Background

1. Charge to the Working Group: At the 37th Session the Codex Committee on Pesticide Residues (CCPR) agreed that an electronic Working Group, composed of the members listed below, would develop a discussion paper on criteria to clarify when the Committee may advance or hold recommended draft MRLs and to develop other proposals in order to improve the decision-making process in the CCPR.

Introduction

2. It was discussed at the 37th Session of the CCPR in 2005 that while the Committee was considering proposals to accelerate the risk assessment process in the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), delays in the finalization of MRLs also occurred in the CCPR, in particular when objections based on national risk assessments were made to the adoption of maximum residue levels that had been evaluated and recommended by JMPR. Objections to proposed Codex MRLs have caused many MRLs to be held up for lengthy periods at various steps of the Codex elaboration procedure. The types of objections raised include that a particular country or group of countries:

- do not have an MRL established, for example, because they are in the process of carrying out a national evaluation on the same substance;
- have a lower or higher MRL established;
- have concerns about other regulatory issues outside the current scope of Codex or are doing an evaluation outside the current scope of Codex (e.g. a cumulative risk assessment);
- have established different toxicological benchmarks than those of the JMPR;
- or have used different risk assessment methods or data, for example more refined or higher tier risk assessment methods or data than were employed by the JMPR.

1 Australia; Canada; Crop Life International; European Community; Japan; New Zealand; and the United States
3. In order to begin addressing these issues the working group was asked to develop a discussion paper on criteria to clarify when the Committee may advance or hold recommended draft MRLs and to develop other proposals in order to improve the decision-making process in the CCPR.

4. The Working Group decided to approach this topic by first considering:
   
   - the different purposes for setting MRLs at the national level and by Codex
   - currently available documents--in order to determine what guidance/principles related to decision-making on draft MRLs have been approved previously

**Different Purposes for Setting MRLs at the National Level and by Codex**

5. At the national level, MRLs are set to protect consumer health, while meeting all of the other requirements of national law and regulation. MRLs provide a mechanism for enforcing (or measuring/ensuring compliance with) national Good Agricultural Practices (GAP), that is, authorized uses. When deciding on these national authorized uses, dietary intake risk is only one aspect that needs to be addressed by national regulators. Occupational health, residential exposure, environmental impact, effectiveness of pest control, etc. also need to be considered.

6. At the national level, different countries have different exposure and risk assessment methods, policies, and data, often leading to different exposure and risk assessment end-points. Examples include:
   
   - use of probabilistic risk assessments versus, or in addition to, deterministic risk assessments;
   - application of aggregate and cumulative risk assessments;
   - use of national diets or diets for specific consumer groups;
   - differing standards for and treatment of residue data, for example, specific minimum data requirements for residue data, based on the importance of the crop, different possibilities for extrapolation, and differences in treatment of data, e.g. mixing data from different trials, or different ways of deriving the MRL from the data;
   - use and consideration of processing factors;
   - use of monitoring and survey data, etc.

7. In addition, even when the risk assessment end-points are the same, differences in national risk management practices (such as the use of different safety factors and differences in use of human data in risk assessment) may still lead to different outcomes.

8. In the framework of Codex, MRLs are set to protect the health of consumers and to ensure fair practices in food trade. The MRLs are primarily intended to apply in international trade, and are not intended for monitoring compliance with national GAPs. The levels generally reflect the highest national GAP supplied with adequate supporting data to JMPR, provided that residues arising from this GAP are demonstrated to be sufficiently protective of consumer health. With this proviso the MRL-setting process relies on members recognizing the GAP of other nations. JMPR, an international scientific advisory body, independent of national governments and Codex recommends MRLs. JMPR’s primary function is the provision of scientific advice to Codex, members of FAO and WHO, and other interested parties. Given the current differences in national government assessments, the important role of a recognized and well-respected body capable of undertaking science-based international data assessments to support standard setting bodies such as Codex, in particular the CCPR, cannot be over emphasized. Both the FAO Panel and the WHO Core Assessment Group have striven to apply up-to-date, consistent scientific principles and data standards in their respective areas. Over the years, these scientific principles and data standards have generally been enhanced to reflect best international practice, consistent with the regulatory processes at the national level.

