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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

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Proposed Process for Examination of Alternative GAP when Acute Intake Concerns are Identified by JMPR

Prepared by the United States of America

PURPOSE

This paper seeks to summarize the suggestions that have previously been made by the CCPR and JMPR on examination of alternative GAP in cases where there are acute intake concerns. It proposes an explicit process to be used in these cases. Clarification of the process will provide both JMPR and registrants the explicit instructions which they need to address this issue.

BACKGROUND

At the 2005 CCPR meeting it was proposed that when the ARfD is exceeded for a particular GAP and chemical/commodity combination (using the current JMPR procedure which recommends MRLs based on supervised trials with the highest residue values and supporting GAP), the JMPR should consider alternate country GAPs with adequate supporting field trials until it locates the GAP resulting in the highest residue value for which the IESTI is below the ARfD and for which an MRL *can, therefore, be recommended.* The modification would allow the recommendation of an MRL that can be used for trade purposes and is a practical way of removing the current "obstacle", where standards are either being deleted or held up indefinitely because of intake concerns. (Alinorm 05/28/24; para. 67-68)

As a follow-up to this proposal it was decided that when commodities were returned to Step 6 for three times, JMPR should be requested to examine residue data from alternative GAPs and to recommend MRLs which have no dietary intake concerns. (Alinorm 05/28/24; para. 81) Three compounds were referred to JMPR for evaluation of alternative GAP (aldicarb, disulfoton, and fenamiphos).

At the 2005 JMPR meeting, it was noted that aldicarb was evaluated by JMPR in 2001, disulfoton in 1994 and 1998 and fenamiphos in 1999. JMPR noted that there were serious problems basing a new evaluation on obsolete GAP and no evaluations were actually performed. The JMPR requested guidance from CCPR on the best way to proceed. The JMPR suggested two approaches.

- Retrospective Approach—CCPR would refer the compound to JMPR and request reconsideration of GAP in specific cases. *It would also request the manufacturer(s) and*

national governments to provide appropriate up-to-date GAP information to support the proposed evaluation.

- Prospective Approach—During a residue evaluation where the IESTI is exceeded, JMPR should draw attention to available information on alternative GAPs and associated supervised trials data where the IESTI would not appear to be exceeded.

At the 2006 CCPR meeting the Committee agreed 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.

At the 2006 JMPR meeting three retrospective and one prospective analysis were conducted.

- For the aldicarb retrospective situation, no new GAP information and no new field trial residue data were received for banana. New field trial data and GAP were received from the Netherlands for potato. Examination of existing information for banana did not suggest a lower MRL, and examination of the new field trial data for potato did not lead to a lower MRL estimate.

- For the disulfoton retrospective situation, new GAP information was submitted by the manufacturer for broccoli, cabbage, cauliflower, and lettuce. New field trial data were submitted only for cabbage (Japan), and the number of trials was insufficient. Evaluation of existing JMPR field trial data against the new GAPs produced no MRL estimates that would alleviate the dietary intake issues.

- For the fenamiphos retrospective analysis, new GAP information and new field trial data were received for peppers, tomato, and watermelon, three commodities with MRLs residing at Step 6 because of acute dietary intake concerns. Evaluation of the new data did not lead to estimation of lower MRLs.

- A prospective analysis situation existed with pyraclostrobin. Residue data for head lettuce that reflected the US GAP indicated through the IESTI calculation that the ARfD might be exceeded. The use of European trials (greenhouse) and the associated GAP yielded high residue with an IESTI calculation that did not exceed the ARfD. Therefore, the alternative GAP was used as the basis for the MRL recommendation.

The lessons learned from the 2005 and 2006 JMPRs included:

- A new data submission would almost certainly be needed for retrospective analyses. Thus, it is necessary to request the manufacturer(s) and national governments to provide appropriate up-to-date GAP information to support the proposed evaluation. This would usually require the submission of new field trial data and the *corresponding labels*.

