codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ACHIEVING GLOBALLY HARMONIZED MRLs THROUGH CODEX

I. Background

1. At the 2008 CCPR meeting the U.S. recommended the development of a process for new chemicals in which JMPR would conduct an independent, parallel review and recommend MRLs *before* national governments or other regional registration authorities establish MRLs. It was proposed that the process be developed by using an upcoming global joint review chemical[1] (fluopyram) as a pilot. The potential scope of use of any new process that may be developed is addressed in Para. 40 below.

2. The 2008 CCPR established an Electronic Working Group to prepare a paper describing in more detail the proposed pilot process. The paper was to take into account the issues noted in the CCPR discussion and the input from the JMPR concerning the implications for their work, which was to be provided by the 2008 JMPR. The detailed proposal for the pilot would be presented to the CCPR in April 2009. Pending CCPR agreement, a pilot would be conducted with fluopyram, which was placed on the Electronic Working Group on Priorities list for 2009. (See Appendix I for the full report of the 2008 CCPR on this subject).

3. The anticipated benefits of the proposed process, from a global perspective, are summarized below. In addition, Paras 30-39 attempt to weigh the anticipated costs and benefits of the proposed process. It should be noted that this is somewhat speculative without having the information that will be available after actually conducting a pilot.

4. The idea for JMPR to recommend MRLs before national governments or other authorities was a recommendation of the first Global Minor Use Summit held in Rome in 2007. The harmonization of MRLs was a central issue discussed at the summit along with the many problems that arise when MRLs are not harmonized. The idea was born as everyone was beating their heads against the wall trying to figure out how to have globally recognized (and harmonized to the extent possible) MRL standards. It was mentioned in this summit that there is an international body (CAC) whose mission is to establish international MRLs and how difficult it is to achieve any harmonization after national authorities have set MRLs and then Codex MRLs are set after national MRLs are established. The idea was expressed that it would possibly advance MRL harmonization if national authorities had the benefit of knowing what the Codex MRL would be (JMPR recommendation minimally). They would then have the choice of attempting to harmonize prospectively rather than after the fact, which is resource draining for most authorities.

[1] 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.

5. In order to fully appreciate the benefits of this proposal it is necessary to take a broad perspective, which includes all of the international processes that affect MRL setting and use (or lack of use) of Codex MRLs, including the complete evaluation and registration processes. Production of agricultural products is a globalized industry. The recent 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*.

6. 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.

7. As discussed below in Para 37, as these global processes become routine, they have saved resources of regulatory authorities through sharing of the review work and this is potentially the case for the JMPR. The global process saves registrant resources in data development, preparation of application packages, and by providing predictable registration decision timeframes which allow simultaneous global market access—a process that would be facilitated by having JMPR review up-front in the process. It can be assumed that consumers ultimately benefit from this reduced cost of regulation and, as noted above, they directly benefit from the faster transition to safer pesticides.

A commenter on the original draft of this paper noted that when more resources are spent on new actives less resources will be spent on existing ones. This is an issue that has been previously discussed by the CCPR with the agreement being reached that 50% of the work done each year in Codex will be for new chemical MRLs. This agreement was based on recognition of the importance of ensuring the transition to safer pesticides and the fact that consumers in all countries benefit when the establishment of Codex standards allows producers to transition to newer, safer pesticides. CCPR must continue to recognize and address issues surrounding the older chemicals and help ensure that the older chemicals that meet current safety standards continue to remain available. Nevertheless, the paramount issue, and the paramount benefit of Codex work is ensuring the safety of the food supply.

II. Issues to be Addressed in a More Detailed Proposal for the Pilot

8. The 2008 CCPR instructed this Electronic Working Group to prepare a paper describing in more detail the proposed pilot process taking into account the issues noted in the CCPR discussion and the input from the JMPR concerning the implications for their work. The following two paragraphs summarize the issues raised by the CCPR and the input from the JMPR.