9. Changes in international practices have come through the initiative of the JMPR, which has been at the forefront in the development of new scientific thinking for both chronic and acute dietary risk
assessment, or as the result of interactions with and recommendations from the CCPR and from expert international consultations sponsored by WHO and FAO. Despite these changes and despite other advancements in many aspects of international harmonization and cooperation, it can be expected that JMPR assessments will continue to differ from specific national assessments in some aspects, particularly when national governments are also required to take into account other non-food safety aspects when determining their national authorized uses and the associated MRLs. It is accepted that there will always be differences that stem from the availability of much more refined residue and food consumption data at the national level compared to the international level.

10. While efforts to decrease the differences in risk assessment and risk management practices at the national and international levels continue, it would be useful for the CCPR, as the risk management body ultimately making recommendations to the Codex Alimentarius Commission (CAC), to propose guidance specifically addressing how these differences should be considered when determining whether to advance MRLs recommended by the JMPR. This paper specifically focuses on proposing a procedure to lodge a science-based objections to an MRL recommended by the JMPR and how these objections should be handled.

Available Guidance or Principles Related to Decision-Making on Draft MRLs

11. The Working Group reviewed the adopted Codex texts and available CCPR and JMPR documents to determine what, if any, principles or guidance related to decision-making on draft MRLs had been approved previously.

12. As might be expected, the most relevant material appears to be 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, the Statements of Principle Relating to the Role of Food Safety Risk Assessment, and the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius and other texts contained in the Procedural Manual of the CAC. In addition, the CCPR and the CAC have most recently been working on “Draft Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues”, which were adopted by the CAC at its 28th Session in July 2005 at Step 5 and advanced to Step 6 (ALINORM 05/28/41, Para. 85). The next Session of the CCPR will consider the Risk Analysis Principles at Step 7.

Working Group Approach

13. Given that the CAC has provided fairly detailed and relatively recent guidance on the subject under consideration, the working group began by considering whether the guidance is clear and understandable as evidenced by the fact that everyone has the same interpretation. The working group determined that while the guidance is fairly clear and understandable, it is not detailed and specific enough in every case to provide effective procedural direction on how to handle objections to advancing MRLs.

14. Because the CAC principles stress the functional separation of risk assessment and risk management while recognizing that interaction between risk managers and risk assessors is essential for practical application, and the importance of documentation of the risk management factors that influenced a decision the working group decided to divide the remainder of the discussion paper into the following sections:

- Risk Assessment (Safety/Science) Issues
- Risk Management Issues
- Procedural Issues
- Analysis of Recent CCPR Objections
- Summary of Recommendations

15. The first three sections discuss issues that have been raised and the working group’s thoughts on how the available guidance addresses these. In instances where the available guidance does not specifically address a question, the Working Group proposes more specific guidance for consideration by the CCPR,
keeping in mind that the input of Codex Committee on General Principles may need to be sought on the
guidance.

16. The Working Group reviewed the Reports of the two most recent CCPR Sessions and summarized the
reasons and documentation provided for objecting to recommended MRLs; and the decision made by the
Committee. In each instance, the working group has provided its thoughts on whether the reasons and
documentation are adequate and appropriate and what they believe the decision of the Committee on
allowing the objection should be based on the CAC principles as clarified and specified in the first sections
of this paper. This information is presented in the section, “Analysis of Recent CCPR Objections”. The final
section summarizes the working group’s recommendations.

Risk Assessment (Safety/Science) Issues

17. It is clear from the documents reproduced in Annex I to this paper that JMPR is the independent
international body established to provide risk assessments to the CCPR, among other interested parties, for
risk management decision and recommendation to the CAC. Given that JMPR has done their work and
made recommendations to the CCPR on maximum residue levels (including indications of where the chronic
and/or acute reference doses may be exceeded), the question is: Are there legitimate reasons for CCPR
blocking advancement of MRLs on the basis of food safety concerns, beyond the agreed principle of not
advancing MRLs where JMPR has clearly indicated a potential dietary intake concern?

18. The consensus and primary recommendation of the working group is that any legitimate reason for
preventing advancement of an MRL on the basis of food safety concerns be science-based and substantiated
by supporting data or other relevant information.

