

US EPA ARCHIVE DOCUMENT

**International Pesticide Registration Activities
Update for the Pesticide Program Dialogue Committee
November 29-30, 2012**

Overview

A global joint review is an evaluation of a pesticide dossier through work-sharing between two or more countries. The participating regulatory authorities establish a schedule for the review and determine the work split for the various science disciplines. Once the primary study reviews are finished, a secondary review is completed. Each country uses the data reviews to develop individual risk assessments for the active ingredient, taking into account the specific uses being registered in their jurisdiction.

The goals of global joint reviews are to harmonize the review requirements to the extent possible, including harmonizing of the import tolerances (called Maximum Residue Limits or MRLs in Canada and many other countries). MRLs are the maximum residue level of a pesticide permitted in or on food or feed grown in the U.S. or imported into the U.S. from other countries. Harmonizing global joint reviews will reduce trade irritants. Furthermore, countries will ensure that the efficiencies and experience gained by the joint review process are reflected in other relevant international organizations (e.g. FAO/WHO Joint Meeting on Pesticide Residues (JMPR) and Codex Committee on Pesticide Residues (CCPR)), thereby helping developing countries manage their pesticide regulatory systems.

Joint Reviews:

Current Joint Review Activities

- Ten new active ingredient joint review projects are currently underway. There are two ongoing second entry joint review projects which are new uses for active ingredients that were originally jointly reviewed. Sixteen joint review projects have been completed to date.
- In addition, there are joint review projects to evaluate new import MRLs; an Experimental Use Permit; and a product chemistry review of alternate source of active ingredient.
- Regulatory authorities participating in the joint review process include: Australia, Brazil, Canada, China, European Union, Mexico, Japan and the United States. The number of joint review partners is likely to increase as Korea and Taiwan have expressed interest in participating in the joint review process in the future.
- From September 2011 through September 2012, work on minor use joint review projects were completed for seven active ingredients. Five minor use joint review projects are currently in progress.

Planned Activities

- There are nine new active ingredient joint review projects that are currently planned for submission before 2015. One second entry joint review is projected for submission later in 2012.

- Fifteen minor use joint review projects are scheduled for submission during the remainder of 2012 - 2013.

MRL Harmonization:

- To reduce the potential for trade barriers, the joint review process strives to achieve harmonized MRLs for all crops being registered. To date, 15 joint review projects have been completed. A recent analysis of MRL harmonization on the trilateral global joint reviews indicates that MRLs are harmonized on ~72%; MRLs are close (within 0.5ppm) for ~17% of the total. Approximately 11 % of the MRLs were not harmonized.

United States-Canada Regulatory Cooperation Council (RCC):

- On February 4, 2011, President Barack Obama and Prime Minister Stephen Harper announced the creation of the United States-Canada Regulatory Cooperation Council (RCC) to increase regulatory transparency and coordination between the two countries. One of the initial areas of focus of the RCC is agricultural production, in particular further alignment of crop protection product approvals and establishment of tolerances and maximum residue limits (MRLs) for major and minor uses of pesticides in both countries. EPA and the Canadian Pest Management Regulatory Agency have a longstanding history of exceptional regulatory cooperation in the area of pesticide regulation. However, further convergence could promote greater work-sharing and information-sharing between Canadian and U.S. regulators as well as help to align MRLs and tolerances of pesticides, facilitating trade on a wider variety of agricultural commodities.
 - There are four project areas identified under the RCC: Encourage Joint Submission of Use Expansions and Fully Aligned Labels; Develop Joint Guidelines for Residue Trials; Address Obstacles to Joint Registration; and Align Data Collection Processes/Procedures for Residue Trials. Each of the project areas include specific timelines (0-3 months; 3-6 months, etc.) associated with tasks identified in the project area.
 - Several areas of focus include a minor use joint review and import MRL pilot for spirotetramat; development of joint guidelines for residue trials; common electronic confidential statement of statement of product specifications (formerly confidential statement of formula); harmonized MRLs in 11 current and 7 projected joint review projects; and exploration of the possibility of combining residue field trial data and use of data to evaluate a residue proportionality project.
 - The United States and Canada have held several stakeholder engagement activities, including a recent consultation held on October 24, 2012, in Ottawa, Canada.