

# codex alimentarius commission



FOOD AND AGRICULTURE  
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**Agenda Item 12**

**CX/PR 06/38/11**  
**March 2006**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX COMMITTEE ON PESTICIDE RESIDUES**

**Thirty-eighth Session**

**Hotel Vila Galé, Fortaleza, Brazil, 3 - 8 April 2006**

#### **Evaluation of the Pilot Project for Estimation of National MRLs as Interim Codex MRLs for Safer Replacement Pesticides**

*Prepared by the United States*

1. The 37<sup>th</sup> Session of the CCPR discussed at great length the results of the Pilot Project on Establishment of National Government MRLs as Codex Interim MRLs for Safer Pesticides. Among other conclusions, it was decided that the Pilot Project Working Group would prepare a paper containing an evaluation of the Pilot Project for consideration by the next Session of the CCPR.

2. A paper (CX/PR 05/37/13-Add.1) which was prepared for the 37<sup>th</sup> Session of the CCPR collated and analyzed the comments from member states and the JMPR on the Pilot Project on establishment of national government MRLs as Codex interim MRLs for safer pesticides. The paper:

- Contained a preliminary appraisal of technical issues for consideration at the 2005 CCPR
- Provided the 2005 Working Group on Priorities the basis for:
  - addressing and seeking to resolve these technical issues
  - making recommendations to the CCPR on advancement or deletion of proposed interim MRLs
  - resolving issues related to the process

3. Based on the above information together with the recommendations of the Working Group on Priorities, the 37<sup>th</sup> Session of the CCPR made the following decisions concerning the Pilot Project:

- All of the proposed Interim MRLs in the pilot project were recommended for adoption at step 8(I). Thus, it was decided to advance the proposed Interim MRLs for trifloxystrobin, fludioxonil and bifentazate (noting some concerns of the Delegation of the EC on the sufficiency of the database for proposed MRLs for bifentazate) for adoption at Step 8 with an indication that they were Interim (I) MRLs which should last not more than 4 years.
- The Delegation of the EC recalled that the Pilot Project Working Group did not have a mandate to present recommendations on specific substances for adoption at Step 8(I), which was not yet recognized in the Codex Procedure and that this should not be confused with Step 8 of the official Procedure. The Delegation suggested that the Committee seek guidance from the CCGP and the

Commission in order to decide how to proceed, and in particular, whether to undertake new work under the Pilot Project for additional substances.

- The Secretariat clarified that following the request of the Commission the next Session of the CCGP will consider the proposal to clarify the term “Interim”. The Secretariat also recalled that the Commission had approved new work on a pilot project concerning the development of MRLs but that no proposal had been made to amend the Codex Step Procedure. The Secretariat also noted that while proposed Interim MRLs did not formally fit for circulation at Step 3 of the Procedure, the proposed MRLs were circulated for government comments in CL 2004/48-PR. The Secretariat indicated that proposed Interim MRLs, if recommended by the Committee, should also be sent for comments before adoption by the Commission.
- The FAO Joint Secretary to the JMPR suggested that it was better to use the proposed draft JMPR MRLs as Interim MRLs and to be more flexible with the 50/50 ratio of new compounds and periodic review compounds changing the priority to 70/30, if new less hazardous compounds were available for evaluation...It was indicated that in this case there will be no conflict with the separation of risk assessment and risk management and that there will be a possibility to comment and adjust MRLs which will also be adopted at Step 5.
- The Committee agreed to attach Attachment III of document CX/PR 05/37/13-Add.1 on the Proposed Revised Interim MRL Process to the 2005 Committee report for comments in order to ensure transparency of the process.
- The Committee agreed not to propose new compounds for the Pilot Project and decided that the Pilot Project Working Group would prepare a paper containing the evaluation of the Pilot Project for consideration by the next Session of the Committee.
- The Committee concluded that, in order to speed up the process of establishment of MRLs for safer replacement pesticides, there was a need to use the proposed draft JMPR MRLs for which there will be no intake concerns as Codex Interim/Temporary MRLs<sup>1</sup>.
- The Committee agreed to ask the Commission to approve new work on the amendment of the MRL elaboration procedure and that the JMPR and the Codex Secretariat with assistance of the Chairperson would prepare a document for consideration at the next Session with the understanding that these proposed draft MRLs will also follow the currently established Codex Step Procedure and will be adopted at Step 5.
- The Committee noted that more flexibility was necessary in scheduling new safer pesticides for evaluation by the JMPR and decided that the ratio 50/50 for new/old compounds could be increased in favor of accommodating new safer compounds, if available.