- The JMPR recognized that the *likelihood* of finding alternative GAP resulting in lower residue levels should be considered before resources are devoted by the manufacturers to submitting new data and by the JMPR to reviewing those data. Thus, the JMPR made several recommendations for improving the alternative GAP evaluation process. The Meeting noted that different situations can give rise to an MRL with a dietary intake concern, and that these situations should be recognized before making an alternative GAP analysis request and in supplying data to support that request.

    - If the MRL in question is set at (or slightly above) the limit of quantitation (LOQ), the only mechanism for resolving the concern is the development of an analytical method with a lower LOQ and analysis of samples with the lower LOQ.

- If the HR/MRL relates to an IESTI that exceeds the ARfD by a factor of 2 or less (100 – 200%), then an alternative GAP with longer PHI or a lower application rate may lead to an acceptable lower HR/MRL.

- If the HR/MRL relates to an IESTI that exceeds the ARfD by a substantial amount (>200%), an alternative GAP that is very different will most likely be needed.

- If the highest residues for a pesticide-commodity combination are in a borderline area for acceptability of short-term intake, probably at least seven or eight relevant trials would be needed for the assessment, even for a minor crop.

PROPOSED PROCESS

The following process reflects the directions of the CCPR and the lessons learned thus far from the JMPRs attempts to implement consideration of alternative GAP.

Retrospective Analysis (Initiated at CCPR Meetings)

1) The CCPR identifies pesticide/commodity combinations returned 3 times to Step 6 and refers them to the JMPR for alternative GAP analysis.

2) A CL is issued soon after CCPR identifying the pesticides for which alternative GAP information is needed.

   - The letter reminds submitters of the lessons learned

   - The submitter should be encouraged to consider the situation that has resulted in the dietary intake concern and determine, if possible, whether the available new data will make a difference before supplying the data. In cases where it cannot be determined if the new data will result in a new MRL recommendation, then the data should be submitted.

   - Both residue data *and the corresponding labels* must be submitted for the information to be useful. Generally, a label without field trial data or field trial data without a label will not suffice.

3) JMPR identifies the relevant compounds for the upcoming year in its data-call-in notice.

   - The Data-call again reminds the data submitters of the points noted in #2

4) Member governments, manufacturers, and interested parties submit information on the availability of relevant data for identified pesticides (#2) and actual data packages (#3) to the JMPR Secretaries (usually the FAO Secretary).

5) JMPR evaluates the alternative GAP information and makes recommendations.

6) CCPR reviews the JMPR recommendations and proceeds to withdraw MRLs where no resolution of the dietary intake concern has been possible.

Prospective Analysis (Routinely Conducted by JMPR During Evaluation)

1) During each residue evaluation where the IESTI is exceeded, JMPR should draw attention to available information on alternative GAPs and associated residue trials where the IESTI would not appear to be exceeded and recommend an MRL associated with this alternative GAP.

2) If acceptable alternative GAP is not available the JMPR should clearly state the particular situation that exists (as described in lessons learned above). Although the JMPR did not make this recommendation, we propose adding the following to the process. The JMPR should also indicate an approximate "acceptable" Highest Residue (HR) as one of the conclusions of their analysis, i.e., a value that would yield an acceptable IESTI calculation. This information should be in the JMPR Report. This would provide a benchmark for interested parties and would help to alleviate the submission of non-relevant data to JMPR.

3) CCPR reviews the JMPR recommendations and decides on MRLs recommended on the basis of alternative GAP.

4) Countries, manufacturers, and interested parties are invited to give attention to the situations where there are exceedances of the acute RfD and alternative GAP were not available. This necessitates considering the particular situation as outlined in the JMPR report.

5) Having analyzed the situation governments, manufacturers, and other interested parties should be able to supply both labels and field trial data that support an alternative GAP within the 3 year period that will have elapsed until the pesticide/commodity combination is returned 3 times to Step 6 and is referred to the JMPR for alternative GAP analysis.