CODEX ALIMENTARIUS COMMISSION





Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.net

Agenda Item 6(b)

CX/PR 12/44/6 March 2012

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

44th Session Shanghai, P.R. China, 23 - 28 April 2012

PILOT PROJECT FOR JMPR RECOMMENDATION OF MRLS BEFORE NATIONAL GOVERNMENTS OR OTHER REGIONAL REGISTRATION AUTHORITIES FOR A GLOBAL JOINT REVIEW CHEMICAL

BACKGROUND

- 1. At the 40th Session of the Codex Committee on Pesticide Residues (April 2008), the Delegation of the United States of America introduced a proposal to initiate a pilot project using an upcoming new chemical that is being evaluated using the global joint review process. In this process several national governments or other authorities receive the application at the same time, work together on the evaluation, and then make their independent regulatory decisions, while focusing on harmonization, where possible. Under this proposal, the JMPR would receive the dossier at the same time as national governments and would conduct their own independent evaluation in parallel. The Delegation expressed the view that among the benefits of the new process would be increased harmonization/ acceptance of Codex MRLs, thus facilitating trade of food and feed, and that, it was therefore important to explore all possibilities in order to make the work of Codex as relevant timely, and efficient as possible. It was noted that new process would need to ensure that sufficient data are available to allow an independent JMPR assessment and that proposed GAP were sufficiently defined and binding so that the recommended MRLs would represent the actual use practices that are ultimately registered.
- 2. The WHO JMPR Secretariat pointed out that there were a number of advantages to JMPR performing toxicological evaluations in parallel with national authorities since it would help to eliminate some discrepancies in the outcome of ADI and ARfD setting among various authorities.
- 3. The FAO JMPR Secretariat generally supported the proposal to initiate a pilot project and noted that setting international standards prior to national standards was an established practice in other international standards setting bodies such as IPPC, and that it helped harmonization and acceptance of such standards. However, the Representative pointed out that this pilot project would have significant implications for the work of the FAO Panel of JMPR and the extent of these implications was not clear at this stage and would need to be carefully considered by the JMPR experts.
- 4. After some discussion, the Committee agreed to establish an electronic working group led by the United States of America to prepare a discussion paper describing in detail a proposed pilot process for JMPR recommendations of MRLs before national or regional authorities for consideration by the Committee.¹
- 5. At the 41st Session of the Codex Committee on Pesticide Residues (April 2009), the Delegation of the United States of America introduced the document which described the proposed pilot process. The Delegation indicated that the idea for this pilot project had come from the Global Minor Use Summit and noted that the discussion paper explained in detail the proposed process, advantages and disadvantages of such a process emphasizing that it would provide JMPR recommended MRLs before national/regional authorities registration occurs and this would facilitate global harmonization with Codex MRLs. The Delegation indicated that it was expected that the advantages of such a process would outweigh the disadvantages and emphasized that the outcome of the pilot project would help CCPR and JMPR to make an informed determination on whether to progress the concept of parallel evaluations, hopefully leading to greater harmonization of MRLs. The Delegation also pointed out that no government or other authority would give up its independent rights for pesticide registration and that the JMPR would remain an independent scientific body following its governing requirements and meeting its responsibilities.

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ALINORM 08/31/24, paras. 163-173.

6. The JMPR Secretariat informed the Committee that JMPR was in support of this initiative to enhance global harmonization of MRLs. JMPR supports the proposal of a pilot project since only through practical experience can all potential issues be identified in particular for residue evaluation.

