), las sustancias químicas (como los «metales pesados», las dioxinas, los niveles excesivos de plaguicidas, los medicamentos de uso veterinario y los aditivos), los radionucleidos y otras sustancias indeseables.*

Debe incluirse la definición de sustancias indeseables del Código sobre Buena Alimentación Animal en la lista de definiciones del apartado correspondiente.

Punto 34. Además del nivel de un peligro en el pienso, hay que conocer cuánto pienso ha consumido el animal y durante cuánto tiempo.

Hay que tener más claramente en cuenta el destino del peligro en el animal. En este sentido puede ser útil la sugerencia que hace Canadá, en el documento CX/AF/12/6/4 Add. 1, de tomar elementos de la correspondiente sección de la reunión de expertos de la FAO/OMS de 2007.

Punto 35. Hay que explicar mejor las referencias a los conceptos de pKa/pKb y log Kow, si se incluyen.

Punto 38. La UE preferiría suprimir la referencia entre paréntesis a las grasas animales, pues no hay razón alguna para tomarlas como ejemplo específico.

Punto 41. El término «el resultado» podría sustituirse por «el formato del resultado».

**INDONESIA**

Indonesia would like to congratulate the 6<sup>th</sup> session for the excellent effort in the elaboration of the proposed draft Codex standard and guidelines on animal feeding. The documents have been thoroughly prepared and are now at a certain stage of development. Indonesia is largely satisfied with the text as it currently stands and would like to make only some minor technical comments.

With the kind of the *ad-hoc* intergovernmental Codex Task Force on Animal Feeding, Indonesia would like to provide the following comments regarding the **Proposed draft Guidelines on application of risk assessment for feed (revised version) (CX/AF/12/6/4 Add.2)**

**General comments**

Indonesia noted that Switzerland, as host country of the *ad hoc* Task Force, prepared the first version of the Proposed Draft Guidelines on Application of Risk Assessment for Feed which were circulated for comments at Step 3 in 2011. Preparation of the second version of the proposed draft by Switzerland was done based on valuable comments given by many countries. In this regards, Indonesia would like to congratulate Switzerland that has worked very well on preparing the revised proposed draft Guidelines based on the written comments at Step 3.

Taking into account the main changes in the second version of the proposed draft Guidelines specifically in the section of **DEFINITIONS**, Indonesia would like to make comments as follows:

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

*Rationale:* Aquaculture is production of edible product of aquatic animal origin

**Feed ingredient:** A component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant, animal or aquatic origin, or

other organic or inorganic substances (*Code of Practice on Good Animal Feeding*, CAC/RCP 054-2004). For those ingredient originally from animal should refer to CAC/GL 24-1997 General Guidelines for Use of the Term “Halal”

*Rationale:* We propose that the Feed ingredients should not include any ingredient that is not accepted by or not suitable for society such as religion and culture.

**Feed Supplement:** natural substance(s) that already existed in the feed but it's quantity is insufficient, therefore needs to be supplemented to make up for a deficiency. These include vitamins, amino acids, and minerals.

*Rationale:*

- We propose there is a need to distinguish the definition(s) of feed additive and feed supplement.
- Analogue with the definitions of Food Additive and Food Supplement

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

*Rationale:* We suggest to avoid of using the same word with the term that would be defined

## **MALI**

### **Observations d'ordre général :**

Le Mali félicite la Suisse pour la préparation de l'Avant-projet de lignes directrices sur l'application de l'évaluation des risques en matière d'aliments pour animaux.

Il approuve globalement l'avant-projet et est favorable à sa progression à la prochaine étape de la procédure.

### **Observations d'ordre spécifique**

- retenir les définitions du Manuel de Procédure du Codex comme définitions de l'avant-projet de lignes directrices ;
- Biffer les références des définitions pour ne pas trop surcharger le document.

## **PHILIPPINES**

(i) **General comments:** Philippines would like to thank the Secretariat for the revision of the draft document and for the opportunity to provide comments on the “Proposed Draft Guidelines on Application of Risk Assessment for Feed” at step 3 of the Procedure. Philippines would like to submit the following comments shown below

### **(ii) Comments on paragraphs:**

Paragraph 9 - Definitions

In the definition of “Contaminant”, “holding” should be changed to “handling” to read as follows:

Contaminant means any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or **handling** of such food or as a result of environmental contamination.

We recommend inclusion of the term “Hazard identification” as defined by the Codex Procedural Manual since this has been used as part of the procedures in risk assessment and also for consistency's sake since all the other procedures in risk assessment were defined and therefore important that the reader has an understanding of its meaning. The definition should read as follows:

Hazard identification: The identification of biological or chemical agents capable of causing adverse effects and which may be present in a particular food or group of foods (Codex Alimentarius Commission: Procedural Manual)

Paragraph 30 - Hazard Characterization

Insert “available” before “data” and insert “inadequate” before “to characterize” to read as follows:

If (inadequate data are) **available data are inadequate** to characterize a hazard in feed, it may be necessary to consider generating such data.