4. Based upon the analysis and information presented in last year’s paper (CX/PR 05/37/13-Add.1) and the discussions and recommendations coming from the 37<sup>th</sup> Session of the CCPR, the Pilot Project Working Group proposes the following conclusions and recommendations:

- The process recommended by the Pilot Project Working Group at the 37<sup>th</sup> Session of the CCPR was workable, but had the following serious limitations (as discussed in detail in CX/PR 05/31/13-Add.1).

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<sup>1</sup> The Pilot Project Working Group notes that at the 22<sup>nd</sup> Session of the Codex Committee on General Principles (11-15 April 2005) during the discussion of the definition of the term “interim”, the Secretariat informed the Committee that in the past, interim adoptions were made by the Commission in order to commit itself to review its decisions in the light of imminent developments relative to the subject matter by specifying *the steps to be taken and the timeframe to be observed for undertaking review*. Otherwise, standards or definitions adopted on an interim basis were considered to have the same status as those of “non-interim” nature. The Committee agreed that the Secretariat would prepare a discussion paper, for consideration at the next session of the Committee, describing the instances where the Commission had adopted standards and related texts on an interim basis as well as proposals to clarify the term “interim” and the conditions under which the Commission could adopt standards and related tests on an interim basis.

- Obtaining relevant data and information was extremely resource intensive and still did not necessarily result in obtaining all of the desired data and information. Thus, for example the original process called for the nominating country to nominate the highest MRL value currently established and obtain the relevant information from the country where the MRL was established. For a variety of reasons, this was not always possible. The revised proposal called for the nominating country to only propose interim MRLs which are established in their country (or established in other countries from which they have *already obtained* the relevant national government information). The burden of supplying additional information was then placed on individual member countries. Thus, other member states would have approximately two months to supply the nominating country the relevant materials to nominate other uses of a chemical already approved for interim MRLs or higher MRLs for commodities already nominated.
- As the result of lack of complete agreement on the data necessary for review, the packages were very lengthy and complex (in an attempt to provide all of the data that any member country might want to review).
- In addition to the logistical problems with obtaining appropriate data, analysis of the information was also potentially extremely resource intensive. Many member countries commented that the time allowed to review the very long data package was not sufficient and/or that resources were not available to review such complex packages.
- Despite the decision of the Committee to recommend advancement of all of the MRLs included in the Pilot Process to Step 8(I), there were continued reservations of some member states about several aspects of the process including: the separation of the risk assessment and risk management functions, the definition of a “safer” pesticide, and the status of Interim MRLs in Codex.
- The Pilot Project Working Group recommends that the process proposed by the FAO Joint Secretary to the JMPR at the 37<sup>th</sup> Session of the CCPR, and supported in subsequent discussions by the Committee, should be used for the elaboration of Interim MRLs. This recommendation is based on the following considerations:
  - The proposed process eliminates many of the issues that remained with the use of national government MRLs as Interim Codex MRLs.
  - While the JMPR route will continue to be labor intensive and incur the expenditure of time needed to schedule and review, this path relies on an established, independent process with which all member countries and registrants are familiar.
  - It maintains the clear separation of risk assessment and risk management
- The Pilot Project Working Group recommends that the process discussed and the conclusions reached at the 37<sup>th</sup> Session of the CCPR be made explicit and any remaining issues be addressed in order that the relevant proposed draft JMPR MRLs can immediately begin to be used as Interim MRLs.
- The Pilot Project Working Group defers to the JMPR and the Codex Secretariat with assistance of the Chairperson for proposal of a specific process for the elaboration of interim MRLs.