

US EPA ARCHIVE DOCUMENT

Pesticide Program Dialogue Committee  
International Activities Update

Many initiatives have been undertaken or championed by the US to move towards the goal of the establishment of MRLs that will not result in trade irritants and encourage the use of newer, reduced risk pesticides in the US and globally. Below are updates on these initiatives:

1. Global Joint Reviews

A global joint review is the simultaneous evaluation of a pesticide dossier by multiple national pesticide authorities. The primary review of the dossier is shared by the authorities participating in the joint review. 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/peer 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 tolerances or MRLs to avoid trade irritants.

To reduce the potential for trade barriers and encourage the use of newer, reduced risk pesticides, the global joint review process strives to achieve harmonized MRLs for all crops being registered. Currently, there are nine global joint review projects ongoing. Six additional global joint reviews are anticipated for submittal in 2012 - 2013. Six global joint review projects have been completed since 2007 and are listed below.

- pyrasulfotole
- pyroxsulam
- chlorantraniliprole
- spirotetramat
- thiencarbazon
- saflufenacil

EPA recently conducted a preliminary analysis of the MRLs established as part of the global joint review process. The preliminary analysis reviewed the original crops registered as part of the global joint review. The analysis indicated that MRLs were harmonized for most commodities (57%). MRLs were close (within 0.5 ppm) on an additional 32% of the commodities.

The global joint review program is the most efficient process to achieve MRLs that are harmonized. The program is expanding both in countries participating and companies submitting new active ingredients for global joint reviews.

The Agency is committed to effectively working with existing and future global joint review partners, searching for areas of greater collaboration, harmonization, and efficiency.

## 2. NAFTA Grower Priority Database

The US - Canada Grower Priority Database is a tool for growers, registrants, and regulatory agencies to address trade barriers and trade irritants between NAFTA countries (Mexican priorities are expected to be incorporated in the future). The database captures grower identified priorities for resolving differences in available crop protection tools and Maximum Residue Levels (MRLs) in the United States and Canada. This approach is expected to provide a more systematic way to identify and address the grower priorities for MRL establishment and resolution of MRL trade issue. The database can be found at [www.uscanadagrowerprioritydatabase.com](http://www.uscanadagrowerprioritydatabase.com).

The US grower priorities for commodities currently in the database are updated annually beginning in August of each year. This incorporates a four month process using an online priority update website system which includes a four week period when grower groups log on to the priority update system to edit existing priorities, add new priorities, and add comments. This is followed by a four week period when registrants log on to the priority update system and review the grower priority submissions. Registrants add comments and correct brand names. Finally there is a four week period when growers can review their priorities in light of registrants' comments. The updated US grower priorities are uploaded in November/December each year. New commodities can be added to the database twice a year beginning in February and August, following the same four month process.

A meeting is being scheduled between representatives from EPA and Health Canada's Pest Management Regulatory Agency (PMRA) to discuss how each government is currently using the database, how to incorporate the database into the work plan, how to improve upon the current database, and the future of the database. Some statistics from the data base indicate: 648 priorities have a US MRL and do not have a Canadian MRL (i.e., Canada has not established a specific MRL-the database will indicate the Default MRL of 0.1 ppm), 2 priorities are exempt from the requirement of a tolerance in the US with no MRL established in Canada, 1 priority has a Canadian MRL with no US MRL, 32 priorities have no MRL established for either country and 184 priorities have both a US and Canadian MRL, but differ numerically.

## 3. OECD MRL Calculator

The United States was active in efforts of the Organization for Economic Co-operation and Development (OECD) to develop a MRL Calculator with the goal of standardizing the calculation of MRL values based on the same residue data set across all OECD member countries. It consists of an Excel spreadsheet that is simple to use without requiring extensive statistical knowledge from the user. The OECD calculator has been made public on the OECD website at ([http://www.oecd.org/departement/0,3355,en\\_2649\\_34383\\_1\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/departement/0,3355,en_2649_34383_1_1_1_1_1,00.html)) and

OECD member countries have begun to use the calculator to establish MRLs. JMPR has also agreed to use the OECD MRL Calculator when determining Codex MRLs and has agreed to identify when they have chosen not to rely on the OECD calculator to set a MRL and their rationale for not using it.

#### 4. Crop Grouping Initiative

There is an ongoing multiyear joint project involving NAFTA partners (Canada, Mexico and U.S.), the International Crop Grouping Consultants Committee (ICGCC) and the Codex Committee on Pesticide Residues (CCPR) to evaluate crop (commodity) groups and data extrapolation. The NAFTA partners are working to revise existing crop groups (40 CFR 180.41), add new crops and create new groups/subgroups. The goal of the project is to have the same crop groups in all three countries (Canada, Mexico and the United States). Additionally the NAFTA partners are working with International stakeholders to modify Codex crop groups to better support global trade and use of extrapolation.

To date, EPA has completed two phases of this project. The specific crop groups which have been created (or enhanced) recently are; the bulb vegetable group (Crop Group 3-07), the berry and small fruit group (Crop Group 13-07), the edible fungi group (Crop Group 21), the fruiting vegetable group (Crop Group 8-10), the citrus fruit group (Crop Group 10-10), the pome fruit group (Crop Group 11-10), and the oilseed group (Crop Group 20). This is an ongoing effort and additional phases are in process now. Canada and Mexico have also adopted these approaches to crop grouping. Additional information on this project can be found at [regulations.gov](http://regulations.gov) under the Docket # EPA-HQ-OPP-2006-0766.

