

CODEX COMMITTEE ON PESTICIDE RESIDUES

46th Session

Nanjing, China, 5 – 10 May 2014

AGENDA ITEM 10

**Revision of the Risk Analysis Principles applied by the Codex Committee
on Pesticide Residues**

(CX/PR 14/46/11)

European Union Competence

European Union Vote

The European Union (EU) would like to thank the electronic working group chaired by Costa Rica and co-chaired by Chile for the revision of the Risk Analysis Principles in accordance with the mandate of the 45th session of the Committee on Pesticides Residues. The EU generally agrees that the changes made by the electronic working group are well in line with the principles agreed during the 44th and 45th session of the CCPR.

The EU would like to propose the following amendments to clarify the text:

Paragraph 4: Replace the text: "The WHO ...and an Acute Reference Dose (ARfD) where appropriate" by the original text "The WHO ...and an Acute Reference Dose (ARfD) where sufficient data are available". The need for sufficient data is not explicitly mentioned elsewhere for toxicological data.

Title between paragraphs 16 and 17: Replace "MRL for specific food groups and feed" by "MRL for specific groups". The change is needed as the sub-headings "MRL for fat-soluble pesticides" and "Establishment of Extraneous maximum residue Limits (EMRL)" do not fall into the category "food group" or "feed".

Paragraph 19 (in brackets): The EU proposes to keep the paragraph as it is needed to clarify the procedure for dual or triple use substances.

Paragraph 21 b: Add "or in milk or milk fat" after "in muscle and fat" in order to align paragraph 21 b to the addition made in paragraph 21 a.

Paragraphs 39 and 40: The order of the two paragraphs should be reversed as first the ADI or the ARfD are established and then the exposure assessment carried out.

Existing paragraph 40 (proposed to be re-numbered into 39): the paragraph should deal both with the establishment of the ADI and the ARfD. This is logic as later on there are specific paragraphs for the exposure assessment of chronic risk (existing paragraph 39) and acute risk (paragraph 41). A first sentence should therefore be added to read as follows: "The JMPR establishes ADI values and calculates the International Estimated daily Intake (IEDI)." The second sentence should then be slightly modified and start as follows: "The JMPR also establishes...ARfD...".

Paragraph 41: The last sentence of the paragraph: "This procedure has been referred to as "prospective alternative GAP analysis" should be deleted as the procedure as such is sufficiently clear, but it is not clear where the terminology comes from.

Paragraph 42: The EU supports the proposal for re-wording of paragraph 42 made by several delegations in the eWG (e.g. Japan, USA, Argentina, Switzerland) which was not taken on board. Replacing of the text for paragraph 42 with the text below should be reconsidered:

"Under this procedure, ~~having analyzed the situation,~~ if an acceptable alternative GAP is not available ~~at the moment of the evaluation,~~ interested parties ~~should be able~~ **have the opportunity** to supply both labels and field trial data that support an alternative GAP within the next year. ~~If a GAP is provided but no field trial data according to this GAP, JMPR may consider a rough estimate on the safety of the use using the proportionality principle according the agreed criteria in which case the proposed MRL may be returned to Step 6 three times. The data will be evaluated by JMPR on request of CCPR as soon as they become available.~~ ***If there is a commitment to provide information supporting alternative GAP, the information must be provided before the draft MRL is returned to Step 6 three times. Submitted data are evaluated by JMPR, on request of CCPR, as soon as possible after they become available. If there is no commitment to support alternative GAP, or no data are supplied despite a commitment being made the CCPR should proceed to withdraw the draft MRL.***

Paragraph 71:

Replace "compounds" by "pesticides" in the second sentence.

Paragraph 75 g: After the first sentence further explanation on the four year rule should be provided by adding the following text: "The four-year rule is applied when insufficient data have been submitted to confirm or amend an existing CXL. The CXL is recommended for withdrawal. However, members/observers may provide a commitment to JMPR and CCPR to provide the necessary data for review within four years. The existing CXL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted."

Paragraph 86 b: Delete "active compound".