The European Union (EU) would like to thank Argentina as a chair and Costa Rica as a co-chair of the working group for preparing the “Draft Revision of the Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues”. We highly appreciate the valuable work on the draft. However, we would like to make a few comments.

The EU generally supports the adoption of the revised risk analysis principles and will not object to their final adoption. However, the EU cannot exclude to object on a case by case basis – as it already does – especially if the evaluation provided for substances falling under case B situations would not be satisfactory from a consumer safety point of view.

In fact, the EU continues to have concerns about the derogations introduced for substances no longer supported by the original manufacturer (case provided for under B in § 5.4).

In particular, the EU believes that it is not appropriate that for old compounds, for which the original studies might have been performed according to now-outdated protocols and standards, critical data are missing for a complete evaluation. Similarly, the EU believes that for those compounds sufficient information should be available to enable the establishment of health-based guidance values.

Page 3, “5.2.1 Procedure for the preparation of the Priority List”, fifth paragraph:

Nominations of compounds are restricted to new compounds. This is not acceptable. Therefore, the following wording is proposed:

“All nominations for compounds are submitted by members to the Chair of the EWG on Priorities and the JMPR Secretariat using the form in the FAO manual.”

Additionally it is proposed to add a footnote at the end of the fifth paragraph to indicate where to find the form in the FAO Manual:

Page 3, “5.2.1 Procedure for the preparation of the Priority List”, last paragraph:

It does not seem necessary to mention that CCPR will include two reserve compounds; this is already common practice in the EWG on Priorities. Therefore, it is proposed to delete this paragraph.

Page 3-4, “5.2.2 Criteria for the elaboration of the Priority List”, “New Chemicals”

In this chapter it is mentioned three times that the “member country” should provide data and meet the JMPR data call-in deadline. We agree that according to JMPR Manual the form for nomination should be provided by member countries. But it should be born in mind that this chapter refers to new chemicals where member countries do not have own data in hand. Therefore, it is proposed to change the text, which refers to the commitment to provide data by replacing “member country” by “members, manufacturers or observers”. This would be more in line with the actual procedure.

Page 4, “5.2.2 Criteria for the elaboration of the Priority List”, “Periodic Re-Evaluation”

The second bullet point (new introduced in the text) is not a prioritization criteria – it is a nomination criteria for the periodic re-evaluation. The associated prioritization criterion is covered by the eighth bullet point.

In addition, a public health concern - as mentioned in chapter 7, point 7.2 - is a nomination criteria.

Therefore, the chapter “Periodic Re-Evaluation” should begin with the nomination criteria for periodic review: The following wording is proposed:

“Periodic Re-Evaluation

Before a nomination is accepted the following criteria must be met:

- Chemical have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years and/or
- A public health concern has been claimed”

The new added second bullet point should be deleted.
Page 4-5, “5.2.2 Criteria for the elaboration of the Priority List”, “Follow-up and Others Evaluations”

The wording in the second paragraph concerning the application of the four-year rule seems to be misleading. In the bullet points 4 and 5 the cases when to apply the four-year rule are mentioned. For clarification the application of the four-year rule could be described in a more detailed manner in these bullet points.

Therefore, it is proposed to delete the following wording of the second paragraph:

"Noting that members may request, and CCPR may agree to, the application of the four-year rule”

In addition it is proposed to replace the text of the fourth and fifth bullet points as follows:

- “A data deficiency is noted by JMPR during an evaluation and a member country commits to provide the required information. Members may request and CCPR may agree to the application of the four-year rule. In this case members, manufacturers or observers have to provide a commitment to the JMPR and CCPR to submit the necessary data for review within four years. The JMPR recommendation is held in the Step Procedure for a period not exceeding four years;
- A Codex MRL is recommended for withdrawal. Members may request and CCPR may agree to the application of the four-year rule. In this case members, manufacturers or observers have to provide a commitment to the JMPR and CCPR to submit the necessary data for review within four years. The CXL is maintained for a period not exceeding four years pending the review of the data.”

Page 5, 5.4 MRLS PERIODIC REVIEW PROCEDURE

The numbering of chapter 5.4 should be changed to 5.3 as currently no chapter 5.3 is included in the text.

Page 5, 5.4.2 PHASE II - Status Report on Data Commitments and CCPR Follow-up (Year 2, CCPR session), 1. Status report on data commitments [new number 5.3.2]

In the Note a typing error should be corrected:

Note: If there is no commitment, the EWG on Priorities report will inform about the potential deleting CXLs.

Page 6, 5.4.1 PHASE I – point 2. III) In the case provided for in C

The first bullet point should be complemented by an additional clarification as follows:
- "A list of CXLs that member or observer are willing to support (provided that a complete data package has been submitted by the manufacturer as described in case A, except for the CXL that are not anymore supported by the manufacturer)."

Page 7, 5.4.2 PHASE II – point 2. II) Procedure for Case B

In the second bullet point the sentence “, however, it is likely that conservative….missing information”, is not appropriate for a procedural manual. The sentence was given as an example in the JMPR report but should not become automatic. JMPR has to keep the freedom of its conclusions.

