

**AD-HOC INTERGOVERNMENTAL CODEX TASK FORCE  
ON ANIMAL FEEDING**

(7th Session) Berne, Switzerland, 4-8 February 2013

**European Union comments on**

**Agenda Item 5**

**Proposed draft guidance for governments on prioritizing hazards in feed  
(CX/AF 13/7/5)**

***European Union Competence  
European Union Vote***

The European Union (EU) would like to congratulate Switzerland for the continuation of the work on this topic. Please find herewith the EU comments on the abovementioned document.

**General remarks**

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

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

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

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

**Specific comments**

**INTRODUCTION**

**Paragraph 2**

The EU suggests modifying the paragraph as follows:

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

## SCOPE

### Paragraph 3

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

### Paragraph 4

To ensure consistency with the document "Proposed guidelines on application of risk assessment for feed", this paragraph should be identical to paragraph 18 of that document.

### Paragraph 5

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

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

## DEFINITIONS

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

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

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

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

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

The **definitions of transfer** in the two documents are not identical at present. Additionally, the definition should cover more clearly both the transfer of a chemical hazard and the transmission of a biological hazard. It should also include a note about the metabolism or biotransformation of the hazard in the animal. The EU would ask whether it is necessary to

indicate under which circumstances a transfer rate can be established (steady state, regular consumption of the feed by the animal or of the edible product by humans, etc.).

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

## **PRIORITIZATION OF HAZARDS IN THE FRAMEWORK OF CODEX RISK ANALYSIS**

### **PRIORITIZATION PROCESS**

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

#### **Paragraph 24**

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

The EU proposes to add a new paragraph:

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

#### *Step 4 Prioritization*

#### **Paragraph 26**

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

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

#### **Paragraph 27**

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

#### **Paragraph 28**

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

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

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

### **Paragraph 2**

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

### **Paragraph 4**

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

### **Paragraph 9**

The EU would like to propose the following change:

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

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

### **Paragraph 11**

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

### **Paragraphs 14 and 17**

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

### **Paragraph 15**

The EU proposes to add the term "*e.g.*" Aflatoxin B<sub>1</sub> can occur in "*e.g. copra.....*"

### **Paragraph 19**

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

### **Paragraph 22**

The following change is proposed:

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

### **Paragraph 22 bis**

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

*"Non dioxin-like PCBs have been widely used in a number of industrial and commercial applications. Although the manufacture, processing and distribution of PCBs have been prohibited in almost all industrial countries since the 1980s, their entry into the environment still occurs. Following exposure of farmed animals, including aquaculture, non dioxin-like PCBs will accumulate in meat, liver and particularly in fat tissues. Occupational exposures to PCBs have been reported to be associated with an increased risk of cancer of the digestive system and possibly other sites."*

### **Paragraph 24**

The EU proposes the following wording:

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

### **Table I of Annex1**

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

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

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

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

Mycotoxin formation is not only connected to humidity. For example draught plants can be vulnerable to fungi that lead to high concentrations of aflatoxin B<sub>1</sub>.

### **ANNEX 2: EXAMPLES OF THE PRIORITIZATION PROCESS**

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

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

## **Step 1**

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

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

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

## **Step 3**

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

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

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

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

## **Step 4**

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

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

Overall, the scores and their aggregation are not clear.

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