- 7. The Committee noted that the central issue for the pilot project was that the work of JMPR would be based on the proposed labels and GAPs, rather than registered labels. The FAO JMPR Secretariat drew the attention of the Committee to the fact that successful completion of an evaluation by JMPR required registered label information, including GAP, for the estimation of MRLs and reminded that GAPs for a pesticide mean more than just the maximum proposed use pattern as described by the 2008 JMPR.
- 8. The WHO JMPR Secretariat emphasized that while the pilot project was not in accordance with existing procedure, i.e. only proposed but not yet registered GAPs, it could be done on an exceptional basis to identify issues for such a process. If GAPs change significantly after evaluation by JMPR then MRL proposals were not valid. However, only a pilot process can really address such issues in practice.
- 9. The Delegation of the United States of America noted that while this presents the possibility that the GAP may change, it is necessary in order to realise the two central benefits of the proposed process; for registration authorities to have the benefit of knowing the JMPR recommended MRLs before they set their own MRLs and to allow JMPR to work in parallel with the global joint review teams rather than following along after their assessments are completed, both of which may be expected to aid in harmonization of MRLs in the future. The Delegation further noted that issue of the GAP possibly changing was addressed in the discussion paper. First, it would be necessary to document for the CCPR that the GAP which was evaluated by the JMPR was the GAP that was registered and only those MRLs would be eligible for advancement. Second, it was acknowledged that some GAPs would change and for those the JMPR would have to do some re-evaluation of the residue side. The Delegation drew the attention of the Committee to the fact that the pilot project provides an opportunity for doing the work in a new way, that is expected to promote harmonization, that the discussion paper addressed the questions that were being raised in relation to the pilot project; that doing a pilot on a new chemical would provide useful information.
- 10. Several delegations expressed their view in regard to the advantages and disadvantages of this proposal and after an extensive discussion, the Committee did not reach an agreement to initiate the pilot project.²
- 11. The 42nd Session of the Codex Committee on Pesticide Residues (April 2010) reconsidered this matter based on a document prepared by the Delegation of the United States of America. The Delegation reiterated that the paper proposed a pilot process in which JMPR would conduct an independent, parallel review along with a global joint review team and recommend MRLs before national governments or other regional registration authorities establish MRLs. The Delegation indicated that a paper had been prepared responding to the concerns that were raised at the last meeting and proposing to conduct a pilot project on sulfoxaflor in 2011.
- After some discussion the Committee decided to request the 33rd session of the Codex Alimentarius Commission (July 2010) to allow initiating the pilot project in which JMPR would conduct an independent, parallel review along with a global joint review team and recommend MRLs before national governments or other regional registration authorities establish MRLs on sulfoxaflor in 2011.³
- The 33rd Session of the Commission approved the pilot project as proposed by the Committee⁴. The project document providing the rationale for this proposal is attached to this document for information by the Committee (see Annex I)⁵. The JMPR 2011 evaluated sulfoxaflor and the outcome of the evaluation can be found in the Report 2011 available for downloading at the FAO website: http://www.fao.org/fileadmin/templates/agphome/documents/Pests Pesticides/JMPR/Report11/JMPR 2011 Report.pdf. The proposed MRLs on sulfoxaflor arising from the JMPR 2011 are available in Annex II to this document to facilitate their consideration by the Committee.

CONCLUSION

- Based on the outcome of the JMPR 2011 and the timeframe foreseen for the completion of this pilot project (see point 9 of the project document) if there are no safety concerns associate with the use of this compound, MRLs for sulfoxaflor should be proposed for adoption at Step 5/8 by the 35th Session of the Commission in July 2012.
- 15. The Committee is invited to consider the MRLs for sulfoxaflor in the framework of the pilot project, the outcome of the JMPR 2011 evaluation and the outcome of the independent global joint review chemical (see CX/PR 12/44/7) and to decide whether these MRLs should be forwarded to the 35th Session of the Commission for adoption at Step 5/8 or be retained at Step 4 waiting for the completion of the independent global joint review chemical and reconsider these MRLs at its 45th Session in 2013.

² ALINORM 09/32/24, paras. 162-176.

³ ALINORM 10/33/24, paras. 195-202, Appendix XII.

⁴ ALINORM 10/33/REP, Appendix VI.

⁵ CX/CAC 10/33/7-Add.2.