9. The issues raised at the CCPR meeting that need to be addressed in a more detailed proposal for the pilot are:

- Inconsistencies with existing Codex and JMPR policies and procedures
- Late changes of proposed GAP (since there would be no registered labels)
- Availability of sufficient data/timing of submissions
- Necessity to maintain the independent status of the JMPR
- Handling of differing interpretations of the same data

10. The issues raised by the JMPR meeting that need to be addressed in a more detailed proposal for the pilot were: (See Appendix II for the full report of the JMPR Meeting related to this subject.)

- Data need to be available at least 6 months prior to the meeting of the JMPR in order to conduct the pilot on fluopyram [The data package was submitted to the JMPR (Dr. Tritscher and Madame Yang) on December 11, 2008]
- Governments involved in the pilot project should ensure that the proposed GAP is as final as possible before submission of the residue data to the JMPR
- The JMPR recommendations based on the proposed GAPs (unapproved labels) should be acknowledged as such by the CCPR and a procedure should be developed to ensure the CCPR that the labels were subsequently registered and that the GAP was not changed or, if it was changed, how it was changed

- Interaction is required between the JMPR evaluator preparing the first draft of documents for the meeting and reviewers from governments and authorities participating in the pilot project; the process timeframes should align with JMPR timeframes including the time needed to prepare papers for the meeting; therefore, the JMPR Secretariats will need to assign evaluators/reviewers and provide them with the necessary contacts and access to relevant information

III. Proposed Detailed Pilot Process Addressing Issues Raised by the CCPR and JMPR Meetings

11. The global joint review chemical proposed for the pilot is the new Bayer CropScience fungicide, fluopyram. The participants in the joint review are Germany (project lead and EU rapporteur), Canada, and the United States. Japan is also participating as a peer reviewer.

12. The major milestones in fluopyram's review schedule are outlined below. This information is included because we think that it is necessary in order for the Committee to make a decision on whether it would be possible to do a pilot with fluopyram in 2009. It should be noted that this is not the schedule that would be recommended if it were decided to implement an established process for JMPR to recommend MRLs before other authorities. This would have to be determined after a pilot was conducted.

- May 2008
    - Submission of main data package (including grape, strawberry, and tomato uses)
- October 2008
    - Submission of additional crop field trial data for additional uses (pome fruit, root and tuber vegetables, bulb vegetables, leafy vegetables, brassica (cole) leafy vegetables, legume vegetables, fruiting vegetables, cucurbit vegetables, citrus fruits, stone fruits, small berries, tree nuts, cereal grains (except rice), grasses, herbs and spices, artichoke, canola/rape, hops, peanut, sunflower, tropical fruits)
- December 2008
    - Submission of complete data package (combination of the two data packages above) to the JMPR Secretariat and nomination as a special project
- February 2009
    - Germany completed primary toxicology reviews
- March 2009
    - U.S. completes residue chemistry (grape, strawberry, tomato)
- May 2009
    - Complete secondary reviews (May 15)
- October 2009
    - Exchange risk assessments among review participants
- November/December 2009
    - Complete risk assessments and regulatory work (for some authorities)
- Early 2010
    - Registration and establishment of MRLs (for some authorities)

13. The issues raised during the CCPR and JMPR meetings have been consolidated and addressed in detail below.

14. Availability of sufficient data and timing of submissions were raised by both the CCPR and JMPR as issues. The JMPR noted that data for the pilot chemical would need to be available at least six months prior to the meeting of the JMPR. The data package was submitted to the JMPR (Dr. Tritscher and Madame Yang) on December 11, 2008. It is proposed that it be nominated to the CCPR Electronic Working Group on Priorities as a special project. This avenue was suggested by the JMPR secretariats because it will allow work to begin in anticipation of the approval of the pilot in the regular CCPR process (or work could continue in the status of a special project at JMPR).

15. Despite the fact that the timing may work out in this case, the constraints on timing presented by the lack of flexibility of the JMPR schedule and the desire of registrants to obtain registrations as quickly as possible may seem formidable at this point in time (as the many timing issues initially did to governments and other authorities engaged in global joint reviews). These issues, however, should not be an obstacle to doing a pilot and developing a process. If the pilot is successful and an ongoing process is recommended, then national governments and other authorities and chemical manufacturers will have choices that might include:

- companies might decide it is advantageous to submit their chemical on a schedule that works within the current JMPR schedule (as the registrant for fluopyram did)
- national governments or other authorities might decide it is advantageous for them to finance additional meetings of the JMPR

The point is that the implications of a successful pilot are not fully knowable at this time, but the history of joint reviews has been that if you develop a workable process that benefits everyone, then registrants, governments, and other authorities will find a way to use it.

