

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 10 (iii)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

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ACHIEVING GLOBALLY HARMONIZED MRLS THROUGH CODEX¹

Prepared by the United States of America

(1) **Proposal**

CCPR should develop a process for new chemicals that allows establishment of Codex MRLs (or at least allows JMPR recommendation of Codex MRLs) *before* national governments establish MRLs.

The first step in developing such a process is to approve a change in the CCPR prioritization criteria that would allow new compounds on the JMPR agenda before national registrations have occurred.

[Note: This process would apply to the original establishment of MRLs for new chemicals only and not to the periodic review program or special evaluations.]

If CCPR agrees in principle with this proposal, it is recommended that the process be piloted with an upcoming new chemical that is being evaluated using the global joint review process².

This proposal is based on the following principles:

- Making Codex truly the most important international reference point for MRL development by making it a focal point for achieving the goal of globally harmonized MRLs
- Maintaining the independence of the JMPR review process
- Achieving a time frame within JMPR that will not slow down the approval processes national governments

¹ Included upon request of the Government of the United States of America.

² Global joint reviews are evaluations of new active ingredients conducted by multiple national governments or other authorities at the same time and working together. The chemical company submits applications to the various participants at the same time and the review work is divided among them. Independent regulatory decisions are made, but there is a focus on harmonizing the outcomes, especially the MRLs. An example is the review that is currently being completed for the new chemical chlorantraniliprole (E2Y-45). This review included Australia, Canada, Ireland and the United Kingdom (representing the EU), and the United States. It is anticipated that the MRLs will be harmonized among all the participants.

(2) **Background**

The work of Codex has, of course, always focused on global issues and setting MRLs for global use in protecting the health of consumers and ensuring fair practices in the food trade. As the global economy expands this work has become increasingly important. However, there has not been complete success in achieving truly global MRLs that all countries use.

(3) In the discussion on the paper “Enforcement of Codex MRLs” (CX/PR 07/39/10) presented at the last CCPR session, it was very clear that the necessity of using Codex MRLs and the consequences of varying MRLs across the globe are not shared equally by member states. It was clear that, despite the existence of Codex, there is still a great disparity in many international standards. The first Global Minor Use Summit held in December 2007 provided further evidence of the importance of finding ways to harmonize MRLs across the globe. A major theme of the Summit was the importance to support and expand the harmonization work that is currently underway with an emphasis on the end result: “Harmonize national MRLs and/or accept Codex MRLs.”

(4) As governments seek to address this problem, there has been general recognition that Codex is the place where the work of global MRL harmonization must take place since:

- The harmonization of MRLs on a global basis would, hopefully, be a natural outgrowth of Codex’s work, assuming that national governments adopt Codex standards
- Codex provides a forum which is truly international.

(5) **Benefits of the Proposal to Establish Codex MRLs for New Chemicals Before MRLs Are Established by National Governments (or other entities)**

- It makes sense! If the recognized goal is to achieve globally harmonized MRLs and Codex is the forum essential to accomplish this goal—Why, then, does the Codex establishment of MRLs *follow* the national government establishment of MRLs—a process that seems *designed* to cause problems as nations seek to harmonize with Codex *after* their work is done and after it has been codified in ways that are difficult to change?
- If Codex establishes (or JMPR at least recommends) the MRLs for new chemicals first, *before* national governments, then national governments will know what MRLs they should be harmonizing with as they complete their work on a chemical. If national authorities have the benefit of knowing what JMPR will recommend and what is then highly likely to be adopted by Codex, then they can try to harmonize with the Codex MRL upfront or, if not, they are making a conscience decision to not harmonize.
- Such an approach may allow less room for individual country divergence from the established Codex MRLs and more observance, in practice, of WTO rules.
- The result should be that harmonization/acceptance of Codex MRLs will increase, leading to increased trade of food and feed and other agricultural products.
- Many of today’s procedures were developed prior to the existence of the current information technology possibilities, therefore, data exchange and communication possibilities are very different now from the time when the current procedure was defined. It is important to explore all of these possibilities in order to make the work of Codex as timely and as efficient as possible and ensure that international mechanisms do not fall behind new developments.

- As work continues on developing global residue trials, these may allow Codex and national governments access to the exact same residue information at the same time, making harmonization at once easier and more necessary.
- Finally, it is worth noting that global harmonization efforts are building on each other. More and more countries are seeking to be involved in the global joint reviews. More and more companies are exploring the possibilities and advantages of participating. A global residue program is being piloted. Piloting a new Codex process with a global joint review chemical would build upon these efforts. It would be a very bad result for everyone if many national governments work together and, in fact, establish harmonized MRLs and Codex later establishes different ones.

(6) **Issues to be Addressed**

Among the potential issues to be addressed are:

- It is recognized that scientists on the JMPR participate as independent scientific experts, and do not represent their employers, governments, or other institutions. Further, it is recognized that it is of *paramount* importance that the independence and integrity of the evaluations are maintained, both in appearance and in actual fact. An integral part of any new process would be to continue to ensure this independence.
- Currently there is a requirement that a chemical be registered and that registered labels representing existing GAP be provided to JMPR. The new process would need to ensure that sufficient data are available to allow a JMPR assessment and that proposed GAP were sufficiently defined and binding so that the recommended MRLs represent the actual use practices that are ultimately registered.
- Various issues surrounding the timing of the work, including the fact that the JMPR meets only once a year and is not a standing group and the tight timeframes facing national governments in their review of new chemicals.

(7) These issues may seem formidable, but given the importance of the goal of achieving global MRLs that nations of the world can and will actually adopt and considering the incredible difficulties and costs resulting from MRLs that are not harmonized--surely it is worth investing the time to explore such a process with an attitude of finding a way to make it work.

(8) **Recommendation to the CCPR**

- The CCPR establish a working group to develop a detailed proposal for a new process that would allow JMPR to recommend MRLs for new chemicals before national governments establish their MRLs
- Mandate the working group to develop the process by using an upcoming global joint review chemical as a pilot
- Ask the Commission to approve an exception to the current CCPR prioritization criteria that would allow the pilot chemical on the JMPR agenda before national registrations have occurred.