

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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WORLD
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Agenda Item 11

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-ninth Session

Beijing, China, 7 - 12 May 2007

PAPER FROM THE JOINT FAO/WHO JMPR SECRETARIAT ON SEVERAL ISSUES RELATED TO THE WORKING RELATIONSHIP BETWEEN JMPR AND CCPR

BACKGROUND

1. In recent years JMPR and CCPR have introduced various initiatives to accelerate the discussion and adoption process of Codex MRLs for pesticide residues such as work-sharing, criteria for prioritization, formalized procedure for filing concerns with recommendations from JMPR and consideration of alternative GAPs when acute intake concerns exist.
2. Most of these proposals were discussed, agreed and adopted at the 38th session of CCPR, the 23rd session of the CCGP and at the 29th Session of the Commission. The Joint FAO/WHO Secretariat has prepared this document in order to facilitate the implementation of these decisions and to demonstrate how these changes will affect the working relations between JMPR and CCPR as well as the working arrangements of JMPR.
3. This document contains recommendations for these proposals, which are presented to the Committee for its consideration and comments.

WORK SHARING

4. JMPR gained experience from two work-sharing pilot projects on trifloxystrobin (JMPR Report, 2004) and quinoxifen (JMPR Report, 2006). After the finalization of the second pilot project, the following recommendations were made at the 2006 meeting of JMPR:
 5. It should be noted that this statement concludes the formal pilot phase of JMPR for work-sharing where specific candidate compounds were identified by the CCPR. Work-sharing is now of potential value for any substance on the agenda. This requires a sound mechanism to identify reliably and at an early stage whether evaluations are available from national and regional authorities.
 6. The Joint Secretariat suggests that information on the availability of, and access to, existing national and regional evaluations should be provided on a mandatory basis in the documents submitted with the proposals for nomination for evaluation to the CCPR Working Group on Priorities.
 7. Furthermore, sponsors and member governments of Codex are requested to take all the administrative and legal steps necessary to release such documents from national and regional authorities, including granting access to all relevant original studies, in order to assure their timely transfer to the Joint Secretariat.
8. **Recommendation I:** The Committee is invited to consider the revision of the document entitled "Pesticide Information for CCPR Working Group on Priorities" by adding an entry about available

evaluations from national and regional authorities (see proposal for a new item 11 in Annex A of this document).

9. **Recommendation II:** The Committee is invited to take note that calls for data for future JMPR meetings will include requests for submission of available national and regional evaluations, including access to all relevant original studies; Codex members and observers are asked to arrange for the submission in a timely manner.

CRITERIA FOR PRIORITIZATION

10. The Codex Alimentarius Commission adopted at its 29th session *Revised Criteria for Prioritization Process of Compounds for Evaluation by JMPR* (ALINORM 06/29/41, p 78ff). Whereas the main body of the document discusses and defines the criteria that apply to prioritization, the final *Note* of this document describes more closely the specific procedural steps required if further evaluation of an already evaluated pesticide is initiated:
11. Indents iv. and v. of the *Note* describe the procedure whereby Codex members request an evaluation (new commodity/pesticide combination; review of MRL due to change in GAP). Both procedures have been amended (23rd CCGP, ALINORM 06/29/33, par 31 and Appendix III) , and the new wording demands that such requests are considered by the CCPR before being added to the JMPR agenda.
12. It is the understanding of the Joint Secretariat that such requests are submitted/copied for consideration to CCPR in order to allow CCPR to comment or take action on them, i.e. to prioritize such requests taking into account other compounds on the tentative schedule.
13. Therefore, in future, the Joint Secretariat will automatically add the evaluation addressed in indents iv. and v. to the agenda of JMPR meetings, but not to the agenda of the meeting held in the same year as the CCPR, except for purposes of clarification as addressed in indent vi. This is also necessary in order to ensure transparency and to allow other parties to take note of the scheduling of a pesticide and to provide available data.
14. It should also be noted that requests for evaluations of a single commodity/pesticide combination will not be filed separately if the pesticide in question has already been included in the JMPR re-evaluation programme. In such a case, the request and the data have to be submitted in response to the call for data when the re-evaluation of the pesticide is announced.
15. Indent vi. of the *Note* describes the procedure whereby CCPR "*requests clarification or reconsideration of a recommendation from the JMPR. In such cases the relevant Joint Secretary will schedule the request for the next JMPR.*" It is the understanding of the Joint Secretariat that this procedure covers questions raised by CCPR on the evaluations of the last JMPR and concerns filed by members using the relevant form (Annex B) as agreed at the 38th session of the Committee.
16. **Recommendation III:** The Committee is invited to comment on these proposals and note them.

FILING CONCERNS REGARDING MRLS PROPOSED AT STEP 3

17. At its 38th Session, the CCPR discussed the criteria for the advancement of JMPR recommendations in the Codex step procedure and amended the *List of Risk Management Policies used by CCPR* with the two paragraphs¹ reproduced in the box below:
18. The Circular Letter asking for comments on MRLs proposed by JMPR will stress that concerns need to be substantiated and therefore a description of the specifics of the data, using the agreed concern form, is required (see also Annex B). Two situations may occur when an MRL qualifies for Step 5:
19. **Situation A:** The concerns are raised in a timely manner, i.e. they are raised before or at the meeting using the concern form and sufficient information about the data/information is made available

¹ This draft document was sent by the CCPR via CCGP to the Commission at Step 8; the proposed mode of working will be amended pending further changes introduced by both bodies.

preferably one month after the CCPR. JMPR held in the same year will assess the new data/information and provide the reply to the next meeting of CCPR .