16. While there are potential issues with data and timing of applications, certain advantages of the proposed process should be noted. In the proposed process the exact same data package (for human health) will be submitted to JMPR as is submitted to all governments and other authorities. Thus, there is no possibility of data issues arising from incomplete packages as is sometimes experienced by JMPR. In order for JMPR to be assured of a complete package, the data should be submitted to JMPR after the global joint review partners have agreed on the completeness check or any responses to deficiencies thorough the completeness check should also be submitted to JMPR.

17. JMPR noted that interaction is required between the JMPR evaluator preparing the first draft of documents for the Meeting and reviewers from governments and authorities participating in the global joint review. Thus, the process timeframes should align with JMPR timeframes including the time needed to prepare papers for the meeting, therefore, the JMPR Secretariats will need to assign evaluators/reviewers and provide them with the necessary contacts and access to relevant information.

18. It will be imperative that the designated lead for the global joint review also works with the JMPR Secretariat to organize interactions, where necessary, among the joint review participants, JMPR, and the manufacturer. The global joint review process is becoming routine and the participants understand both the importance of these interactions as well as how to manage them. The proposed pilot would provide an opportunity to work out the details of these interactions, which may vary depending on the issues that arise with any given chemical review. It should be noted that the timelines JMPR currently has to work under are more rigid than those for joint reviews and this lack of flexibility will necessitate careful management of the process.

19. As shown in the timeline provided above for the proposed pilot, during the February 2009-June 2009 timeframe all study reviews will be completed by governments and other authorities including the secondary reviews. All study reviews, comments, and resolutions of issues are recorded in the on-line system CIRCA. These can be made available for viewing by the JMPR reviewers. At a minimum, this extremely transparent process will make it easy for the JMPR evaluators to see the issues that were identified in the global review; the resolution of the issues and the thinking behind the resolution. It is also possible that short meetings with the relevant global joint review participants could be arranged through the designated lead of the global joint review work.

20. While it will be necessary to provide appropriate interaction between the JMPR members and the global joint review team, it is of paramount importance, as noted by the CCPR meeting, to maintain the independent status of the JMPR. The CCPR also asked how differing interpretations of the same data would be handled in the proposed process. This is explained in detail below.

21. 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
- There would never be any requirement that the expected outcome of any process that is developed is harmonized endpoints/MRLs just as it is not a requirement that the outcome of any particular chemical 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 the case of any specific chemical review, if harmonized endpoints and/or MRLs is the outcome of the process, that should be viewed as a bonus
    - 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 have tried to harmonize up-front to the extent possible and, where differences remain, these are thoroughly documented for all to see and understand. Open points are discussed by the review team and an evaluation table developed, if required.

In summary, JMPR's own interpretations and recommendations would be what they report as the outcome of their Meeting. To the extent that the JMPR Meeting has differing interpretations of the data, where known at the time the report is written, the differing interpretation, and hopefully a full explanation of the differences, is what would be reported. Similarly, governments and other authorities would have the JMPR recommendations, as well as all of the information from the global joint reviews available to them when they make their own independent regulatory decisions, but their decisions would still be their own independent decisions meeting their own governing requirements.

22. According to the above outline of the proposed process for the pilot:

- JMPR would make their recommendations in September 2009
- In the early 2010 timeframe, when governments and other authorities begin making their registration and MRL establishment decisions they would have the JMPR recommendations available to them prior to making final decisions on MRL establishment

23. Both the CCPR and JMPR meetings expressed concern that the proposed process, by definition, would not include having registered labels available at the time of the JMPR meeting. This opens up the possibility of changes in GAP that would not be considered by the JMPR meeting, possibly resulting in establishment of MRLs that do not correspond to registered GAP. It was noted by the JMPR meeting that GAP for a pesticide means more than just the maximum proposed use pattern (rate of application, pre-harvest interval, and efficacy); it also includes advice relevant to worker/operator and environmental exposure as well as management of pesticide resistance. JMPR was concerned that national government evaluation of these additional aspects may lead to changes in the GAP that is ultimately registered. JMPR, therefore, recommended that those governments involved in the pilot project should ensure that the proposed GAP is as final as possible before the September JMPR meeting. However, as noted and explained in Paras 24-25 below, it must be recognized that there will be cases in which there are changes in the GAP that is ultimately registered and the process must include steps to deal with those cases.

