codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 13 (a) **CX/PR 10/42/16**
April 2010

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

42nd Session
Xian, China, 19 - 24 April 2010

ACHIEVING GLOBALLY HARMONIZED MRLS THROUGH CODEX

Prepared by the Unites States of America

Background: At the 41st session of the CCPR in 2009 the paper "Achieving Globally Harmonized MRLs Through Codex" (CX/PR 09/41/6) was discussed. This 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. In the discussion at the 2009 CCPR, several issues arose which precluded some delegations from supporting the proposed chemical, fluopyram, as a pilot chemical for this process. For details of consideration – see ALINORM 09/32/24, paras 162 – 176) available from:

http://www.codexalimentarius.net

Recommendation: The Delegation of the United States, at the request and urging of many other Codex delegations is proposing to discuss the pilot process again at the 2010 meeting. The essence of the proposal remains the same and can be found in the attached document from the 2009 CCPR (CX/PR 09/41/6). In order to advance the discussion, this addendum attempts to address some of the issues that arose during the discussion of this proposal at the 2009 meeting. The United States recommends the following actions:

- The Committee confirm their support for conducting a pilot of this process and their willingness to consider candidate chemicals
- The Committee consider as a pilot, a specific chemical currently proposed for a global joint review which might be a possible pilot chemical and, if it is found acceptable, would need to be included on the schedule for the 2011 JMPR.

Response to Issues Which Arose During the 2009 Meeting:

(1) The issues surrounding the fact that only three of the commodities for fluopyram were guaranteed by the Joint FAO JMPR Secretary to be completed. In response to this issue, another issue arose and was expressed by the EU and Australia concerning the criteria for determining how a suitable chemical would be selected. Both expressed the opinion that a pilot chemical should have varied use patterns in a number of countries and uses on a variety of commodities.

There was a lot of discussion at the 2009 meeting as a result of the proposal to do only 3 of the uses of fluopyram. This situation had nothing directly to do with the pilot process proposal. It was never intended that the pilot would be done on less than all of the proposed uses of the pilot chemical. The proposal of

doing only 3 uses of fluopyram was made and became an issue only because the JMPR schedule was crowded and the Joint FAO JMPR Secretary was unwilling to devote resources to the pilot when she was not sure if the pilot would end up being supported at CCPR and then at the CAC. Thus, she had proposed that she could guarantee that 3 uses would be done but could not guarantee more than that.

This issue is not discussed one way or the other in the paper from last year because it was never anticipated that less than the full set of uses proposed would be done. The U.S. is fully supportive of doing all of the uses of whatever chemical is used for a pilot process. If resources were again an issue, then the pilot of this process would have to wait until such time as resources were available to do an entire chemical. It should be noted, however, that the pilot chemical would have to come from the vary limited pool of global joint review chemicals for which the timing of submission make it possible for the JMPR to work in parallel with the global joint review team. Thus, it is not possible to put a lot of other caveats on what the chemical uses would be. One possibility might be to run a number of pilots before seeking to establish a "permanent" process, if the use pattern of a particular chemical was viewed as limited.

(2) Regarding, the EU proposal that the process should only be used for low-risk substances:

As noted in the 4th bullet under Paragraph 40 of CX/PR 09/41/6, one of the specific areas that would be considered in reviewing the outcome of the pilot would be to "determine in what situations the new process could be used..." Thus, we believe that whether the process should be restricted to only reduced risk compounds might better be discussed after the pilot as a part of this larger discussion and evaluation of the results. Also, as noted in that bullet, "...the United States believes that the proposed Codex process is most appropriate for new chemicals within the global review process..." We note in that regard that the chemicals so far nominated for global joint reviews have been ones for which the company expects there to be few issues. However, even if a chemical had an issue--as has turned out to be the case for fluopyram, we believe that involving the WHO in the discussion of the issue *up-front* would be very beneficial to everyone. In the case of fluopyram, for example, one authority has one opinion on the issue (which is a cancer issue for which mode of action studies are being conducted) and other countries have another opinion. While the "whole world" is considering the issue, it would have been extremely useful to have the WHO panel involved as well.

(3) Regarding the EU concern that the outcome of the pilot should be thoroughly evaluated:

We are not certain that we understand why this is an issue. The whole point of doing a pilot is to thoroughly evaluate the results of the pilot in order to make recommendations. Paragraph 40 in CX/PR 09/41/6 lists some of the issues that would be addressed in the evaluation of the pilot and Paragraph 42 lists other outputs that would be produced for discussion by the CCPR when they consider whether to actually establish a new process. We are not sure what could be added to make it clear that a thorough evaluation would be done, however, we believe that any specific item that the EU wanted addressed in the evaluation of a pilot should be addressed.

(4) Regarding Australia's contention that, "…no tangible scientific or statistical evidence had been forwarded to demonstrate any level of MRL disharmonization.":

The US maintains a database at www.mrldatabase.com which shows, for each MRL established in the US, all of the other MRLs established by other countries worldwide and by Codex for that specific pesticide/commodity combination. A quick review of this database shows the very wide disparity of MRLs.

The US can offer the following observations: (1) lack of harmonization of MRLs is a major problem for the United States; (2) a major focus of work in the OECD is harmonization of methods, for example the work on the MRL calculator, in order to achieve harmonization of outcomes to the extent possible; and (3) through our work on the global minor use summit and other work with developing countries it is our understanding that lack of MRL harmonization is a major issue for them. .

(5) Finally, regarding the rather large and heartfelt disparity in opinions expressed at the meeting last year:

We believe that when the proposed process is looked at only from the point of view of Codex--it does not make a lot of sense and we can see why, when considered only from this perspective, people would think

there is no point to it. It is only when looked at from the perspective of what is being done in the global joint reviews and related efforts at harmonization, that it makes sense to try to involve JMPR and CCPR in that effort. To the people involved in these other global harmonization efforts the pilot process seems to be the logical next step. The clash of these perspectives has, we believe, contributed to the current impasse. We would therefore propose, that it be agreed that the process is only applicable to global joint review chemicals. Currently, the paper from last year (CX/PR 09/41/6) says (paragraph 40) that the results of the pilot would be used to "...determine in what situations the new process could be used...the United States believes that the proposed Codex process is most appropriate for new chemicals within the global review process..." The US proposes that we agree up-front that global joint review chemicals are the only really viable use of this proposed process.