

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 12

CF12/CRD12

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON CONTAMINANTS IN FOODS

12th Session

Utrecht, The Netherlands, 12 - 16 March 2018

PROPOSED DRAFT GUIDELINES FOR RISK ANALYSIS OF CHEMICALS INADVERTENTLY PRESENT IN FOOD AT LOW LEVELS (AT STEP 4)

Comment submitted by EU and AU

EUROPEAN UNION (EU)

The European Union and its Member States (EUMS) welcome and appreciate the work on the draft Guidelines for risk analysis of chemicals inadvertently present in food at low levels by the electronic Working Group chaired by New Zealand and co-chaired by the Netherlands.

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

- In relation to §18 - Recommendations to CCCF: While the EUMS agree to have feed for the time being not specifically addressed in the proposed draft guidelines, the EUMS are of the opinion that it is not appropriate to explicitly exclude feed from the scope of the proposed draft guidelines and refers to the conclusion mentioned as regards the reply to Question 6, that there might be value in considering extrapolation of any cut-off values resulting from the application of these guidelines to feed, in particular for "double-use" commodities such as cereals, oilseeds, ...

As regards Appendix I:

- Point 3. Scope

- In (iii) it is proposed to delete "food crop" before phytotoxins
- In (iv) it is proposed to delete corrosion inhibitors as example of environmental contaminants.

- Point 5. Principles

- In (c) as the cut off value is dependent on the characteristics of the contaminant (cf. e.g. the Cramer classification scheme) it is appropriate to replace "A cut-off value(s) of no public health concern ..." by "An appropriate cut-off value(s) (taking into account the characteristics of the compound) of no public health concern ..."

- Point 8. Application of the decision tree for risk management decision making

- It is more accurate to refer to "Annex 1 of Appendix 1" instead of to "Appendix 1"
- Point 8.2: In order to avoid confusion with point 8.4, it is proposed to replace "and their submission for rapid evaluation as soon as possible" by "and **their intention to submit** all available information for rapid evaluation as soon as possible".
- Point 8.7, third paragraph: It is more accurate to refer to "Annex 3 of Appendix 1" instead of to "Appendix 3".

- Point 11. Training

- It is proposed to replace "it is likely that the risk assessors will be employees of the competent authority" by "it is likely that the risk assessors will be employees of the competent authority or government body/agency".

- Annex 1 of Appendix I: Decision tree

Step 2: In line with the comment on point 5 (c) it is proposed to replace "Apply the cut-off value" by "Apply the appropriate cut-off value"

The boxes (2) referring to "formal risk assessment" should be in blue or should be replaced by "request formal risk assessment" (in the latter case the boxes can remain in black).

There should be also an arrow directly from the two boxes "risk management decision" (end of the decision tree) to the box "Notify exporting country". Consequently, the dotted arrows from box "No food safety concern" and "Formal risk assessment" to the box "Notify exporting country" should be deleted.

AFRICAN UNION (AU)

Position 1: African Union supports the establishment of the Guidelines for risk analysis of chemicals inadvertently present in food at low levels and the recommendation made thereof, namely

- Agree to the definition of an emerging contaminant
- The use of a cut-off value as an initial risk management step,
- The use of an internationally agreed rapid risk assessment methodology,
- That feed is excluded from the proposed draft guidelines

Issue and rationale: The matter was brought by New Zealand following challenges facing regulatory authorities in dealing with foods containing traces of chemicals. CCCF11, approved development of risk analysis guidelines to address chemicals inadvertently present in food at low levels and CAC40 approved the work. An EWG chaired by New Zealand and co-chaired by The Netherlands was established and it prepared the guidelines and made the following recommendations for consideration by CCCF12:

- Agree to the definition of an emerging contaminant,
- Agree on the use of a cut-off value as an initial risk management step,
- Agree that an internationally agreed rapid risk assessment methodology is used,
- Agree that feed is excluded from the proposed draft guidelines

Definition of emerging contaminants: African Union recommends a clear definition of chemicals that can be classified as “emerging” to ensure a harmonized way to recognize these chemicals. This is important because at least two groups of chemicals can be inadvertently found in foods. A chemical that is not anticipated in a food in question may be present at a detectable concentration or a chemical that is known and regulated in another food is found in a food in question at a detectable concentration. Thus, the definition must be capable of distinguishing an emerging chemical from any other chemical. It must also be acceptable to all stakeholders.

Use of internationally agreed rapid risk assessment methodology. Use of a conventional methodology would ensure similarity in outcomes of risk assessment by different teams.

Exclusion of feed. The guidelines are governing trace contaminants, the presence of which in feed, may not be of a significant human health risk.

Position 2: African Union supports the EWG recommendation that CCCF12 should seek scientific advice from JECFA on the following:

- The criteria for establishing appropriate cut-off values, with the specific questions developed and timeframes,
- The role of JECFA in identifying and reviewing an internationally agreed rapid risk assessment methodology.

Rationale. Cut-off value and the methodology for rapid risk assessment have to be derived using scientific risk assessment approaches. JECFA is the body responsible to provide scientific advice on international issues on food contaminants.