Need for Harmonized MRLs Continues

Increased discussion over the past couple of years by crop protection companies and commodity associations on the need for Codex MRLs and lack of harmonization of MRLs.

Increased number of other countries voicing same concern.

Increased pressure by public for safe food supply.

Progress made but goal has not been reached.

Proven that reviewing pesticide registration actions and setting MRLs in same timeframe promoting harmonization.
December 2007 the first Global Minor Use Summit was held in Rome, Italy hosted by the Food and Agriculture Organization and organized by IR-4, US EPA and USDA.

Five action items came out of this summit all aimed at obtaining more registrations and MRLs for minor uses and a greater degree of harmonization of MRLs.

One action item focused on conducting pilot projects.

Pilot project was proposed that would “explore the concept of a simultaneous JMPR review and national regulatory reviews of a new pesticide active ingredient to facilitate the establishment of Codex MRLs prior to national MRLs”.

An Idea: Global Minor Use Submit 1, December 2007
CCPR meeting in April, 2008 the US delegation introduced a document which recommended the development of a process for the evaluation of new chemicals to allow JMPR to recommend MRLs before national governments established MRLs for an active ingredient.

It was 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 national MRLs are established.

US Delegation proposed that CCPR initiate a pilot project using a new active ingredient being evaluated using the joint review process.

JMPR would receive the dossier at the same time as the national authorities participating in the joint review and would conduct their own independent evaluation in parallel.
Proposed Pilot Project to JMPR

US Delegation expressed several benefits of such a new process:

- Increased harmonization/acceptance of Codex MRLs thereby facilitating trade of food and feed.
- Important to explore all possible process changes in order to make the work of Codex as relevant, timely and efficient as possible.
- The US Delegation proposed to establish a working group to develop a detailed process.

During discussion of the proposal a number of issues were raised:

- Need to maintain independent status of JMPR;
- Late changes of a proposed gap;
- Timing of submissions;
- Availability of sufficient data;
- Handling of differing interpretations of the same data;
- Inconsistencies with existing Codex and JMPR policies and procedures.
WHO Secretariat saw many advantages to such a process and it would eliminate discrepancies in the outcome of the ADI and aRfD.

FAO Secretariat generally supported the proposal; noted setting international standards prior to national standards was an established practice in other international standard bodies.

But...noted that this pilot project would have significant implications of 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 JMPR 2008.

CCPR Co-chair noted that pilot projects lead to new procedures that greatly increased the efficiency of the work of the Committee.

Agreement to establish an electronic working group led by the U.S.
And then the discussion began....

CCPR 2009: US Delegation prepared a discussion paper describing in detail a proposed pilot process. In the CCPR 2009 meeting report there are 15 paragraphs on the discussion. No agreement reached to conduct the pilot; many delegations expressed disappointment on an opportunity lost.

CCPR 2010 and Eyjafjallajokul: US Delegation presented another paper addressing concerns raised. Decision to request the CAC to allow initiating new work on this pilot (after some information was added and format was changed).

JMPR 2011 (September 2011): sulfoxaflor was reviewed by the JMPR.

CCPR 2012: All MRLs remained at Step 4 awaiting the authorized national GAPs for consideration by JMPR. CCPR informed of the progress of the joint review.

May 6, 2013: U.S. registered Sulfoxaflor and established MRLs.

CCPR 2013 (May 6-11, 2013): 30 MRLs are advanced to Step 5/8 for sulfoxafor; 4 held at Step 4 because GAP reviewed by JMPR was different than registered by the US.

CCPR 2014: Beans advanced to Step 5/8; others still held at Step 4.

CCPR 2015: MRLs held at Step 4 advanced to Step 5/8.
Results of the Pilot - sulfoxaflor

Codex MRLs were established in very short time after the U.S. registration of sulfoxaflor.

Lack of support by vocal delegations.

A critical review was to be done but was never placed on the agenda.

U.S. Delegation abandoned the idea of a second pilot project.
A Second Try…

Time passes… delegations change….

Lack of MRLs and harmonization remains!

Canadian Ministry of Agriculture hosted a workshop entitled “Missing MRLs” in October 2017.

Concerns voiced:
• New chemistries used on commodities cannot be exported due to lack of MRLs – particularly Codex MRLs.
• MRLs not harmonized.
• Need for efficiency and improved timing in MRL setting.
• APEC pilot – once scenario is to defer to Codex – but there needs to be a Codex MRL!

Suggestion to try JMPR participation of the JMPR in an international joint review of a new compound again.
Proposal from Delegation of Canada: “Consideration of Opportunities and Challenges related to the Participation of the JMPR in an International Joint Review of a New Compound”.

Cited reliance on pesticides to improve crop quality and yield and protect the food supply; pesticide registration varies among countries and some rely on Codex MRLs; growers using newer pesticides unable to export their products to countries relying on Codex MRLs due to a lack of Codex MRLs.

Canada, Australia, Costa Rica, Kenya, Mexico, Uganda, and the U.S. proposed the creation of an electronic working group encouraging engagement of delegations and JMPR in a discussion on the opportunities and potential challenges associated with the participation of the JMPR in an international joint review of a new compound.
Symposium on Joint Reviews of New Pesticide Active Ingredients.

• American Chemical Society Meeting: Tuesday, August 21, 2018; Boston, Massachusetts.

• Symposium will address topic of joint submissions for registering new pesticides.

• 15 speakers from governments and crop protection industry.

• Aim to identify key actions needed to bridge technical and political gaps so that joint submissions become “the way” for register
Thank you for your attention!