CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 10 **CX/PR 12/44/13-Add. 1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

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COMMENTS on the Revision of the Risk Analysis Principles applied by the Codex Committee on Pesticide Residues, submitted by Argentina, Brazil, Chile, Costa Rica, and United States of America

Argentina and Brazil

General Comments

Argentina and Brazil would like to thank the EWG presidency for the work carried out on the Risk Analysis Principles applied by CCPR preliminary draft, that in general follows it; for the effort made to integrate the texts on: Risk Analysis Principles applied by the Codex Committee on Pesticides Residues, the criteria for the establishment of priority lists of compounds procedures for the JMPR's evaluation -Joint FAO/WHO Meeting on Pesticides Residues-, the MRL periodic review procedure, and the form to be filled out with concerns and the appropriate clarifications, as well as for having harmonized the text with the document on Principles of the Practical Application for the Risk Analysis Applicable within the frame of Codex Alimentarius and the Statements of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which other factors are taken into account, all this within the framework of the mandates received in due course, besides considering the debates that took place in the last CCPR meeting, and the comments and proposals made by EWG members.

This year we would like to specially highlight the full adaptation of the text submitted, which in turn, at length respects the Assembly Mandate, born from the Unanimous Agreement reached in the 2011 CCPR Assembly, based on the proposals made by Brazil in the CRD 28.

Moreover, Argentina and Brazil want to underline the valuable opportunity to exchange views with other EWG members, which 14 member countries attended during this period, besides the European Union and Crop Life International. This resulted in the flexibility of some initial positions.

Over the past year, two rounds of comments on the fundamental aspect of reevaluation and another round on the rest of the paper were carried out.

Among the above mentioned rounds, a technical meeting requested by Australia took place in Buenos Aires in November 201. Both Brazil and Argentina took part in it.

Specific comments

Argentina and Brazil share the structure and the index of the new document, which has been rearranged according to what the General Principles Committee suggests (CL 2010/1-GP), as much as the wording improvement in the Spanish version proposed by Spanish speaker members.

We agree on the proposal of not reopening issues which are already dealt with in this and other areas of the Codex such as MRLs for fat-soluble pesticides and MRLs for products of animal origin; particularly, in relation to the Periodic Review Procedure, clearly the ones included in the unanimously carried agreement reached in the previous Assembly according to the paragraph 131, report from the 43rd session of the CCPR (REP11/PR).

Similarly, we share the current comprehensive proposal, which is also complete and respects the mentioned agreement, taking further into account the changes and additions proposed by AWG members, the following issues being particularly relevant:

a) The hierarchy of the consumer's healthcare.

b) The scientific-base respect any legislation that produces any changes in regulations in Codex should have, when it adds, modifies or eliminates something.

c) The clear compliance with the Statements of the Codex Principles.

d) The clarification of the respective roles of each participant in the Procedure.

e) The definition of requirements to be fulfilled to modify Codex MRLs situation.

f) The inclusion of three different categories of requirements to adjust the procedure to the document on the Principles of Practical Application for the Risk Analysis Applicable within the frame of Codex Alimentarius.

g) The studies specification to be submitted in order to gain efficiency and shorten deadlines, when considering the JMPR's work overload.

h) The respect for the value of efforts already made in previous studies not called into questions by others of the same kind.

i) The assurance of fair international trade practices.

Discussions on some issues in other areas of the Codex where there are very appropriate comments on some of our concerns have not gone unnoticed to us, as it is the case in CX/PR 12/44/15 when it reads:

"Screening early in the process to identify those compounds that are anticipated to have little exposure (and perhaps lower toxicity) to determine the need toevaluate the full dossier"

Chile

Note:

Our comments are highlighted in yellow; in red is what we consider that should be deleted and in green what we do not totally understand.

General comment:

We find that the distribution of this document is much better, there is a progress in relation to document CX/PR 11/4/12, presented at the CCPR43, year 2011. The document is easier to understand, we find that the division into two documents is more appropriate, leaving apart what is related to 'periodic review' and the fact that only exists a proposal about the "MRLs Periodic Review Procedure". However, we still have some stylistic comments, and ask for more accurateness in the scope of some terms, in order to be able to have a final opinion about key aspects of this document.