Page 7, 5.4.2 PHASE 2 – point 2. III) Procedure for Case C

The first sentence should be complemented by an additional clarification as follows:

If a commitment is made to provide and identify or develop data to support the CXLs, as provided in Case C, and if enough data has been submitted by the manufacturer to support the active substance, the review of the new data or Good Agricultural Practices (GAPs) is scheduled for review by the JMPR.

Page 8, 5.4.3 Flow chart - Summary of Periodic Review Procedure for Codex MRLs

It is very difficult to find a relationship between the steps in the flowchart and the previous paragraphs. It is suggested to improve either the structure of the paragraphs consistently with the flow chart or to at least refer to specific paragraphs of section 5.4 in the boxes of the flowchart.

We believe that the case where a health concern appears after the first JMPR evaluation should be added to the decision tree (e.g. 4th branch of the tree with acute risk concern), and a direct deletion of the CXL should be possible without entering the four-year rule.

Therefore, we propose reviewing the decision tree as in figure 1. This should be reflected in section 5.4.2 and a new sub-paragraph should be included at the end of page 7 with the following text:

"4. Sufficient information to conclude on an intake concern for an existing CXL

If the JMPR evaluation concludes that the available data clearly indicate an intake concern for an existing CXL, then that CXL will be proposed for deletion at the following CCPR."
Therefore, the EU proposes reviewing the decision tree as follows:

**PESTICIDE SELECTED FOR PERIODIC REVIEW**
A LIST IS SUBMITTED

- CCPR – INVITE TO COMMITMENT
- COMMITMENT TO SUPPORT DATA (CASE A) or B) or C)
- JMPR EVALUATION AND PROPOSALS
  - SUFFICIENT DATA ARE SUBMITTED TO CONFIRM CXL
    - THE CXL IS MAINTAINED
  - SUFFICIENT DATA ARE SUBMITTED TO SUPPORT NEW MRL
    - THE NEW MRL IS CIRCULATED AT STEP 3
    - EXISTING CXL DELETED AFTER NO MORE THAN 4 YEARS
  - INSUFFICIENT DATA ARE SUBMITTED TO CONFIRM CXL OR TO SUPPORT NEW MRL
    - COMMITMENT IS MADE BY THE TIME OF THE NEXT CCPR TO PROVIDE DATA
      - CXL MAINTAINED FOR NO MORE THAN 4 YEARS FOLLOWING AVAILABILITY OF JMPR REPORT OR WRITTEN NOTIFICATION RESULTS
    - NO COMMITMENT IS MADE TO PROVIDE DATA
      - CXL RECOMMENDED FOR DELETION BY CCPR

- INSUFFICIENT DATA ARE SUBMITTED TO CONFIRM CXL OR TO SUPPORT NEW MRL
  - SUFFICIENT DATA TO CONCLUDE ON AN INTAKE CONCERN
    - CXL RECOMMENDED FOR DELETION BY CCPR
  - 2ND JMPR EVALUATION AND PROPOSALS
    - SUFFICIENT DATA ARE SUBMITTED TO CONFIRM CXL
      - CXL IS MAINTAINED
    - SUFFICIENT DATA ARE SUBMITTED TO SUPPORT NEW MRL
      - NEW MRL CIRCULATED AT STEP 3
    - INSUFFICIENT DATA ARE SUBMITTED TO CONFIRM CXL OR TO SUPPORT NEW MRL
      - CXL IS RECOMMENDED FOR DELETION BY CCPR
Appendix 1 – Part B

Page 13, 3. Risk Assessment Policy

The bullet point “The Criteria for nomination, prioritization and scheduling of compounds” occurs twice.

Page 15, 3.1.4 MRLs for processed or ready-to-eat foods or feeds

The amendment in the first bullet point (insert: “from its consumption”) seems to be an unnecessary restriction compared to the heading “processed or ready-to-eat foods or feeds”. We should have in mind that a couple of processed products are very important as animal feed and it might be difficult to address this by means of consumption. Further clarification is necessary before accepting the addition. Therefore after the word “consumption” the words “by humans and/or animals” should be added.

Page 17, 6.1 Utilisation of Steps 5/8 for Elaboration of MRLs, Steps 5/8 Procedure (Recommendation to omit Steps 6 and 7 and adopt the MRL at Step 8)

After the first bullet point “If the preconditions listed above are met;” the second bullet point is missing. The second bullet point should start “If a delegation has a concern with advancing a given MRL, …”.

We agree that the (new) second and third (as well as the fourth) bullet points based on the Swiss proposal were accepted. Nevertheless, we feel that the bullet points two and three need further clarification in the light of text in section 7 to clarify the timelines. Therefore, the following wording is proposed:

- “If a delegation has a concern with advancing a given MRL, a concern form must be submitted following the procedure described in section 7 at least one month before the CCPR session;
- If that concern can be addressed at the CCPR session, and the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 5/8;”