ANNEX I - PROJECT DOCUMENT CX/CAC 10/33/7-ADD.2

CODEX COMMITTEE ON PESTICIDE RESIDUES

PROPOSAL FOR NEW WORK:

PILOT PROJECT FOR JMPR RECOMMENDATION OF MRLS BEFORE NATIONAL GOVERNMENTS OR OTHER REGIONAL REGISTRATION AUTHORITIES FOR A GLOBAL JOINT REVIEW CHEMICAL

BACKGROUND

The 42nd Session of the Codex Committee on Pesticide Residues agreed to request the Commission to allow initiating a pilot project in which JMPR would conduct an independent, parallel review along with a global joint review team and recommend MRLs before national governments or other regional registration authorities establish MRLs. It was proposed that the new chemical sulfoxaflor would be used as the pilot chemical and would be reviewed at the 2011 JMPR. A global joint review is an evaluation of a new chemical conducted by multiple national governments or authorities at the same time and working together where the chemical company submits applications to all participants at the same time; the work is divided among participants; and independent regulatory decisions are made with an effort to harmonize the outcomes, where possible. In conformance with the understanding among the governments and other authorities participating in global joint reviews, no government or other authority gives up its independent rights and its responsibilities to meet its governing requirements, in the same way, JMPR remains an independent scientific body following its governing requirements and meeting its responsibilities. The challenge is one of timing and organization to coordinate the review in such a way that the JMPR and global joint review processes can proceed in parallel.

1. Purposes and the scope of the standard

This proposal is not for the creation of a new standard although new MRLs would be proposed for the pilot chemical. Rather the proposal is to *pilot* a new process that involves a slightly altered way of JMPR and CCPR doing their usual work. This proposal, for JMPR to recommend MRLs before national governments or other regional registration authorities, is expected to further the harmonization of endpoint selection and MRL setting on a global basis. The global joint review process seeks to harmonize endpoint selection and MRL setting, to the extent possible, among national and regional authorities. Extending this process to Codex would involve bringing all of the globally available expertise together into the international standard setting process so that endpoint selection and MRLs are as fully harmonized globally as possible. This would allow technical issues to be resolved quickly and effectively.

The objectives of the pilot are to:

- (1) Determine whether and how various procedural/process issues associated with the proposal (e.g. availability of sufficient data/timing of submissions, inconsistencies with existing Codex and JMPR policies and procedures, necessity to maintain the independent status of the JMPR, resource implications for the JMPR, handling of differing interpretations of the same data, late changes of proposed GAP, etc.) can be addressed *in practice*.
- (2) Assess the outcomes (successes and failures, costs and benefits) of the proposal *in practice*.

2. ITS RELEVANCE AND TIMELINESS

The CCPR has discussed, for the last two years, the *possible* issues, costs, and benefits of the proposal for JMPR to recommend MRLs before governments or other regional registration authorities establish national or regional MRLs for global joint review chemicals. Conducting a pilot of the process will provide *actual information* which will allow the Committee to:

- Evaluate the feasibility and value of the proposed new process;
- Determine whether such a process should be implemented for new active ingredients reviewed by 3 or more national authorities as a joint review; and,
- Recommend a plan for future implementation (if that were the decision of the Committee).

3. THE MAIN ASPECTS TO BE COVERED

Below are the main aspects of the project plan. The work to be done by the JMPR is no different from the work currently being done, rather the issues are ones of timing and coordination with the joint review team.

- Nomination and placement of Pilot Chemical on Priority List;
- Submission of complete (and identical) data packages to national authorities participating in the joint review and JMPR by required timeframes;
- Incorporate the JMPR review into the joint review project plan;
- Provide JMPR with any reviews completed by the joint review national authorities for their information as is currently done;
- JMPR recommendation for ADI and MRLs will be considered by the national authorities involved in the joint review prior to finalizing their registration decisions and MRLs;
- National authorities on the joint review project team will prepare a report on utility of having the JMPR recommendations (WHO and FAO) prior to finalizing their registration (including the establishment of MRLs) decisions;
- Joint review project team will prepare a report for consideration at the CCPR meeting. Included in this review will be a confirmation of the GAP associated with the registration decisions;
- MRLs will be considered by the CCPR for elaboration.

