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Agenda Item 10

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ORIGINAL LANGUAGE

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

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COMMENTS on Revision of the Risk Analysis Principles applied by the CCPR,

submitted by Argentina, European Union and CropLife International

Argentina

Taking into account the time elapsed since the beginning of the revision of this document, with the creation of a working group in 2008 upon Argentina's request in 2007, and the enormous work and effort made by all the members of the group to reach an agreement, we generally support the contents of the document, but we wish to stress that by keeping the "periodicity" of reevaluations, the inconsistency found by Argentina remains.

Teniendo en cuenta el tiempo transcurrido desde el comienzo de la revisión de éste documento, con la creación de un Grupo de Trabajo Electrónico en el año 2008, resultado de una solicitud de Argentina en 2007 y, el enorme trabajo y esfuerzo realizado por todos los Miembros de dicho Grupo para lograr un acuerdo, acompañamos en general el contenido, pero señalando que con el mantenimiento de la "periodicidad" de las revaluaciones, la inconsistencia oportunamente señalada por Argentina se mantiene.

European Union

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".

CropLife International

Unfortunately CropLife International did not receive any draft from the EWG and therefore was unable to submit any input earlier to the working group. We nevertheless hope that our comments provide helpful feedback to the text proposed in **CX/PR 14/46/11**.

Paragraph 4

Current text:

WHO Core Assessment Group considers available data, encompassing a wide range of toxicological endpoints, with the aim of estimating an Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) where appropriate.

Proposed change:

The WHO Core Assessment Group considers metabolism, pharmacokinetic studies, as well as toxicological studies to evaluate acute and chronic effects, observational studies and other available data, encompassing a wide range of toxicological endpoints, with the aim of estimating an Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) where appropriate.

Rationale:

The term 'available data' does not provide sufficient guidance and does not reflect the details of the data call-in issued by WHO each year. Secondly, providing more details in this paragraph is more consistent with the level of detail listed for the FAO data requirements in Paragraph 5.

Paragraph 77a

Current text:

The pesticide is supported by the manufacturer

Proposed change:

The pesticide is supported by a sponsor, e.g. the manufacturer who is committed to submit a complete data package to meet JMPR's data requirements.

Rationale:

Beside the manufacturer the sponsor might by a governmental organization, a grower organization or another public or private entity etc. The nature of the sponsor is not that relevant, but it needs to specified whether a 'full' data package can be made available.

Paragraph 77b

Current text:

Case B: The pesticide is not supported by the manufacturer

Proposed change:

The pesticide is not supported by the previous sponsor e.g., a manufacturer and it is not known whether the information available for submission by the new sponsor will fully meet JMPR's data requirements

Rationale:

The change clarifies the different conditions for Case A and B in Para. 79

Paragraph 79b

Current text:

Case B:

A list of pesticides and all uses supported;

Toxicological information that address the key questions for the human health assessment, including establishment of an ADI and/or ARfD, when required. In addition, information to derive the definition of residues for enforcement of a MRL and to conduct the dietary risk assessment;

Data on a sufficient number of supervised trials in or on food and feed crops reflecting the current use patterns specified on the relevant labels required for estimation of maximum residue levels and STMR and HR values. Trial data may be complemented by relevant selective survey residue data;

Other relevant information, such as available assessments by competent authorities and publications from a recently conducted literature

Proposed change: [The text has been copied from the JMPR report 2012 paragraph 2.1]

Case B:

For situations where a company no longer sponsors the product (typically older active ingredients), the information available may not comprise a full data package. In these cases, in order to maintain consistency in the quality of its assessments, JMPR would adhere to the following principles:

- The requesting country/sponsor should be responsible for providing information on the intended uses, specification of the technical active substance used in the country and a justification for assessment by JMPR.
- The information required would be such that it would be possible to address the key questions for the human health assessment, including establishment of an acceptable daily intake (ADI) and/or acute reference dose (ARfD), when required, and the definition of residues for enforcement of MRLs and dietary risk assessment. Furthermore, data on a sufficient number of supervised trials in or on food and feed crops reflecting the current use patterns specified on the relevant labels are required for estimation of maximum residue levels and supervised trials median residue (STMR) and highest residue (HR) values. Trial data may be complemented by relevant selective survey residue data. A complete list of information required is described in the FAO JMPR Manual.
- It is the responsibility of the requesting country to provide the available data and other relevant information, such as available assessments by supranational and national authorities and publications from a recently conducted literature search.
- If literature studies are to be relied upon, JMPR will weigh such studies for their quality and design. Because raw data will not be available, there needs to be sufficient information on methods and results to enable the study findings to be reconstructed.
- If critical data are missing, then JMPR may still determine whether an assessment is possible; in such cases, however, it is likely that conservative assumptions will be used to address the missing information. For example, in the evaluation of propylene oxide in 2011, JMPR used an additional safety factor of 10 in establishing the ADI and the ARfD, because of limitations in the database.
- If sufficient information is not available to enable the establishment of health-based guidance values, JMPR may provide alternative guidance, such as characterization of the margin of exposure, or may conclude that it is not possible to provide any guidance in the absence of additional information. The suitability of the submitted information can be assessed only on a case-by-case basis.

Rationale:

The level of detail provided by the JMPR gives excellent guidance to interested sponsors. It underlines JMPRs commitment to analyse the available information even if not all data requirements are met and clarifies that a final judgement on the acceptability of the information can only made case by case.

Paragraph 88

Current text:

If CXL are deleted and the pesticide is persistent in the environment is required to establish EMRL to cover international trade after CXL are deleted.

Proposed change:

Upon deletion of CXL(s), it may be necessary to establish EMRL(s) to cover international trade if the pesticide is persistent in the environment.

Rationale:

Clarification of existing sentence

Paragraph 89

Current text:

If members or observers intend to express a concern with advancement of an MRL or the evaluation of a pesticide, they should complete and submit the concern form in Annex A

Proposed change:

If members intend to express a concern with advancement of an MRL or the evaluation of a pesticide, they should complete and submit the concern form in Annex A

Rationale:

Concerns forms should be submitted by members only

Paragraph 91

Current text:

When a concern form is not submitted one month prior to the CCPR session, JMPR will consider the concern at a following meeting and CCPR would subsequently decide on the status of the MRL.

Proposed change:

When a concern form is not submitted one month prior to the CCPR session, and the majority of members in the CCPR support the MRL advancement, the MRL will be advanced to step 8. On request, reservations of members not supporting that MRL advancement will be noted. As well the JMPR can be asked to consider the concern at the meeting following the CCPR meeting and report to the CCPR which then will decide on whether or not the CXL needs to be revoked.

Rationale:

The original text implies that any concern form which is submitted later than one month before the CCPR, has to be addressed by the JMPR in their next meeting. This is not always the case for concerns submitted 'in time'. Secondly all concerns submitted late will delay the MRL setting process, which contradicts the objective of the concern forms to support a transparent and quick decision making process.

Paragraph 95

Current text:

If members or observers intend…

Proposed change:

If members intend….

Rationale:

Submission of concern forms should be limited to members