The EPA expects that a proposed rule for Phase III of the Crop Group Project for NAFTA Countries will publish in the Fall of 2011. This proposed rule will propose to establish Crop Group 12-10: Stone Fruit Group and Crop Group 14-10: Tree Nut Group. There are also several pending petitions currently under review and are expected to be proposed under Phase IV of the Crop Grouping Project for a revised crop group for leafy vegetables, a revised crop group for *Brassica* vegetables, a new crop group for stalk and stem vegetables, a revised crop group for herbs and spices, and at least two new crop groups for tropical fruits for edible peel and inedible peel.

At Codex the U.S. is supporting efforts for the *Revision of the Codex Classification of Foods and Animal Feeds* and the institution of the use of crop groupings and representative crops to establish MRLs. Several efforts are underway in this area and the U.S. worked to consolidate these under Codex to hopefully end up with a harmonized global system of Classification—a lot of which is based on the work currently underway with the NAFTA partners. The CCPR has recommended that eleven groups for Bulb vegetables, Fruiting vegetables (other than cucurbits), Berries and small fruits, Edible fungi, Citrus fruits, Pome fruits, Stone fruits, Oilseeds, Tree Nuts, Herbs, and Spices be held at Step 7 pending the finalization of the revision of the Classification.

The U.S. has highlighted the importance of the early completion of the revision of the Classification so that the revised commodity groups could be implemented in international trade as soon as possible. This would assist in promoting MRL harmonization and in removing

technical barriers to trade. During the April 2010 CCPR meeting, it was agreed that it may be possible to advance all commodity groups within a particular commodity type as they are completed. In particular, all the fruit types (Berries and small fruits, Citrus fruit, Pome fruit, Stone fruit, and the Tropical fruits) may be completed by the next session and could all be advanced together. The Committee agreed to forward the proposed draft revision of the Classification for the two commodity groups Assorted Tropical and Sub-tropical Fruits – Edible Peel and Assorted Tropical and Sub-tropical Fruit – Inedible Peel to the Codex Alimentarius Commission (CAC) for adoption at Step 5. [http://www.codexalimentarius.net/web/index\\_en.jsp](http://www.codexalimentarius.net/web/index_en.jsp) Further, if all of the fruit types are completed during the April 2012 CCPR meeting, consideration will be given to advancing them to Step 8, for inclusion in the Classification system. This is a major step forward in this important effort.

## 5. Codex

Historically, U.S. specialty crop producers had difficulty exporting commodities treated with newly registered pesticides (many of which are reduced-risk) because Codex Maximum Residue Levels (MRLs) had not been established for the new pesticides and therefore, importing countries would not accept the treated food commodities. The US Delegation has worked closely with the CCPR to streamline the Codex MRL process for recently registered pesticides. As a result there are now examples of Codex MRLs being established for commodities within a year of the US registration. Below are some highlights of accomplishments during FY 11 regarding Codex and activities expected to further facilitate the movement of commodities grown in the United States in international channels of trade.

All U.S. nominations both for new compounds and additional uses of existing compounds were scheduled for review by the Joint FAO/WHO Meeting for Pesticide Residues (JMPR) during the April 2011 CCPR meeting.

The 2011 JMPR review schedule includes sulfoxaflor, an unregistered chemical being considered under a pilot project. During the 2010 Session, the CCPR approved, without objection, the US proposal described as the ‘pilot project,’ which proposed a process for the evaluation of new chemicals by JMPR before finalization of any national review/registration (*Achieving Globally Harmonized MRLs through Codex*). The U.S. plans to follow up on this area and may nominate an additional chemical for review in this effort.

The U.S. Delegation supported all of the MRL recommendations from the CCPR meeting. Approximately 318 MRLs, based on the consideration of 25 pesticides, were advanced to Step 8 for adoption by the Codex Alimentarius Commission (CAC). This was the sixth year that the accelerated procedure, along with the criteria for decision-making, were used with great success—283 of these 318 MRLs were advanced using the accelerated 5/8 procedure. An additional 33 MRLs were advanced using the accelerated 5/8 procedures for 17 pesticides for fruit and berry spices as well as 16 pesticides for root or rhizome spices.

The U.S. Delegation is also involved in efforts to have JMPR to identify ways to increase the current review capacity for chemicals. This is especially important for new active ingredients. Currently there are 12 new compounds scheduled for review by the JMPR in 2013. Members of

CCPR and manufacturers are being asked to identify 5 new compounds that can be moved from the 2013 schedule to 2014 noting that JMPR resources allow only a maximum of 11 compounds for evaluation (approximately 7 new and 4 periodic re-evaluation). Further, there are 6 new compounds already scheduled for review in 2014. So once all of the current nominations are rescheduled, it is expected that at least 5 new compounds that have already been nominated for review will have to be considered by the JMPR in 2015. Therefore, it is not likely that any additional new compounds nominated by Member Countries at the 2012 CCPR meeting could be scheduled for JMPR review until 2016.

It is worth noting this increase in demand is indicative of the success of the process improvements that have been implemented in the past several years by the CCPR for the scheduling and review of chemicals by the JMPR. Since the work of the JMPR and CCPR serve an important role for the facilitation of world trade of food commodities and in order to build on these successes and for the CCPR to remain relevant, the U.S. Delegation has been working with CCPR and JMPR to consider ways to increase the capacity for JMPR review. The U.S. Delegation has raised this issue at the April 2011 CCPR meeting, the July 2011 CAC meeting and representatives from the U.S. presented a paper on this issue asking JMPR to discuss options at the September 2011 JMPR meeting. The U.S. Delegation plans to continue to raise this issue until solutions can be found.

#### 6. Bilaterals

OPP continues to provide technical support to regulatory authorities on an ad hoc basis. The focus of those bilateral inquiries frequently involves food trade and food safety. Partner national authorities often request Data Evaluation Reviews (DERs) of interest for ascertaining MRLs or chemical-specific regulatory positions. These actively support sound international trade policies and regulatory programs for pesticides.