Criteria for Selection of Pilot Chemical: New pesticide active ingredients that are being jointly reviewed by 3 or more national authorities are potential candidates for the pilot project. The timing of the submission of the registration application and the joint project plan would need to be considered to allow for the work of the JMPR to occur prior to the national authorities issuing registration decisions and establishing MRLs. The broadness of the use pattern would also be considered in selecting a chemical for the pilot project.

How will JMPR/CCPR consider MRL recommendations when registered product labels become available?

The proposed process, by definition, would not include having registered labels available at the time of the JMPR meeting. It must be recognized that there may be cases in which there are differences in the proposed GAP that was used by the JMPR assessors and the GAP that is ultimately registered. The process must include steps to ensure that the GAP evaluated by the JMPR is the GAP that is on the registered label and to deal with those cases in which the GAP has changed. The following steps have been proposed to address this important issue. It is also certainly possible that the pilot process would provide other proposals for addressing this central issue.

- The designated global joint review lead must keep the JMPR Secretariat informed of any changes that are made to the proposed labels
- As a final step in the process, a report must be submitted by the nominating country to the CCPR meeting
 documenting that the registrations that were the basis of the JMPR recommendations have actually occurred and
 the registered GAP is the same as what was considered at the JMPR meeting
- Only those MRL recommendations that are covered by the report would be eligible for advancement at the CCPR meeting

The main purpose of the pilot is to provide information on the feasibility and value of the proposed new process. The following questions were agreed to by the 42nd Session of the CCPR to be used to guide the assessment of the outcomes of the pilot project:

- Was it possible to set up a viable process that allowed for effective parallel work while maintaining the independence of the JMPR decision making process?
- Did the process effectively address JMPR/CCPR procedural/process issues, or what procedural/process changes would be necessary to effectively implement the proposed process?
- What were the added costs of the process (to the JMPR panel, the JMPR joint secretaries, the CCPR, the national authorities involved in the joint review, the manufacturers)?
- What were the added benefits (to the JMPR panel, the JMPR joint secretaries, the CCPR, the national authorities involved in the joint review, the manufacturers, member countries)?

- To what extent were harmonized endpoint selection and harmonized MRL recommendations achieved?
- The evaluation of the results of this project should be compared to other work sharing projects without participation of JMPR (e.g. fluopyram, chlorantriniliprole), in particular attention should be paid to:
 - 1. The speed by which MRLs are set at Codex and in the member countries,
 - 2. The level of MRL harmonization achieved at the final stage of the project, when all member countries have set national MRLs,
 - The amount of duplication of work (E.g. when the risk assessment has to be redone or the residues reevaluated),
 - The burden on the budget of JMPR,
 - The benefits for developing countries and minor uses.

4. An assessment against the Criteria for the establishment of work priorities:

As noted above, the proposed pilot process involves doing the same work, in the same timeframe as is currently done. Thus, there is no issue of completing the work within a reasonable period of time or of the proposal falling in an area outside the Committee's terms of reference. The following assesses the proposal against the criteria for establishment of work priorities.

4.1 General criterion--Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

This proposal is expected to provide benefits from all of the points of view noted. Production of agricultural products is a globalized industry. The advent of global joint reviews is an outgrowth of this reality as well as a response to it and it is revolutionizing the way that pesticides are regulated. Codex, *the international standard setting body for MRLs*, needs to be a part of this global process. Involving Codex in the global joint review process up-front provides the additional benefit of having all of the globally available scientific expertise applied at the beginning-- reducing rework and providing the final link in ensuring that results are globally harmonized *to the extent possible*.