PART I – PERIODIC REVIEW

RISK ANALYSIS PRINCIPLES APPLIED BY THE CCPR REGARDING THE EVALUATION AND REEVALUATION PROCEDURES

5.2 PREPARATION OF CCPR PRIORITY LIST OF PESTICIDES

5.3 CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR

Before proposing a pesticide/commodity for prioritization, it is recommended that members check if the pesticide is already in the Codex system.

General Criteria

5.3.1 Criteria and procedures for proposing pesticides for Codex priority lists

5.3.2 Criteria for selecting food commodities for which Codex MRLs or EMRLs should be established

Criteria for Prioritization

5.3.3 New Chemicals

When prioritizing new chemicals for evaluation by the JMPR, the Committee will consider the following criteria:

I. If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals having the same function (insecticide, fungicide, herbicide, etc.);

Note: In order to satisfy the criterion that the proposed new chemical is a "safer" or "reduced risk" replacement chemical, the nominating member or observer is required to provide:

a) the name(s) of the chemicals for which the proposed chemical is likely to be an alternative;

b) a comparison of the acute and chronic toxicities of the proposed chemical with other chemicals having the same function (insecticide, fungicide, herbicide);

c) a summary of acute and chronic dietary exposure calculations encompassing the range of diets considered by CCPR;

d) other relevant information to support classification of the proposed chemical as a safer alternative chemical; and

e) once other aspects have been addressed, consideration must be given to agronomic variables of the chemicals.

II. The date when the chemical was nominated for evaluation;

We maintain the comment of 2011: The scope of this criterion "date when the chemical was nominated for evaluation" should be explained in detail, that is, how it is applied, the purpose of prioritizing, together with stating whether there is a maximum term.

III. Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission; [a firm date = una fecha en firme]

IV. The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists;

V. Allocating priorities to new chemicals so that about 50% of evaluations are for new chemicals, if possible.

We maintain the comment of 2011: We consider that it is appropriate that new products constitute at least 50% of the products to be evaluated, but this is not a criterion for prioritizing among the new compounds but a definition in relation to reevaluations (old products), and therefore it should be placed as a paragraph after these criteria.

We agree to delete the criterion on "economic aspects", (proposed by Brazil and India).

5.3.4 Periodic Re-Evaluation

When prioritizing chemicals for periodic re-evaluation by the JMPR, the Committee will consider the following criteria:

I. If scientific data concerning the intake and/or toxicity profile of a compound indicates some level of consumers' health concern;

II. Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;

III. If no ARfD has been established by Codex or if established ADI or ARfD are of consumer concern and an information available from members on national registrations and/or the conclusions from national/regional evaluations indicated a consumer's health concern;

We think that this point III, is part of point I; these are specific aspects, therefore it is not totally understood.

IV.The CCPR has been advised by a member that the residues from a compound has been responsible for trade disruption;

V. The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation – Not Yet Scheduled;

We maintain the comment of 2011. We request that the scope of this criterion is explicitly stated, that is, how it is applied and the purpose of prioritizing.

VI. The date the data will be submitted;

VII. If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently;

VIII. The availability of current labels arising from recent national re-evaluations;

Note: The labels should be available by the time of the JMPR evaluation.

IX. Whether the data is submitted under the four-year-rule for evaluations.

Note: The four-year-rule is applied when insufficient data have been submitted to confirm or amend an existing Codex MRL The Codex MRL is recommended for withdrawal. However, manufacturers, members or observers may provide a commitment to the JMPR and CCPR to provide the necessary data for review within four years. The existing Codex MRL 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.

We maintain the comment of 2011: The scope of the proposed criterion is not understood, in the sense of how is prioritization applied; it seems that what is highlighted in green should be "if the data is presented according to...". Furthermore, the end of the sentence should refer to 're-evaluations' and not to 'evaluations'.

General note: Considering the criteria mentioned above and regarding the purpose of the Statute of the Codex Alimentarius Commission, the priority will be to protect the health of the consumers and ensure fair practices in the food trade.

The idea in the "general note" should be included at the beginning of point 5.3.4, in order to highlight it more.

5.3.5 Other evaluations

When prioritizing proposed toxicological or residue evaluations by the JMPR the Committee will consider the following criteria:

I. The date the request was received;

II. Commitment to provide the required data for review by the deadline of data submission for the evaluation of the toxicological and/or residues studies by the JMPR;

III. Whether the data is submitted under the 4-year rule for evaluations;

The scope of the proposed criterion is not understood, in the sense of how is prioritization applied; it seems that what is highlighted in green should be "if the data is presented according to...". Furthermore, the end of the sentence should refer to 're-evaluations' and not to 'evaluations'.