19. This conclusion seems straightforward based on the principles and guidance already provided.
However, there are further questions, listed below, that arise related to this most basic principle. The
working group considered them to fall in the realm of risk management, and therefore, they are addressed in
the next section.

- Is it acceptable to prevent advancement of MRLs when there are science-based issues that the
  objecting country has with the methods and procedures used by JMPR rather than the specifics of the
  MRL in question?
- If the JMPR has previously considered the objection and/or the data and information being
  submitted, should the objection still be allowed to prevent advancement of the MRL?
- Related to the above, when JMPR has considered an objection and the data/information provided and
  still recommends the MRL, is that sufficient to end the objection and allow advancement of the
  MRL?
- In the interest of transparency in risk management and good risk communication, is it important that
  objections to JMPR recommendations, for example related to science-based issues with current
  JMPR procedures, be officially recorded, if desired by the objecting member? Is this sufficient
  resolution of the issue as it relates to a specific MRL, as opposed to allowing the objection to
  continue to prevent advancement of the MRL?

Risk Management Issues

20. The Working Group considered the above questions in the following context:

- The appropriateness of abstaining from acceptance of the relevant standard as opposed to
  formally objecting to a standard being advanced
- The types of legitimate concerns of governments when establishing their national legislation
  that are not generally applicable or relevant world-wide

21. The Working Group notes that, although the CAC at its 28th Session agreed to abolish the
Acceptance Procedure and delete all sections related to acceptance (ALINORM 05/28/41, paras 34 & 36), it
is still relevant to point out that members may abstain from acceptance of a Codex standard, without
affecting the CCPR decision process, if a CCPR decision or JMPR recommendation is based on a policy or procedure contrary to their own. Concerns of this nature should not indefinitely prevent a CCPR decision. Instead the issue should be formally brought to the attention of the Committee. The Committee should carefully consider the issue, and the relevant policy or procedure should be changed or not, depending on the outcome of that consideration. In the meantime, MRLs should advance according to the JMPR/CCPR policies and procedures in place at the time.

22. The Working Group believes the 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, resulting from an expert consultation, a change from within JMPR, improvement in the databases or methodologies, or specific guidance provided by CCPR. This recognizes the fact that there will always be unresolved science-based issues because risk assessment at the national and international levels is a developing, changing, improving process. The periodic reevaluation of the MRLs reflects the understanding that these changes will occur and provides the mechanism for updating evaluations over time.

23. The Working Group recommends that it should be made clear and explicit in the principles and guidance provided by the CAC and CCPR that science-based objections based on the same data/information should be considered only once by the JMPR in relationship to any specific MRL. If the objection does not result in JMPR changing its recommendation on the MRL then the MRL should not be prevented from advancement based on this issue. However, the objection should be officially recorded in the CCPR Report, if desired by the objecting member. This guidance on once only 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. Member countries are encouraged not to submit the same data/information. If the same information is submitted to JMPR, then JMPR should simply note that this information has already been reviewed; no other changes have occurred which would affect the outcome of a new review, and therefore, no review is warranted at this time.

24. The Working Group believes that CCPR members should be encouraged to recognize when JMPR has already considered an objection (related to JMPR methods and procedures) and not ask CCPR/JMPR to reconsider the same data/information in the context of a different MRL. Members, whose objections have been considered once and rejected by JMPR, should not expect to halt the advancement of the relevant MRL(s) but simply ask that their objection be officially noted in the CCPR Report.

25. The consensus of the Working Group is that it is imperative that CCPR should appropriately address any continuing objections, i.e. repeated objections related to the same science-based issue. 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 the risk assessments;

• referring the issue to national governments 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.

26. 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 with the objection noted, if desired by the objecting member.

Procedural Issues

27. The above conclusions and recommendations raise a number of procedural issues, which are addressed in this section.

28. The consensus of the working group is that to implement the primary recommendation of the working group (para. 14), specific guidance should be developed concerning the data/information required to
substantiate an objection. Annex II of this paper contains a draft objection form and guidance notes for consideration. The working group recommends that this form must be completed and available at the CCPR meeting in order for an objection to advancement of an MRL to be allowed and for any objection to be noted in the CCPR report.