These global efforts are essential to the quick transition to the *actual use as opposed to just registration* of newer, safer chemicals because it facilitates the establishment of harmonized MRLs in export markets at essentially the same time as these MRLs are established domestically. Thus, consumers are the major beneficiaries of these global efforts because the quick establishment of harmonized international standards allows agricultural producers to actually transition to newer, safer pesticides –resulting in a safer food supply. This pilot project has received strong support at the CCPR from developing countries because they rely on Codex MRLs and benefit greatly when these are harmonized with the other MRLs established though out the world.

4.2 Criteria applicable to general subjects

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade

The global joint review process helps to address the issue of international harmonization of MRLs. While it would *never be a requirement* that the expected outcome of this process is harmonized endpoints/MRLs just as it is not a requirement that the outcome of any particular joint review is harmonized endpoints/MRLs, the *goals* of the global joint review process include harmonization of endpoint selection and MRLs, *where possible*, thus:

- The process developed (that would now include a parallel JMPR review) should allow all participants to make every effort to harmonize;
- However, success should be defined as developing a workable process and not by the outcome of the process in any specific case;
- In practice, the goals of harmonized endpoint selection and MRLs have been achieved in some cases in the global joint reviews and have not been achieved in others;
- The benefit of the process, even in cases where harmonized endpoint selection and/or MRLs is not achieved, is that participating governments and other authorities (and now the JMPR) have tried to harmonize up-front to the extent possible and, where differences remain, these are thoroughly documented for all to see and understand.

(b) Scope of work and establishment of priorities between the various sections of the work

The scope of the work is no different than in the current process of MRL recommendation. It is expected that the pilot will not involve any substantive change in terms of the initial resource costs of the JMPR review. The JMPR review will proceed as it always does except that the process will have the advantages of the JMPR evaluator having access to the relevant joint assessment documents and deliberations of participating national governments and the full data packages. These advantages may be associated with substantial resource *savings*. As in the case of the global joint reviews, the resource costs of doing the work jointly (or in this case in parallel) will be minimal for the evaluators actually doing the work and any additional costs will likely be associated with **management of the process**. These resource costs will likely be borne within JMPR by the secretariat and outside of JMPR by the joint review team-- all of whom will have to invest the resources necessary for effective and timely interaction.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)

As explained above, this is an extension of the global joint review process. Governments currently participating in global joint reviews include Canada, United States, Australia, New Zealand, EU Member States, Brazil, and Japan. It is expected that, in the near future, China and possibly Kenya will also be participating.

5. Relevance to the Codex strategic objectives:

This proposal is relevant to the key objective of setting *globally relevant* standards. As noted under Point 3 in the "Introduction" of the Strategic Plan for 2008-2013, "The CAC needs to maintain its pre-eminent status as the internationally recognized body for food standard-setting and to call for the use of its standards to the widest extent possible... This will help members to be more aware of the importance on the international harmonization of food safety and quality standards, as well as the enhancement of food control systems for ensuring food safety and quality."

This proposal is most relevant to Goals 2 and 4 of the Strategic Plan. Under paragraph 11 of Goal 2 it states that "The CAC has the goal of elaborating standards that cover the needs of its entire membership to ensure these standards are applicable globally." Perhaps the best way to ensure that MRLs are applicable globally is to harmonize up-front, to the extent possible, before any MRLs are set. This pilot process is expected to provide valuable information on the extent to which this is possible.

Goal 4 refers to promoting cooperation between Codex and relevant international organizations and under paragraph 16, specifically notes that, "The CAC also has a responsibility to provide its technical input and expertise towards the building of international consensus on food standards and regulatory policy matters." The proposed pilot has this as one of its specific goals, that is, to pilot a process in which the technical input and expertise of the JMPR can be used more effectively by changing the timing of that input. In this way the recommendations of the JMPR would be available to international regulatory authorities before decisions are made on new global joint review chemicals.

6. Information on the relation between the proposal and other existing Codex

Documents

This proposal relates to the recommendation of MRLs for a new chemical which would not be significantly different from the usual process and would not be related to any existing standards or other documents.

7. IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC

Advice

The requirement for and availability of expert scientific advice would not be any different than for any other chemical for which JMPR is doing an evaluation for recommendation of MRLs.

8. IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR

The proposal involves JMPR working in parallel with a global joint review team. The pilot chemical would be a global joint review chemical, therefore, all of the elements would be in place to obtain the input needed to do the work. Thus, the technical input would not have to be "planned for", but would have to be organized, as described in Section 3. above.

9. The proposed time-line for completion of the New Work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission

A pilot chemical would be incorporated into the Codex Step Procedure in the same way that other chemicals are. Thus, the timeline for MRLs proposed in the pilot process would be exactly the same as for any other MRLs. The current proposal is for a pilot to be done at the 2011 JMPR. The associated MRLs would be proposed for adoption at Step 5 at the 2011 CCPR. If there were no safety concerns noted by the JMPR, and no other issues were brought up at the 2011 CCPR meeting then the MRLs would be advanced to step 5/8 for adoption by the Commission in July 2011.

ANNEX II - ENGLISN ONLY

252 Sulfoxaflor

Main Uses: Insecticide

JMPR:

ADI: 0-0.05 mg/kg body weight 2011 Acute RfD: 0.3 mg/kg body weight (2011)

Residue: Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: sulfoxaflor.

The residue is not fat-soluble.

Note: Recommendations made as part of the CCPR Pilot project and are not based on official GAP (2011 JMPR).

Commodity **JMPR** Code Name MRL (mg/kg) Source Note CXL CCPR Prior CCPR CAC Note CCPR GC 0640 Barley 0.6 44 0640 Barley straw and fodder, Dry 44 VB 0400 Broccoli 3 11 44 0041 Cabbages, Head 0.4 44 11 0404 Cauliflower 0.04 11 44 VS 0624 Celery 1.5 11 0001 Citrus fruits FC 0.9 11 44 SO 0691 Cotton seed 0.4 3 11 44 0269 Dried grapes (=currants, raisins 6 11 44 and sultanas) MO 0105 Edible offal (mammalian) 0.6 44 PE 0112 Eggs 0.1 44 11 VO 0050 Fruiting vegetables other than 1.5 44 except sweet cucurbits corn and mushrooms VC 0045 Fruiting vegetables, Cucurbits 0.5 3 11 44 VA 0381 Garlic 0.01 3 44 (*) 11 FB 0269 Grapes 2 44 11 VL 0053 Leafy vegetables 3 11 44 MM 0095 Meat (from mammals other 0.3 11 44 than marine mammals) ML 0106 Milks 0.2 11 44 VA 0385 Onion, Bulb 0.01 (*) 11 44 0444 Peppers Chili, dried 44 15 11 0009 Pome fruits 0.4 11 44 PM 0110 Poultry meat 0.1 11 44

252 Sulfoxaflor

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JMPR:

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Commodity											
Code		Name	MRL (mg/kg)	Source	Note CXL	Step	JMPR	CCPR	Prior CCPR	CAC	Note CCPR
РО	0111	Poultry, Edible offal of	0.3			3	11	44			
SO	0495	Rape seed	0.15			3	11	44			
VR	0075	Root and tuber vegetables	0.03			3	11	44			
VP	0541	Soya bean (immature seeds)	0.3			3	11	44			
AL	0541	Soya bean fodder	3			3	11	44			
VA	0389	Spring Onion	0.7			3	11	44			
FS	0012	Stone fruits	2		except cherry	3	11	44			
FB	0275	Strawberry	0.5			3	11	44			
TN	0085	Tree nuts	0.015			3	11	44			
GC	0653	Triticale	0.2			3	11	44			
VL	0473	Watercress	6			3	11	44			
GC	0654	Wheat	0.2			3	11	44			
AS	0654	Wheat straw and fodder, Dry	3			3	11	44			