European Union comments for the

CODEX COMMITTEE ON CONTAMINANTS IN FOOD
13th Session

Yogyakarta, Indonesia, 29 April – 3 May 2019

Agenda Item 10

Draft Guidelines for risk analysis of instances of contaminants in food where there is no regulatory level or risk management framework established (at Step 7)

(CX/CF 19/13/8)

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) welcome and appreciate the work on the draft Guidelines for risk analysis of instances of contaminants in food where there is no regulatory level or risk management framework established by the electronic Working Group chaired by New Zealand and co-chaired by the Netherlands.

The EUMS wish to make the following observations and comments on the document:

- Heading **3. Scope**:
    - It is noted that the three conditions outlined in the bullet points are cumulative.
    - It is suggested to simplify the second bullet point as follows: "those detections have not been previously reported in the concerned food".
- Heading **3.1. Inclusions in the scope of these guidelines:**
    - It is suggested to reword the first sentence as follows (with an addition): "The following non-exhaustive list of groups of contaminants would fall under the scope of this document if present in food. However, it is to be noted that within each group there are regulated contaminants, which do not fall under the scope.
    - It is proposed to change the order of the points**.** The following order is proposed: natural toxins, processing induced contaminants, contaminants from materials used during processing of food, environmental contaminants and greenhouse gas mitigation technology.

- While it is acknowledged that the presence of a contaminant related to the greenhouse mitigation technology was the trigger for initiating this work, this is very specific compared to the other more general bullet points. A suggested more general description for this topic could be: "contaminants from products used in agriculture (not expected to be present in food)."

- Heading **3.2. Exclusions from the scope of the guideline:**

  - It is proposed to delete the footnote 2 related to the 3rd bullet point as HBGV can also be established by regional or national risk assessment bodies. The deletion of the footnote is in line with the fact that unregulated contaminants refer to contaminants for which there are no specific Codex, regional or national standards, recommendations or guidelines.

  - As regards the third bullet point, it is also proposed -besides contaminants for which there are health based guidance values (HBGV)- to add contaminants for which there are Points of Departure (POD)/ Benchmark Dose (lower confidence limit) (BMDL) (for genotoxic carcinogens).

- Heading **4. Roles** and **5. Reporting of detections**

  - Given that there might be already rules in place at national level as regards the interactions between laboratories / competent authorities and stakeholder, it might be appropriate to include the following sentence at the beginning of heading 4 and 5: "The provisions in this section are without prejudice to existing national or regional provisions already in place".

  - Reference is made to accredited laboratories: given the nature of the finding "unexpected in the food concerned", it is evident that a laboratory might not be accredited to perform that specific analysis in that food. Therefore, it should be clarified that the accreditation refers to a general accreditation for analysis in food rather than an accreditation for that specific analysis. It is suggested to mention "from a laboratory, accredited or equivalent level for performing analysis in food"

  - Some of the listed information that has to be provided by the analyst to the risk manager is incompatible with the nature of the finding (unexpected finding in food), such as summary statistics of occurrence data, assessment of homogeneity of distribution for the contaminant in the food. Such information is rather related to follow-up actions etc. and should be mentioned as an additional point 6.9 or be mentioned under Heading 7. Further risk management activities.

- Heading **6. Application of the Decision Tree for Rapid Risk Assessment**.

  - Reference is made to "rapid risk assessment" but no reference is made to an indicative timing that this type of assessment would represent. Acknowledging that all cases might be different and certain findings might require more time than others, it is appropriate to provide an indicative timeline for the application of the Decision tree for rapid risk assessment (e.g. 1 week)

- Heading **6.1. Exclusionary contaminant categories:** It is mentioned that a risk manager should exclude applying the decision tree to the mentioned categories of contaminants. However, a risk manager might not have the sufficient knowledge to determine if an identified substance has the potential to bio-accumulate. Therefore, it is proposed to add (in bold and underlined): a risk manager, **possibly following expert advice if needed,** should exclude applying (….).

- In the **last paragraph of heading 6.1**. Besides the possibility to derive a health based guidance value if sufficient toxicological data are available, also the Margin of Exposure (MOE) could be applied for genotoxic carcinogens in case there are sufficient toxicological data to derive a point of departure (POD) and benchmark dose lower confidence limit (BMDL).