24. Clearly, it will be important that the governments and manufacturers involved try and ensure that the proposed GAP is as final as possible before submission of the packages. The fact that the global joint review chemicals are relatively low risk helps to reduce the possibility of major changes in GAP occurring due to risk management concerns at the end of the risk assessment and registration processes. However, it must be recognized that proposed GAP may change and changes in GAP certainly remain as a risk mitigation option (e.g. approving lower rates or fewer applications) for regulatory authorities in making their regulatory decisions. Thus, it will be imperative that during the pilot process the designated lead for the global joint review keeps the JMPR Secretariat informed of any changes that are made to the proposed labels.

25. It will also be necessary that, as a final step in the process, a report 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 MRLs recommendations that are covered by the report will be eligible for advancement at the CCPR meeting.

26. If, for whatever reason, the registrations that were the basis of the JMPR recommendations do not occur for some uses or the GAP is changed subsequent to the JMPR meeting and, therefore, some of the JMPR recommended MRLs do not correspond to registered GAP, the consequences, in terms of resources, would be limited to some of the review work done on the residue data. The toxicology work would remain valid as would the vast majority of the work on the residue work. It would be necessary to reconsider the field trial results for certain commodities and to reconsider the dietary intake calculations for those commodities at a future JMPR meeting which would be managed under the normal CCPR priority setting procedure.

27. Inconsistencies with existing Codex and JMPR policies and procedures were the last issues raised by the CCPR meeting. The only specific inconsistency so far identified is the one discussed above—working on a chemical which has not yet been registered. We have tried to address the process questions in the discussion above. In terms of the procedural question involving the prioritization criterion that states there should be a registered label, it does not seem warranted to change the criteria simply to allow the pilot. It is not known if there will be an actual implementation of this proposed process change, so what is needed is to acknowledge that the pilot does not meet the stated criteria, which was acknowledged when it was originally placed on the priority list for 2009. Since deviations from the prioritization criteria have occurred in the past this does not seem to be such a big issue.

28. We do not know if there are other policies and procedures that might ultimately need to be changed. Indeed, one of the main purposes of doing a pilot is to identify changes to existing policies and procedures that may be necessary if it is decided that actually implementing a new process will be beneficial. Therefore, for the purposes of the *pilot*, the goal should be to identify any inconsistencies with existing policies and procedures and, in the report on the pilot, propose all changes in policies and procedures that would be necessary to actually implement a new process, if the decision is to implement the process.

29. Finally, in response to some comments that have been made with the apparent intention of seeking to avoid too much disruption of JMPR processes, it should be noted that both JMPR secretariats are in favor of doing the pilot. Similar efforts to establish international standards before national governments or other authorities establish their own standards are being undertaken elsewhere. See paragraph 170 of Appendix I-- “The Representative of FAO 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.” A similar proposal is currently being considered in the Codex Committee on Residues of Veterinary Drugs in Food.

30. In response to comments on the original draft of this document, we have attempted to summarize below what we think are the likely advantages and disadvantages of the proposed process.

Costs

31. We think that a pilot will show that this process change will not result in substantive change in terms of the initial resource costs of the JMPR review. If the timing can be worked out, 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 which were noted in the JMPR report, may be associated with substantial resource *savings.* We think that, 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 that any additional costs will 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. It should be noted that there are other resource costs that would occur on a one time basis, to conduct a pilot and establish a new process, if that is the ultimate recommendation. These include setting any appropriate new principles and practices for the evaluation of the pilot chemical, preparing a report from the pilot process for consideration at the 2010 CCPR, and, if it is decided to establish a new process, revising the existing Manual of “Submission and Evaluation of Pesticide Residue Data for Estimation of Maximum Residue Level in Food and Feed.”