IV. The nature of the data to be submitted, and the reason for its submission; for example, a request from CCPR.

Note: Where a pesticide has already been evaluated by the JMPR and MRLs, EMRLs or GLs have been established, new evaluations may be initiated if one or more of the following situations arise:

I. New toxicological data becomes available to indicate a significant change in the ADI or ARfD. In such a case the WHO Joint Secretary will schedule the request for the next JMPR;

II. A data deficiency in an evaluation noted by the JMPR. In response, members, observers or manufacturers may pledge to supply the information to the appropriate Joint Secretary of the JMPR with a copy for consideration by the CCPR secretariat. Following scheduling in the JMPR tentative schedule, the data should be submitted subsequently to the appropriate Joint Secretary of the JMPR;

III. The CCPR may place a chemical under the four-year rule, in which case members, observers or manufacturers should indicate support for the specific MRLs to the Joint Secretary of the JMPR and the Chair of the EWG on Priorities. Following scheduling in the JMPR tentative schedule, any data in support of maintenance of the MRL(s) would be submitted to the Joint Secretary of the JMPR;

IV. A member or another interested party if supported by a member may seek to expand the use of an existing Codex chemical: that is, obtain MRLs for one or more new commodities where some MRLs already exist for other commodities. Such requests should be directed to the Joint Secretary of the JMPR and submitted to the Chair of the EWG on Priorities for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR;

V. A member or another interested party if supported by a member may seek to review a MRL due to a change in GAP. For example a new GAP may necessitate a larger MRL. In this case the request shall be made to the Joint Secretary of the JMPR with a copy to the Chair of the EWG on Priorities for consideration by the Committee CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR;

VI. The CCPR may request a clarification or reconsideration of a recommendation from the JMPR. In such cases the relevant FAO Joint Secretary of the JMPR will schedule the request for the next JMPR.

5.4 MRLs PERIODIC REVIEW PROCEDURE

The periodic Review Procedure consists of two different phases as described below:

5.4.1 PHASE I - Identify Periodic Review Chemicals and solicit data commitments (Year 1, CCPR meeting)

1. Listing Compounds for Periodic Re-evaluation

Compounds are listed *[enlistados]* for periodic re-evaluation according to the process and procedures described in section 5.2. The process provides members and observers a notice of a periodic re-evaluation.

When a compound is listed *[enlista]* for periodic re-evaluation, manufacturers, members and observers are able to support it, regarding the three following possibilities:

A) The chemical and all CXLs are supported by the manufacturers with a complete data package;

B) The chemical and all CXLs are not supported by the manufacturers;

In this case, interested members or observers may support the re-evaluation of the compound and submit residue data and a national monograph on toxicological data to JMPR.

C) The chemical is supported but only one (or some) CXL is not supported by the manufacturers.

In this case, interested members or observers may support the MRL by submitting the GAP or providing new residue data and GAP to JMPR for a new recommendation.

If there is no commitment to support a compound listed *[enlistado]* for periodic re-evaluation or existing Codex MRLs or new proposed MRL for use of such a compound on particular commodities, this is highlighted in the draft Priority List distributed to members and observers by Circular Letter as well as the priorities agenda paper tabled at CCPR.

2. Commitment to Support Chemicals or existing Codex MRLs or new proposed MRL

The commitment of members to provide data for the periodic review should be addressed to the Chair of the EWG on Priorities and the JMPR Joint Secretariat. Manufacturers and observers, when addressing the commitment to a nominating member, should copy it to the Chair of the EWG on Priorities and the JMPR Joint Secretariat.

The following information must be provided in the response:

I) In the case provided for in A

- A list of chemicals and all CXLs supported by the manufacturer;

- A draft list of all chemistry (residue, metabolism, animal transfer, processing, analytical sample storage stability, analytical methods etc.) and toxicology studies and other data that they are willing to provide and the data they commit to make complete data package submissions to the JMPR. Comments on the status of registration at the national level are encouraged;
- A brief summary of all current Good Agricultural Practices (GAPs) at the time of the notification and any potential new GAPs expected before the JMPR evaluation which they are willing to provide and which is pertinent to residue data they are willing to provide (e.g. commodities and countries for with detailed GAP summaries and representative labels can be provided).