29. In summary, objections should follow the procedure outlined below:

- objections to MRLs must be submitted on the required form before or during the CCPR Session; the process would be greatly facilitated, however, if objections were lodged by 1 February prior to the session along with all other comments in the customary circular letter so that objections could be circulated well prior to the session for consideration; this is, of course, predicated on the condition the JMPR report with the evaluations is available on 1 December prior to the CCPR session
- objections should have supporting data or information available to resolve the issue (an exception would be for a recurring objection where the objector does not want JMPR review, but simply to have their objection officially noted in the CCPR Report)
- the form used to lodge an objection must include a description of the data and information available for JMPR review
- the data or information ought to be scientific in nature and must be complete and not merely a summary statement or synopsis of data (the JMPR should not be asked to make a critical appraisal based on summary information)
- the data or information should be made available (subject to the applicant’s approval) immediately or at the latest within 1 month of the CCPR meeting to the appropriate JMPR Secretary (the Chair of the CCPR should be informed of the submission to the JMPR Secretary, but the information/data need be supplied only to the JMPR Secretary)
- the JMPR Secretary will be asked to add the objection to the JMPR schedule for consideration as soon as possible (depending on the JMPR work load) preferably at the following JMPR, i.e., the JMPR meeting in the same year as the CCPR meeting; it should be noted that objections lodged prior to the CCPR will assist the prioritization process
- if the objector fails to meet the 1 month deadline for submission of the data/information, the CCPR will remove the objection at its next scheduled session and the relevant draft MRL(s) will be advanced according to the normal Step procedure

Analysis of Recent CCPR Objections

30. Annex III of this paper contains a summary and analysis of previous objections to advancements of MRLs. The working group reviewed the Reports of the two most recent CCPR Sessions and summarized the reasons and documentation provided for objecting to recommended MRLs; and the decision made by the Committee. In each instance the working group has provided its thoughts on whether the reasons and documentation are adequate and appropriate and what they believe the decision of the Committee on allowing the objection should be—based on the CAC principles as clarified and specified in the first sections of this paper.

Summary of Recommendations

31. All of the members of the working group support the following recommendations, except that the EU does not agree that the position of the JMPR should necessarily be accepted as the best available science (applicable at the international level) until and if a different position is indicated. This difference of opinion, and possible ways to address it, will be highlighted during the discussion of this paper at the CCPR session.

32. The discussion with the EU also served to highlight specific areas where continuing objections are occurring (the minimum data requirements, the criteria used for the evaluation of studies, the methodology for deriving the toxicological endpoints from the studies and deriving the MRL from the trials, including possible extrapolations, and issues with deriving the ARfD). These issues may serve as examples for the
The Working Group Recommends:

- that the clearly stated principles of the CAC are that any legitimate reason for preventing advancement of an MRL on the basis of food safety concerns must be science-based and substantiated by data or other relevant information.

- the 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.

- that science-based objections based on the same data/information should be considered only once by the JMPR in relationship to any specific MRL. If the objection does not result in JMPR changing its recommendation on the MRL then the MRL should not be prevented from advancement based on this issue.

- that this guidance on once only review of the same data/information apply to science-based issues with JMPR methods and procedures as well as issues with MRL specific data/information.

- that member countries be encouraged not to submit the same data/information on more than one occasion. If the same information is submitted to JMPR then JMPR should simply note that this information has already been reviewed, no other changes have occurred which would affect the outcome of a new review, and therefore, no review is warranted at this time. The subject MRL should not be prevented from advancement based on this issue.

- that while MRLs should not be prevented from advancement because of objections concerning current JMPR procedures, it is imperative that CCPR appropriately address any continuing objections, i.e. repeated objections related to the same science-based issue. Appropriate action could be:
  
  o 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 the risk assessments;
  
  o referring the issue to national governments for input with a discussion and decision at the next CCPR; and/or
  
  o 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;
  
  o members recommending any such action by CCPR should provide documentary information supporting their recommendation for the consideration of the Committee.
  
  o in the interim, according to the above recommendations, subject MRLs should be advanced.

- that, if desired by the objecting member, objections should be officially recorded in the CCPR Report.

- that specific guidance be developed concerning the data/information required to substantiate an objection and the process to be used. Annex II of this paper contains a draft objection form and guidance notes for consideration.