32. The other potential resource costs would occur in those cases where the JMPR has reviewed a chemical and, for whatever reason, registration for some uses does not occur or the GAP is changed subsequent to the JMPR meeting and some of the JMPR recommended MRLs no longer correspond to the GAP that is actually registered. In these cases JMPR will have already done work that cannot, at least immediately, be used to establish MRLs and some additional rework will be necessary. As some commenters noted, this is precisely the reason that having a registered label is one of the current prioritization criteria. If, for whatever reason, registration for some uses does not occur or the GAP is changed subsequent to the JMPR meeting and some of the JMPR recommended MRLs no longer correspond to the registered GAP, the consequences, in terms of additional resource expenditures on rework, would be limited to a portion of the review work done on the residue data. The toxicology work would remain valid as would the vast majority of the work on the residue side. It would be necessary to reconsider the residue field trial results for the affected commodities and to reconsider the dietary intake calculations for those commodities at a future JMPR meeting which would be managed under the normal CCPR priority setting procedure. The extent to which this might happen is not known, but as the EU commenters note, the global joint review chemicals are relatively low risk chemicals that do not have major risk issues. This helps to reduce the possibility of major changes in GAP occurring due to risk management concerns at the end of the risk assessment and registration processes.

33. In summary, on the cost side there are cost savings associated with the process because, as noted in the JMPR report, the JMPR evaluator will be assured of having a full data package and will have access to the relevant joint assessment documents and deliberations of participating national governments. The evaluators will, thus, reap the resource savings that have been previously observed in JMPR work sharing activities. These resource cost advantages will be partially offset by additional process management costs and, in some cases, by the cost of rework on the residue side when the registered GAP changes after the initial JMPR evaluation is done. In these cases the recommended MRLs would have to be revisited at a subsequent JMPR meeting. Due to the fact that the global joint review chemicals are relatively low risk chemicals with few issues, it is likely that this type of rework will not be a major issue resulting in major resource costs. Thus, it may turn out that there are no increased costs associated with this process or, at least, no substantial increased costs.

Benefits

34. As noted above, (para 5) the recent advent of global joint reviews is an outgrowth of the globalization of the industries that supply agricultural products as well as a response to this globalization. Global joint reviews are revolutionizing the way that pesticides are regulated and Codex, *the international standard setting body for MRLs*, needs to be a part of this process.

35. In addition to this central fact, the U.S. has come to clearly recognize that these global efforts are essential to the quick transition to newer, safer chemicals. This transition to safer chemicals has been the goal of the passage of major legislation in the U.S. and elsewhere. However, passage of legislation and years of effort to register new chemicals does not ensure that the chemicals which are on the food that people eat have actually changed. In order to speed transition to *actual use*, as opposed to just registration, of newer, safer pesticides it is necessary to establish *harmonized* MRLs in export markets at *essentially the same time* as these MRLs are established domestically. 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. CCPR must continue to recognize and address issues surrounding the older chemicals and help ensure that the older chemicals that meet current new safety standards continue to remain available. Nevertheless, the paramount issue, and the paramount benefit of Codex work is ensuring the safety of the food supply.

36. Involving Codex in the global joint review process up-front provides the additional benefit of having all of the globally available scientific expertise applied together at the beginning-- reducing rework and providing the final link in ensuring that results are globally harmonized ***to the extent possible***.

37. Also, as noted above, we believe that as these global processes become routine, they save resources of regulatory authorities, and potentially JMPR, through sharing of the review work and reducing the need for additional government resources to address trade and other issues that inevitably result from a disjointed and disharmonized system. The seven multi-lateral (3 or more regulatory authorities) joint reviews that have been conducted thus far have demonstrated that the major regulatory authorities can work effectively together to simultaneously review global submissions, using a single format for data submission; sharing the review burden; discussing complex scientific issues; and producing a product that at the very least contains jointly agreed upon scientific reviews and in many cases harmonized endpoints and/or MRL results.

38. The global process saves registrant resources in data development, preparation of application packages, and by providing predictable registration decision timeframes which allow simultaneous global market access—a process that would be facilitated by having JMPR review up-front in the process.