II) In the case provided for in B

- A list of chemicals and CXLs members or observers are willing to support;
- The national monograph on toxicological data and other available scientific studies;
- Current Good Agricultural Practices (GAPs) – label (when there has been no changes in use);
- Supervised residue trial studies conducted according to current GAP, and relevant studies to support new MRLs in animal and processed commodities.

The scope of a national monograph on toxicological data must be clarified. Does it refer to a monograph for national registration? Does it refer to the contents of monographs developed by the JMPR?

Should supervised studies be national?

It would be very important to have a definition of "national monograph on toxicological data"

In case it means compiling international toxicological data, like data of

III) In the case provided for in C

- A list of CXLs members or observers are willing to support;
- Current Good Agricultural Practices (GAPs) – label (when there has been no changes in use);
- Supervised residue trial studies conducted according to current GAP, and relevant studies to support new MRLs in animal and processed commodities.

3. Repeat the Invitation and Notification

5.4.2 PHASE II

Status Report on Data Commitments and CCPR Follow-up (Year 2, CCPR meeting)

1. Status report on data commitments

The Priorities EWG will provide a report and room document to the CCPR on the status of commitments received to provide data for the chemicals identified in year 1. This information will be used to schedule JMPR reviews:

A) Chemicals and CXLs that will be supported by the manufacturers with a complete data package;

B) Chemicals and CXLs that will be supported by members or observers (that is, chemical not supported by the industry);

C) CXLs that will be supported by current Good Agricultural Practices (GAPs) or new residue data and GAPs (that is, CXLs not supported by the industry, even if the chemical is supported).

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

2. Response to data commitments

I) Procedure for Case A

If a commitment is made to provide and identify or develop data to support the chemicals and existing CXLs, as foreseen in Case A), the complete data package will be scheduled for JMPR review. The JMPR review will be conducted consistent with one of the following scenarios:

- Sufficient toxicological data (and other studies) are submitted to support the chemical and it is therefore maintained;
- Sufficient data are submitted to confirm the existing CXL and it remains in place;
- Sufficient data are submitted to support a new proposed MRL, it enters the process at Step 3 and the existing CXL is deleted as soon as the new proposed MRL is adopted by CAC at the latest automatically after no more than 4 years;

The part highlighted in green is not understood; the intended meaning seems to be: while the existing CXL is deleted when the new MRL has been adopted by the CAC within 4 years at the latest, otherwise once this term has expired it is automatically deleted.

II) Procedure for Case B

If commitments are made to provide, identify or develop data supporting the chemicals and existing CXLs, as foreseen in Case B), the JMPR review of the data will be scheduled.

The JMPR review will result in one of the following scenarios:

- A national monograph on toxicological data is submitted to evaluate the chemical;
- Current Good Agricultural Practices (GAPs) are submitted to confirm the CXL which is therefore maintained;
- Residue studies and most recent Good Agricultural Practices (GAPs) are submitted to support a new MRL proposal. It enters the process at Step 3 and the existing CXL will be automatically deleted after no more than four years.

Note: If the submitted data are insufficient, the JMPR may request additional data on a case-by-case basis.

It must be defined what should be understood by national monograph on toxicological data, so that it is clear when the information could be insufficient.

III) Procedure for Case C

If a commitment is made to provide and identify or develop data to support the CXLs, as provided for in Case C), the review of the new data or Good Agricultural Practices (GAPs) are scheduled for review by the JMPR.

The JMPR review will result in one of the following scenarios:

- Current Good Agricultural Practices (GAPs) are submitted to confirm the CXL which is therefore maintained;
- Residue data and most recent Good Agricultural Practices (GAPs) are submitted to support the new MRL proposal. It enters the process at Step 3 and the existing CXL will be automatically deleted after four years.

Note: If the submitted data are insufficient, the JMPR may request additional data on a case-by-case basis.

IV) In any of the three procedures (A, B and C) mentioned above, three scenarios may occur:

- the data support the chemical (except procedure C);
- the data confirm the existing Codex MRL, it remains in place;
- a new MRL is recommended or an amendment of an existing MRL. The new or amended proposal enters at Step 3 of the Codex procedure. The existing MRL remains in place for no more than four years; or;
- the data submitted is insufficient to support the chemical or the existing CXL or the new MRL;

3. Insufficient information to support a CXL

If insufficient data have been submitted to support the chemical or the existing CXL or the new MRL, manufacturers, members or observers are so advised by written notification from the relevant Joint Secretary of the JMPR and/or by issuance of the JMPR Report.