The proposed procedure is outlined in the flow-chart on the following page.
Proposed Process

JMFR Review

JMFR does not recommend MRL

Not considered in this paper

Member wishes to lodge a science-based objection to the advancement of MRL

JMFR recommends MRL

Member does NOT complete form by 1 Feb or during CCPR plenary

MRL advanced at CCPR plenary

Member does NOT complete form by 1 Feb or during CCPR plenary

MRL advanced at CCPR plenary

No JMFR review requested - member asks that objection be noted in Report

Request for Clarification addressed at CCPR session

Request for Clarification cannot be addressed at CCPR session

Clarification Requested

JMFR Review Requested

MRL does not advance pending review by JMFR

Objecting country fails to provide data to JMFR secretary within 1 month following CCPR session

MRL advanced at next CCPR session if no other objections are made

Objecting country provides data to JMFR secretary within 1 month following CCPR session

JMFR Review scheduled and completed (as soon as possible)

JMFR does not recommend MRL

Not considered in this paper

New MRL recommended to CCPR at Step 3

JMFR recommends alternative MRL

JMFR continues to recommend MRL

MRL Advanced; objection or clarification noted in Report

CCPR takes appropriate action to address issues resulting in repeated objections
Objections may be raised at any stage of the Codex Step Process from Step 3 to Step 8.

At Step 3 or Step 6, objections should preferably be raised in response to the relevant Circular Letter by completion of the objection form prior to the next meeting of CCPR. Failing this, objections may be raised during the CCPR meeting. In either case, the completed form and supporting data must be submitted to the appropriate JMPR Secretary within one month of the CCPR session in which the objection is first raised.

If objections are raised at Steps 5 or 8 the completed objection form and accompanying supporting data must be submitted to the appropriate JMPR Secretary by February 1st the following year, prior to the next meeting of CCPR.
Annex I. Available Guidance/Principles Related to Decision-Making on Draft MRLs

**Source:** Codex Alimentarius Commission; *Procedural Manual* (15th Edition); Section I “Statutes of the Codex Alimentarius Commission” (page 3).

Article 1 of the “Statutes of the Codex Alimentarius Commission” provides the most basic guidance stating that the purpose of the Food Standards Programme is:

> “(a) protecting the health of the consumers and ensuring fair practices in the food trade…”

The preeminence of protecting the health of consumers is clear and recognized in all of the procedures and writings of the CAC, CCPR and JMPR.

**Source:** Codex Alimentarius Commission; *Procedural Manual* (15th Addition); Appendix, 159-160.

At the 21st Session of the CAC in 1995 and again at the 24th Session in 2001, the issue of what other factors, in addition to science, may be taken into account in the Codex decision making process was addressed. The outcome of these two sessions is contained in the Appendix of the “Procedural Manual”.
Source: Codex Alimentarius Commission; *Procedural Manual* (15th Addition); Appendix (page 161).

At the 22nd Session of the CAC in 1997 the Commission adopted the statement of principle on the role of risk assessment.


The other part of the Procedural Manual of most relevance is Section III.

Source: “Proposed Draft Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues”, which were adopted by the CAC at its 28th Session in July 2005 at Step 5 and advanced to Step 6 (ALINORM 05/28/41, para.85). The next session of the CCPR will consider the Risk Analysis Principles at Step 7.

These principles are available in the above document.
Annex II. Proposed Form and Guidance for Objection to Advancement of an MRL/or Request for Clarification

Objection to Advancement of an MRL/Or Request for Clarification

| Submitted by: |  |
| Date: |  |

<table>
<thead>
<tr>
<th>Pesticide/ Pesticide Code Number</th>
<th>Commodity/ Commodity Code Number</th>
<th>MRL (mg/kg)</th>
<th>Present Step</th>
</tr>
</thead>
</table>

**Is this a Request for Clarification?**

**Is this an Objection?**

**Is this a Continuing Objection?**

**Objection** *(Specific statement of reason for objecting to the advancement of the proposed MRL).*

**Request for Clarification** *(Specific statement of clarification requested).*

**Do you wish this Objection to be Noted in the CCPR Report?**

**Data/Information** *(Description of each separate piece of data/information which is attached or will be provided to the appropriate JMPR secretary within one month of the CCPR meeting.)*
INSTRUCTIONS:

✓ The form may be used for three purposes:

   o Request a clarification concerning a specific MRL

   o Lodge an objection to a specific MRL and provide supporting information for review by JMPR

   o Note a continuing objection, that is, an objection that has been made before in the context of a different MRL and which is being made again in relationship to this MRL, but for which no review by JMPR is requested (for example, if the submitter wishes to object to the use of a human study)

Clarifications

✓ When requesting a clarification, the submitter should state that in the “Is this a Request for Clarification?” box on the form.

✓ The question(s) needing clarification should be clearly stated and explained in enough detail to ensure that the JMPR can provide an appropriate response.

Objections

✓ When lodging an objection, the submitter should state that in the “Is this an Objection?” box on the form.

✓ Most objections should have data or information available to resolve the issue.

✓ The data/information should be scientific in nature. It must be complete and not merely a summary statement or synopsis of data. The JMPR should not be asked to make a critical appraisal based on summary information. The entire relevant study(s) must be made available. The submission should include enough detail for the JMPR to review the objection and make a decision.

✓ A detailed explanation by the objecting party of the concern with the proposed MRLs may also be included.

✓ The data or information should be made available (subject to the applicant’s approval) immediately (or within 1 month of the CCPR Meeting) to the appropriate JMPR Secretary. If the member country or other interested party fails to make a prompt submission of the data or information, the CCPR will remove the objection at its next scheduled Session.

✓ The Chair of the CCPR should be informed of the submission to the JMPR Secretary, but the information/data need be supplied only to the JMPR Secretary.

✓ The JMPR Secretary will be asked to add the objection to the JMPR schedule for consideration as soon as possible (depending on the JMPR work load) preferably at the following JMPR, i.e., the JMPR meeting in the same year as the CCPR Session; it should be noted that objections lodged prior to the CCPR will assist the prioritization process.

Continuing Objections

✓ When making a continuing objection, the submitter should state that in the “Is this a Continuing Objection?” box on the form.

✓ If this is a continuing objection and the objector does not want JMPR review, but simply for the objection to be officially noted in the CCPR Report, then the objector should state that in the Is this a Continuing Objection?” box on the form.
Annex III. Summary of Previous Objections to Advancement of MRLs