39. In summary, we believe that the potential benefits of including JMPR in a parallel review process will outweigh the costs of establishing such a process because the major issues in the initial review involve timing and coordination (management resources) and not expenditure of additional reviewer resources. These additional management resources may be offset by resource cost savings resulting from the work share aspect of the proposal and the availability of complete data packages. The issues surrounding possible rework resulting from changes in GAP after the JMPR review or failure to register by the time of the CCPR meeting are certainly real, but given that the original work will mostly remain useable this consideration does not seem to outweigh the many benefits of JMPR participation up-front in a global process.

40. The above summarizes our expectations concerning the results of the pilot and again provides the reasons for doing the pilot. The 2010 CCPR meeting, based on the report from the **actual** pilot, would be able to:

- weigh the costs and benefits of the proposed new process
- determine whether such as process should be implemented
- develop a plan for implementation
- determine in what situations the new process could be used (e.g., for all new chemicals, or only for new chemicals within the global joint review process, or only those in the global joint review process that have harmonized use patterns). In response to comments on the original draft of this paper, we would note that based upon experience from the global review process, the United States believes that the proposed Codex process is most appropriate for new chemicals within the global review process, but that this should not be restricted to only those that have harmonized use-patterns. Although the benefits of the proposed new process have mostly been discussed in terms of harmonizing MRLs, the process also provides opportunities for harmonization on the toxicological evaluation side which will help in promoting acceptance of the standards, as noted in Paras. 169-170 of the 2008 CCPR Report, "The Representative of WHO 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. The global review process provides an *already established structure* that organizes the joint review of multiple major authorities. The element missing in this otherwise very inclusive global process is Codex. Establishing a JMPR process that remains independent but allows parallel review of these new compounds and allows recommendation of endpoints and Codex MRLs prior to national governments will avoid the very real prospect of multiple national authorities jointly reviewing a new chemical, possibly harmonizing the ADI, ARfD, and/or MRLs and then having the JMPR, very shortly afterwards, review the same new chemical and possibly come to different conclusions without having any opportunity to harmonize and without any mechanisms to subsequently address the differences. This is a very undesirable situation which can be addressed, possibly very easily, by altering the existing JMPR process to allow a parallel review of these new compounds.

IV. Summary

41. Global joint reviews have changed the way of doing business in the pesticide regulatory world. National governments and other authorities as well as chemical companies have altered their processes to accommodate global reviews because of their many benefits. Global harmonization efforts are building on each other:

- More countries and other authorities are involved in global joint reviews
- More chemical manufacturers are exploring the possibilities and advantages of participating
- A global residue program is currently being piloted

Piloting a Codex process that would allow JMPR recommendation of MRLs before national governments or other authorities would build on these efforts and help to ensure that the global standard setting body is included as an integral part of the process and is not left behind.

42. The output of the pilot process would be a proposed process for consideration at the 2010 CCPR meeting. The report from the pilot would detail:

- a proposed process for consideration by the committee
- the policy and procedural changes that would be necessary to implement the proposed process

- the advantages and disadvantages of the proposed process, for example, in terms of:
    - what aspects save or have the potential to save time and resources
    - what aspects require or have the potential to require more time and resources
    - what is the impact on the scientific review

Appendix I. Relevant Part of the 2008 CCPR Report

ACHIEVING GLOBALLY HARMONIZED MRLS THROUGH CODEX (AGENDA ITEM 10(iii) [15]

163. The Delegation of the USA introduced the document which recommends development of a process for evaluation of new chemicals to allow JMPR to recommend MRLs before national governments. The Delegation emphasized that such a process would facilitate global harmonization with Codex MRLs, where possible by allowing national authorities to know what JMPR will recommend and what is likely to be adopted by Codex, before they establish their own MRLs.

164. The Delegation proposed that the Committee initiate a pilot project using an upcoming new chemical this 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.

165. 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. The Delegation of Argentina supported this view, so that Codex, actually becomes the international forum for the establishment of MRLs, while achieving further consistency with WTO rules. 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.

166. The Delegation proposed that the Committee using the pilot chemical establish a working group to develop the detailed process.