On being advised of the data inadequacy, manufacturers, members or observers may, **by the next CCPR Meeting**, **provide to the JMPR and the CCPR Secretaries a written commitment to generate and submit a dossier** of required data for review **within 4 years**, under the condition that no unacceptable acute/chronic risks have been identified by JMPR.

The part highlighted in blue is not understood, it seems contradictory with the following paragraph, also highlighted in green.

If an unacceptable acute/chronic risk has been identified by the JMPR, on a scientific base, the additional period to submit the dossier of required data will not be granted and the CXL should be proposed for deletion.

The chemical and the CXL is maintained for no more than 4 years following advice of data inadequacy (by direct notification or by issuance of the JMPR Report). The 4 year period may be extended by the CCPR only to the extent necessary for the JMPR to schedule and complete review of the available new data. The new data are scheduled for the second JMPR review and the first part of the PHASE II 2b procedure is repeated.

If the **committed data are not submitted**, or if the data submitted for the initial periodic review **are insufficient** and no commitment is made by the next CCPR Meeting to generate new data, **the CCPR recommends deletion of the CXL**.

Costa Rica

“Costa Rica, similarly to what was expressed by the electronic working group, supports the proposal as long as the inconsistency in the current document regarding the revocation of MRLs without scientific justification is corrected.

United States of America

The U.S. Delegation would like to thank the Delegations of Argentina and Brazil for leading this effort and the work they have done on behalf of the EWG. The U.S. Delegation appreciates the opportunity to provide comments on CX/PR 12/44/13, *Revision of the Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues*. After reviewing this document, the U.S. Delegation has the following comments:

The U.S. proposes to revise the first sentence in the fourth paragraph in section **5.2 Preparation of CCPR Priority List of Pesticides** (p. 3) to read:

Members should send a request for evaluation to the Chair of the EWG on Priorities and the JMPR Joint Secretariat. ~~Manufacturers and observers, when sending a request for evaluation to a nominating member, should copy the request to the Chair of the EWG on Priorities and the JMPR Joint Secretariat~~. **Manufacturers and observers should send a request for evaluation to a nominating member**.

Rationale: The U.S. Delegation notes the new language proposed by CropLife (p. 20), which includes the following sentence: "Other interested parties, when sending a request for evaluation to a nominating member, should copy the request to the Chair of the EWG on Priorities and the JMPR Joint Secretariat." However, the U.S Delegation still believes that it will be confusing to have manufacturers and observers or "other interested parties" copy their initial requests to the Chair of the EWG and the JMPR Joint Secretariat this early in the process. Once the U.S. Delegation receives such requests, they work to determine if the required data are available for submission to the JMPR for review and whether it is appropriate for the U.S. Delegation to make such a nomination. Therefore, it is possible that a request submitted to a Delegation may not be nominated for review by the JMPR. Please note that this proposed revision was originally included in the December, 2011 comments from the U.S. Delegation on the draft text of the ***RISK ANALYSIS PRINCIPLES APPLIED BY THE CCPR*** regarding the evaluation and reevaluation procedures sections 5.2 through 5.4.3.

The U.S. Delegation would like further clarification to the proposed criteria under section **5.3.3 New Chemicals** (p. 4) for prioritizing new chemicals for JMPR evaluation, especially as to how these criteria will be used to prioritize nominations and the process by which the Committee will consider these criteria. The U.S. Delegation also seeks further clarification to section I., concerning "safer" or "reduced risk" chemicals. Specifically, the Delegation would like to ensure that these criteria are not used to exclude chemicals that are not considered "safer" or "reduced risk" from evaluation by the JMPR.

Additionally, under proposed section **5.3.3 I. e) New Chemicals** (p. 4), the U.S. Delegation notes that the March, 2012 version of the document includes clarification of the term "agronomic variables" in **PART III** (p. 40) by noting that the term "is related to some characteristics of a country or a region: weather, soil type, pests and diseases pressure, among others." Though the term has been clarified, there is still potential concern that consideration must be given to these variables. The U.S. Delegation is uncertain how agronomic variables, as defined, would help in making a reduced-risk determination. The U.S. Delegation would like to discuss these criteria further in order to determine how these variables would assist in determining whether a chemical is "safer" or "reduced risk."