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Objection</th>
<th>Data/Information Provided</th>
<th>Decision of the Committee</th>
<th>Comments of Working Group Based on Recommendation in This Paper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Captan</td>
<td>Acute intake concerns</td>
<td>Written Comments</td>
<td>Returned to Step 6</td>
<td>MRL should be advanced and objection noted in CCPR Report OR returned to Step 6 with CCPR request to JMPR for a decision on the issue and objector given one month to submit data supporting objection to JMPR</td>
</tr>
<tr>
<td>Carbaryl</td>
<td>Acute intake concerns</td>
<td>Written Comments</td>
<td>Returned to Step 6</td>
<td>Agree</td>
</tr>
<tr>
<td></td>
<td>Insufficient Database</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diazinon</td>
<td>Previously raised concerns</td>
<td>None</td>
<td>Noting that no new information had been received; Advanced to Step 8</td>
<td>Agree</td>
</tr>
<tr>
<td>Dimethoate</td>
<td>Acute intake concerns</td>
<td>None</td>
<td>Objector asked to review their dietary intake calculations and provide results of their review to the next CCPR. Returned to Step 6</td>
<td>Should require information be sent to JMPR within 1 month for decision making (unless this is a continuing objection in which case they could simply request that the objection be noted in the CCPR Report)</td>
</tr>
<tr>
<td>Folpet</td>
<td>Concerns about the residue definition, variability factors, and intake concerns</td>
<td>Unclear</td>
<td>Objector asked to further specify concerns regarding the use of variability factors and intake concerns and make it</td>
<td>Should require information be sent to JMPR within 1 month for decision making (unless this is a continuing objection in which case they could simply request that the</td>
</tr>
<tr>
<td>Chemical</td>
<td>Intake Concerns</td>
<td>Status</td>
<td>Action Taken</td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>----------------</td>
<td>---------</td>
<td>--------------</td>
<td></td>
</tr>
<tr>
<td>Malathion</td>
<td>Acute intake concerns</td>
<td>Unclear</td>
<td>Objection asked to review dietary intake calculations and provide results of their review to the next CCPR. Returned to Step 6</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Should require information be sent to JMPR within 1 month for decision making (unless this is a continuing objection in which case they could simply request that the objection be noted in the CCPR Report)</td>
<td></td>
</tr>
<tr>
<td>Carbofuran</td>
<td>Acute intake concerns; the primary objector noted they had established an ARfD 10x lower than that established by JMPR and others noted they too had much lower national ARfD’s</td>
<td>Unclear; the WHO Joint Secretary informed the Committee that the relevant information from the objector had been received and that JMPR considered another study to be the critical one.</td>
<td>Returned to Step 6</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>MRLs should have been advanced to Step 8 and the objection noted in the CCPR Report</td>
<td></td>
</tr>
<tr>
<td>Phosmet</td>
<td>ARfD not acceptable because it was based on human data</td>
<td>Unclear</td>
<td>Returned to Step 6 for intake concerns (assume this was simply because of the human data)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Since it is confirmed risk assessment policy used by JMPR to use human data (2002 JMPR General Considerations 2.2) the MRLs should have been advanced to Step 8 and the objection noted in the CCPR Report.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>If not science-based the objection should not be considered by CCPR. CCPR could take action to either change or review the risk assessment policy used by the JMPR, but this should not stop advancement of the MRL.</td>
<td></td>
</tr>
<tr>
<td>Deltamethrin</td>
<td>Objector reserved their position based on acute intake concerns</td>
<td>Unclear</td>
<td>Advanced to Step 8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Agree, This appears to be a case where a continuing concern is noted but the MRL...</td>
<td></td>
</tr>
</tbody>
</table>
Carbosulfan | Objector opposed advancement because the MRLs are associated with carbofuran, which are unacceptable | Unclear | Noted that 2003 JMPR found no intake concerns Advanced to Step 8 | Agree, Continuing objection should be noted in the CCPR Report

Pyraclostrobin | Acute intake concern | Unclear | Advanced to Step 5 (noted acute intake concern) | Agree, assuming this is a continuing objection that does not need to go to JMPR for decision making

### Objections at the 2004 CCPR Session

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Type of Concern</th>
<th>Status</th>
<th>Decision</th>
</tr>
</thead>
</table>
| **Carbaryl** | Acute intake concerns; insufficient database | Unclear | MRLs in question returned to Step 6 | Agree--with objector given one month to submit data supporting objection to JMPR
| **Diazinon** | Unclear | Awaiting information from two members | MRLs in question returned to Step 6 | Agree--with objectors given one month to submit data supporting objection to JMPR
| **Chlorpyrifos-methyl** | Chronic dietary intake concerns | Unclear | Returned to Step 6; objector requested to submit their intake calculations to JMPR | Agree--with objector given one month to submit data supporting objection to JMPR
| **Carbofuran** | Acute intake concerns | Unclear | Returned to Step 6; objector invited to submit their data to JMPR | Agree--with objector given one month to submit data supporting objection to JMPR
| **Phosmet** | Acute intake concerns | Objector informed Committee that it was likely to establish a lower acute RfD than recently established by JMPR and would send their data on how their acute RfD was derived to JMPR when their evaluation was completed | Returned to Step 6 | Possibly agree, unless this is a continuing objection in which case objector should be encouraged to only request that this be noted; however, the objector should be given one month to submit data supporting the objection to JMPR (not until their evaluation is done)
| **Propargite** | Intake concern for | Objector expressed reservation for the | Advanced to | Agree—if no data or other information was
<table>
<thead>
<tr>
<th>Children advancement of some of the MRLs</th>
<th>Step 8</th>
<th>provided for review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbosulfan MRLs associated with relevant carbofuran MRLs</td>
<td>Unclear</td>
<td>Returned to Step 6</td>
</tr>
<tr>
<td>Cyprodinil Concern expressed about the MRL and objector noted that their MRL was much lower</td>
<td>Unclear</td>
<td>Advanced to Step 5</td>
</tr>
</tbody>
</table>