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Ad-Hoc Intergovernmental Codex Task Force on Animal Feeding
(6th Session)

Berne, Switzerland, 20-24 February 2012

European Union comments on

Proposed draft guidelines on applications of risks assessment for feed

(Agenda Item 4, CX/AF 12/6/4)

European Union Competence
European Union Vote

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

(i) General comments

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

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

(ii) Specific comments

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

Heading: Background

Although no comments are requested on the "background" of the document, the EU wishes to make the following remarks to clarify certain issues.

p. 1: "… including primary production": it should be clarified if the term "primary production" refers to food or feed or both.

p. 1 could be replaced with:

"1. These guidelines provide a structured framework based on existing Codex risk assessment methods to address the risks to human health associated with the presence of hazardous chemical, biological and physical agents in animal feed and their transfer through animal feed to food."

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

Heading: Scope

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

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

p. 5 could be replaced by:

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

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

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

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

Heading: Definitions

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

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

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

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

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

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

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

The proposal would therefore read as follows:

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

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

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

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

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

[b] *Codex Alimentarius Commission: Procedural Manual*

Heading: Principles of Risk assessment
Heading: Feed Risk assessment procedure
Heading: Hazard identification

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

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

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

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

Could be replaced with:

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

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

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

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

Heading: Hazard characterization

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

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

[c] Footnotes as in original text.

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

Heading: Exposure assessment

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

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

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

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

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

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

Heading: Risk characterization

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

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

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

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

Heading: Conduct of Feed Risk Assessment

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

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

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

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

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

Heading: Suggested procedure for semi-quantitative risk assessment

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

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

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

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

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

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

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

Example of exposure assessment scoring with reference to a threshold level

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

could be replaced with:

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

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

Or /and

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

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

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

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

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

Heading: Example of risk characterisation output

p. 45 Replace the current wording:

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