

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

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

**European Union comments on**

**Agenda Item 4**

**Proposed draft guidelines on application of risk assessment for feed  
at step 6 (CL 2012/22-AF)**

*European Union Competence  
European Union Vote*

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In general, it is desirable that both this document and the "Proposed draft guidance for governments on prioritizing hazards in feed" use the same definitions and terminology.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Definitions should be identical in this document and in the "Proposed draft guidance for governments on prioritizing hazards in feed".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The **definition of carry over** should be taken from the document: "Proposed draft guidance for governments on prioritizing hazards in feed".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and feedingstuffs** should also be harmonized with the same wording as in CAC/RCP 54-2004 and in the document "Proposed draft guidance for governments on prioritizing hazards in feed".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.