In order to provide clarification, the U.S. proposes to revise the first paragraph in section **3.1.1 MRLs for commodities of animal origin** (p. 10), to read:

> Farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or commodities used in animal feed, (e.g. forage crops, plant parts that ~~could be~~ **are** used in animal feeds, including also by products or coproducts of industrial productions, such as biofuels, entering into the food chain through feed). The results of farm animal feeding studies and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in animal products.

> The U.S. Delegation would also like to suggest adding footnote 6 from p. 13 to follow the statement regarding other legitimate factors in the final paragraph in section 3. **Risk Assessment** Policy (p. 10):

> Statement of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account, Codex Procedural Manual, 18th Edition, page 171.

> Adding the footnote to this section will provide clarity and consistency regarding other legitimate factors.

> Finally, the U.S. Delegation proposes to remove the second paragraph under Note 1 in section **6. Procedure for Submitting Concern** (pp. 13-14). The U.S. Delegation previously provided comments to the proposed draft text of the *RISK ANALYSIS PRINCIPLES APPLIED BY CODEX COMMITTEE ON PESTICIDE RESIDUES* (EXCEPT POINTS 5.2 TO 5.4.3) in December, 2011. In those comments, the US requested clarification regarding the use of the terms "concern" versus "objection" and whether these terms were meant the same thing. The US Delegation notes that the term "objection" has been amended to "concern" in this version of the document. In the December, 2011 comments, the U.S. Delegation also recommended the removal of the second paragraph under **Note 1** in this section. However, this language which addresses "repeated concerns related to the same science-based issue" and a requirement for CCPR to "appropriately address any continuing concerns" has not been removed. As before, the U.S. Delegation recommends that the following paragraph, including the related bullets, be deleted from the text.

~~While MRLs should not be prevented from advancement because of concerns related to concerning current JMPR procedures, it is imperative that CCPR appropriately address any continuing concerns, i.e. repeated concerns related to the same science-based issue. This may also be relevant to issues closely associated with risk management. Appropriate action could be:~~

- ~~referring the issue to JMPR if there is additional or new information, or if the CCPR wishes to provide risk management input to JMPR on the conduct of risk assessments;~~
- ~~referring the issue to national governments or regional authorities for input with a discussion and decision at the next CCPR; and/or~~
- ~~where justified by the nature of the issue, referring the issue to a scientific consultation if the budget is available from FAO and/or WHO, with JMPR and/or CCPR to make adjustments based on the recommendations of that consultation. Members recommending any such action by CCPR should provide documentary information supporting their recommendation for the consideration of the Committee;~~
- ~~in the interim, according to the above recommendations, subject MRLs should be advanced.~~
- ~~if desired by the objecting member, concerns should be officially recorded in the CCPR report and CAC informed through the CCPR report.~~

Rationale: In order to be consistent with previously agreed upon procedures for submitting concern, as summarized in the first part of Section 6, the U.S. Delegation recommends the full removal of the second paragraph and related bullets under **Note 1** in the section. This language states, in part, that it is "imperative that CCPR appropriately address any continuing concerns, i.e. repeated concerns related to the same science-based issue." This statement seems to contradict the premise that CCPR should recognize the JMPR position as the best available science. If JMPR is using the best available science, it is unclear to the U.S. Delegation why a "continuing concern" raised by a member country for more than one chemical must be appropriately addressed by CCPR if JMPR does not believe the concern to be valid and/or if new data or evidence is not presented to support the concern. The language that the U.S. Delegation is proposing to remove contradicts preceding statements that "science based concerns based on the same data/information should be considered only once by JMPR" and "only one review of the same data/information applies to science-based issues with JMPR methods and procedures as well as issues with MRL specific data/information." The language recommended for removal also contradicts the statements that "CCPR should recognize the position taken by the JMPR as the best available science (applicable at the international level) until and if a different position is indicated" and that "science based concerns based on the same data/information should be considered only once by the JMPR in relationship to any specific compound, MRL or CXL."

Before the U.S. Delegation could support this paragraph, further clarification should be provided to support this change in procedure. Such information should include what is meant by "continuing concerns," including how many times a concern needs to be raised to be considered a "continuing concern." For example, are the criteria for a "continuing concern" met when the same objection has been raised for a certain number of chemicals, and does the objection have to be raised at multiple CCPR meetings? Finally, the U.S. Delegation notes that the wording is vague with the use of the statement "appropriate action could be" and it is unclear as to what the outcome and benefit would be of taking the steps then outlined in the bullets. Further clarification of the anticipated outcomes and benefits should be provided.