167. During the subsequent discussions, a number of issues were raised, including the independent status of JMPR, the availability of sufficient data, late changes of proposed GAP, the timing of submissions, the handling of differing interpretations of the same data, and inconsistencies with the existing Codex and JMPR policies and procedures.

168. A number of delegations supported the idea to initiate a pilot project and gain experience from its application, while noting the issues that would need to be addressed.

169. The Representative of WHO 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.

170. The Representative of FAO 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 experts at the JMPR 2008.

171. Some delegations pointed out that the proposal had significant implications for government agencies involved in the registration of pesticides and that the Procedural Manual would require amendments. However, because this important document was made available only shortly before the meeting, there was no time to develop a position on it.

172. The Co-Chairperson reminded the Committee that in the past implementation of the pilot project on the development of interim MRLs had lead to new procedures that greatly increased the efficiency of the work of the Committee and proposed that in this case as well the Committee should establish more an electronic working group under the chairmanship of the United States to prepare a discussion paper should address outstanding issues describing, in detail, the process for evaluation and the pilot project. Several delegations and observers supported this proposal.

173. After some discussion, the Committee agreed to establish an electronic work group[16] led by the United States and working in English to prepare a discussion paper describing in more detail the proposed pilot process taking into account the issues noted above, for consideration by the next session of the Committee.

[15] CX/PR 08/40/13; [16]Argentina, Australia, Brazil, Chile, China, Germany, European Community, Japan, New Zealand, CropLife International

Appendix II. Relevant Part of the 2008 JMPR Report

2. Comments from JMPR on a Pilot Process for JMPR to Recommend Maximum Residue Levels Prior to National Government Registration

Background

At the 40th Session of the Codex Committee on Pesticide Residues (CCPR), the Delegation of the United States (US) presented a document describing recommendations for the development of a process to accelerate the evaluation of new pesticides, which would allow JMPR to recommend maximum residue levels (MRLs) to CCPR before the new pesticide has been registered by national governments. This might facilitate the alignment of national MRLs with Codex.

CCPR agreed to establish an electronic working group led by the US delegation and co-chaired by Australia and Kenya (this is incorrect—there were no co-chairs); the objective of this working group was to prepare a discussion paper describing in more detail a proposal for a pilot process and report back to CCPR at its Forty-first Session (April 2009). CCPR noted that this pilot process would have significant implications. The Joint JMPR Secretariats requested comments from the present Meeting.

Comments from the JMPR on the pilot process

The Meeting indicated that it would embrace any development that would improve the efficiency with which public health is protected from exposures to pesticide residues.

The Meeting considered that there were several potential advantages in the proposal to accelerate the evaluation of new pesticides by giving the JMPR evaluator access to the relevant joint (work-share) assessment documents and deliberations of participating national governments and the full data packages. In particular, many of the technical issues involved would be identified by the governments and authorities during the commenting process. However, the Meeting noted that there are some issues that require further consideration before implementation of any pilot project.

The Meeting emphasized for the pilot that all relevant procedural issues need to be resolved and the data need to be available at least 6 months prior to the annual meeting of the JMPR in September.

Successful completion of an evaluation by JMPR requires registered label information, including good agricultural practice (GAP), for estimation of maximum residue levels. GAP for a pesticide means more than just the maximum proposed use pattern (rate of application, pre-harvest interval, efficacy). It also includes advice relevant to worker/operator and environmental exposure as well as management of pesticide resistance. JMPR is concerned that national government evaluation of these additional aspects may lead to changes in the GAP that is ultimately registered. Those governments involved in the pilot project should ensure that the proposed GAP is as final as possible before submission of the residue data to the JMPR.

For the JMPR evaluation to be completed before final registration of the new pesticide by national governments, interaction is required between the JMPR evaluator preparing the first draft of documents for the Meeting and reviewers from governments and authorities participating in the pilot project. The Meeting noted that increased correspondence would increase time involved but not necessarily change the meeting process. However, the process timeframes should align with JMPR timeframes including the time needed to prepare papers for the Meeting. Therefore the JMPR Secretariats will need to assign evaluators/reviewers and provide them with the necessary contacts and access to relevant information.