- Heading **6.2 Application of the cut-off value.**

    - It might be appropriate to clarify that the application of a cut-off value of 1 µg/kg does not entail an obligation for laboratories to achieve that level of sensitivity for any analysis of unregulated contaminants.

    - Given the rudimentary approach followed, it might not be appropriate for the risk manager to conclude that this results in a no safety concern. It is therefore suggested to use the following wording: "No restrictive management measures to be taken" or "Low probability of adverse health effects".

- Heading **6.5 Toxicological data collection**:

    - It is proposed to use the word "should" instead of "may": the risk assessor **should** access any toxicological data (…)

    - In line with the comment made above as regards the last paragraph of heading 6.1, it is proposed to add MOE besides HBGV in the text between brackets (i.e. TTC vs HBGV/**MOE** approach).

- Heading **6.6. Selection of the TTC /establishment of a HBGV, exposure assessment and risk characterisation**

    - In line with the comment made as regards the last paragraph of heading 6.1, the title of the heading 6.6. should also make reference to establishment of POD/BMDL/NOAEL besides establishment of a HBGV (idem in the first and second paragraph of heading 6.6.)

    - In paragraph 12 of the document it is mentioned that the technical references in footnotes 1 and 4 will not remain in the final document. As the reference in footnote 4 is of major importance, the information contained in footnote 4 has to be included in the body of the text at the end of the paragraph 2 of heading 6.6.

    - In the third paragraph when reference is made to the abbreviated exposure assessment of the food of interest, it should be explicitly mentioned that exposure to the substance from other (food) sources has to be taken into account as much as possible in this rapid exposure assessment.

- Heading **6.8. Decision by the risk manager** It is proposed to delete the last paragraph starting with "Ultimately (…). Alternatively it could be specified that the second criterion refers to a public health concern **generally or to specific subgroups of the population.** This is in line with the information provided in heading 6.2.

- **Annex 1, Decision Tree for Rapid Risk Assessment**

    - In box 1, it is appropriate to explicitly refer to 3.2 and 6.1.: 1. Is the contaminant in a TTC exclusionary category **(see 3.2 and 6.1)**?

    - In order to reflect the provisions referred to in heading 6.2, it is requested to add a box 1b between box 1 and box 2 with the question: "**Could the consignment represent more than a tenth of the daily intake of a subgroup of the population?". And add right of the new box 1b: If "yes" → handle on a case-by-case basis.** If no, continue to box 2.

    - In the box left to box 2, it is better to replace "no food safety concern" with "No restrictive management measures to be taken" or "Low probability of adverse health effects" (see comment on Heading 6.2).

    - In box 6 it is appropriate to make reference to footnote 4 under heading 6.6. "Select appropriate TTC reference value **(see 6.6, footnote 4),** or in case the footnote 4 is deleted "Select appropriate TTC value (**see 6.6, 2nd paragraph).** (see comment under heading 6.6.)

    - Box 7 and box above box 7 (see comment above as regards the last paragraph of heading 6.1)

      Box above box 7: "Sufficient data and time to establish a HBGV **or POD/BMDL/NOAEL"**
      Box 7: 7. Calculate HBGV **or POD/BMDL/NOAEL**

    - Box 11 and the following two boxes: A reference to "risk management decision", might give the impression that this relates only to a decision as regards the fate of the lot/consignment or restrictive measures while, in addition, other actions might be undertaken (such as surveillance) in the case of potential health concern. Therefore, it is suggested to add in box 11 and in the two boxes below 11: "(…) risk management decision **/appropriate follow up** (…)".

- **Annexes 2, 3 and 4**

    - In paragraph 12 it is mentioned that the case studies (Annex 3) and worked examples (Annex 4) will not remain in the final document. The EUMS agree to this.

    - In addition, as no reference in the draft guidelines is made to Annex 2. Derivation of the cut-off value, the EUMS are of the opinion that this Annex should also be deleted from the final document.

    - In order to avoid any confusion and as these annexes are a source of information to assist CCCF with the development of the guidelines (§ 12), it is more appropriate for the Plenary discussion to integrate these annexes as annex to the BACKGROUND section of the document instead of annexes to the guidelines.