20. **Situation B:** The concerns are raised in a sufficiently convincing way and the Committee agrees to hold the proposed MRL at Step 5 but the concern form is not available at the deadline. If the form arrives after the deadline, such a request will be assessed by the following year's JMPR and the reply will be available to CCPR for decision on advancement of MRLs after two years.
21. **Recommendation IV:** The Committee is asked to consider that at each meeting, the CCPR Chairperson will announce the specific deadline that applies for the submission of concerns. When a concern form and the supportive data/information are not submitted within the specified deadline for the same year's JMPR meeting, the JMPR will consider the concern at a future meeting.
22. **Recommendation V:** The Committee is asked to take note that future JMPR reports will contain a special section including all requests submitted to the experts and will provide answers where possible. This section will also identify those compounds to be addressed at the following year's meeting or for which no forms have been submitted.

AVAILABILITY OF JMPR REPORTS BY EARLY FEBRUARY

23. One important precondition for applying the Step 5/8 procedure for proposed MRLs is the publication of the JMPR report by early February. Experience gained at the 2005 and 2006 JMPR meetings shows that this is feasible provided that submissions to JMPR from data sponsors and governments are made in a timely manner (as specified in the call for data).
24. Should a sponsor fail to submit the data and related information (e.g. "work-sharing" documents) by the given deadline, the Joint Secretariat will have the option to postpone the evaluation of the compound to a subsequent JMPR meeting.
25. The availability of the report by early February on the part of the FAO JMPR Panel requires further strengthening of its peer review process which takes place before the pre-meeting of JMPR. This would lead to a change of the current deadlines for the submission of the data directories and the data.
26. The Joint JMPR FAO Panel will therefore enforce, from 2007 onwards, the following deadlines:
 - a. The Data Directory for the compound should be available by 1 September of the year preceeding the meeting when the compound is scheduled for evaluation/re-evaluation, i.e. the Data Directory must be available one year in advance of JMPR.
 - b. The full submission of all data is required by 30 November.
27. **Recommendation VI:** The Committee is asked to take note of these changes and to ensure that sponsors and governments follow the new deadlines.

CONSIDERATION OF ALTERNATIVE GAP

28. At its 37th Session, CCPR requested JMPR to consider a procedure for recommending a maximum residue level that relates to the highest residues from a national GAP where there are sufficient supervised trials data and where the residues do not result in an IESTI (international estimate of short-term dietary intake) that exceeds the acute reference dose.
29. At its 2005 meeting, JMPR agreed that this would be a suitable way and identified two approaches for its implementation: the retrospective approach to consider an alternative GAP when requested to do so by CCPR, and the prospective approach to consider an alternative GAP when an IESTI is exceeded without waiting for a request from CCPR.
30. At its 38th Session, CCPR stated that both approaches should be applied, the retrospective approach being mainly applicable for old compounds, used where needed, and the prospective approach which would become the routine approach.
31. Based on the experience gained with these approaches (see JMPR report, 2006), the Joint Secretariat suggests that in future requests for consideration of a retrospective GAP be removed from the agenda of

JMPR if no updated information is submitted and no support for such an evaluation is provided by sponsors or Codex members by the deadline specified in 26.b. above

32. **Recommendation VII:** The Committee is asked to take note of this suggestion and to consider further the guidance provided by JMPR 2006 concerning the data needed and specifically the statement that “*information on current GAP is always needed*”.

Annex A:

PESTICIDE INFORMATION FOR CCPR WORKING GROUP ON PRIORITIES²

(Proposed by JMPR)

for evaluation _____

for re-evaluation _____

1. NAME:
2. STRUCTURAL FORMULA:
3. CHEMICAL NAME:
4. TRADE NAME:
5. NAMES AND ADDRESSES OF BASIC PRODUCERS:
6. JUSTIFICATION FOR USE:
7. USES: MAJOR
 MINOR
8. COMMODITIES MOVING IN INTERNATIONAL TRADE AND LEVELS OF RESIDUES:
9. COUNTRIES WHERE PESTICIDE IS REGISTERED:
10. NATIONAL MAXIMUM RESIDUE LIMITS:
- 11.³ *NATIONAL AND REGIONAL EVALUATIONS (TOXICOLOGY AND RESIDUE CHEMISTRY) AVAILABLE:*
12. COMMODITIES FOR WHICH THE NEED FOR ESTABLISHING CODEX MRLs ARE RECOGNIZED:
13. MAJOR INTERNATIONAL USE PATTERN:
14. LIST OF DATA (TOXICOLOGY, METABOLISM, RESIDUE) AVAILABLE:
15. DATE DATA COULD BE SUBMITTED TO THE JMPR:
16. PROPOSAL FOR INCLUSION SUBMITTED BY (COUNTRY):

² This information is to be provided by Codex member countries for inclusion of a pesticide in the Codex Priority List.

³ Proposed new entry

Annex B:

**FORM FOR EXPRESSING CONCERNS WITH ADVANCEMENT OF AN MRL/OR REQUEST
FOR CLARIFICATION OF CONCERNS**

Submitted by:			
Date:			
Pesticide/ Pesticide Code Number	Commodity/ Commodity Code Number	MRL (mg/kg)	Present Step
<i>Is this a Request for Clarification?</i>			
<i>Is this a Concern?</i>			
<i>Is this a Continuing Concern?</i>			
<i>Concern (Specific statement of reason for concern to the advancement of the proposed MRL).</i>			
<i>Request for Clarification (Specific statement of clarification requested).</i>			
<i>Do you wish this Concern to be Noted in the CCPR Report?</i>			
<i>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.)</i>			