



EPA MRL Harmonization Initiatives

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EPA's Office of Pesticide Programs

- Principal Business
 - Based on high quality scientific evaluations and open transparent processes:
 - Protect human health and the environment.
 - Ensure access to safe and effective pesticides and pest management technologies.
- International efforts linked to meeting these goals.



OPP: Role in Engaging in International Registration Activities

- Leadership
 - Promote joint registration reviews and harmonization efforts internally and externally
- Advocacy/Championship
 - Identify opportunities for collaboration and cooperation
- Foster Communication
 - Promote dialogue between regulatory authorities
 - Promote dialogue with and among all stakeholders



Opportunities

- NAFTA and Regulatory Cooperation Council (RCC)
- OECD
- Joint Meeting on Pesticide Residues (JMPR) and Codex Committee on Pesticide Residues (CCPR)
- Other Opportunities
 - Bilateral partnerships
 - Summits
 - Commodity /chemical specific issues



North American Initiatives

- Progress towards a North American workplan.
- IR-4 (US) and PMC (Canada) partnerships.
- Worksharing and joint reviews of new active ingredients, use expansions and minor uses routine business; Increased participation of Mexico.
- Resolving trade irritants/technology gap retrospectively and consideration prospectively; Grower Priority Data Base.



North American Initiatives

- Regulatory Cooperation Council – initiative to identify mechanisms to encourage registrants to submit applications for joint review to Canada and the US that include increased numbers of minor uses. Will help facilitate equal access to products and uses in both countries as well as align maximum residue limits where possible (<http://www.trade.gov/RCC/documents/Crop-Protection-Products.pdf>).
- Pilot application of an aligned joint submission for a use expansion that includes a significant number of minor uses and domestic and import MRLs/ tolerances.



Global Initiatives through OECD

- Global joint review process for review of new active ingredients and use expansions.
 - Goal – align regulatory endpoints, MRLs and decisions to extent possible.
 - Countries involved continues to increase (Australia, Brazil, Canada, China, EU member states, Japan, Korea, Mexico).
 - Expansion of companies involved.



Global Initiatives through OECD

- Tool development – OECD calculator ; residue chemistry expert working group (harmonization of residue chemistry guidelines), developed policy for use of proportionality.
- Coordination of issues – pollinator protection and persistent chemicals.
- Minor Use Initiatives
 - Expert Group on Minor Uses (EGMU) - projects aimed at increasing number of products registered for minor uses.



Codex Committee on Pesticide Residues (CCPR) Initiatives

- CCPR Meeting May 2013:
- 397 MRLs for 35 pesticides were advanced to Step 8 for adoption by the CAC (361 of the 397 MRLs were advanced using the accelerated 5/8 procedure).
- 18 MRLs were recommended by applying proportionality.
- 37 of the 397 MRLs are for crop groups including nine MRLs advanced on the updated fruit groups that were advanced to Step 8 during the 44th CCPR meeting and adopted by the CAC during the 35th Session.



CCPR Initiatives

- Revision of Codex Classification of Animal Food and Feeds (aka Crop Grouping)
 - Fruit commodity groups were forwarded to Step 8, and the Draft Principles and Guidelines including Table 1 on fruit commodities were adopted by the CAC during the 35th Session.
 - Proposed additional crop groups and representative commodities.
- Work Group on Minor Uses and Specialty Crops re-established to complete work on defining number of field trials required for minor crops by JMPR.
- 2013 CCPR agreed to forward the Principles and Guidance for the application of proportionality to estimate MRLs to the CAC for adoption.



CCPR Initiatives

- In 2010 the CCPR approved the US proposal for a pilot project, whereby JMPR would evaluate a chemical before finalization of any national review/registration.
- The 2011 JMPR reviewed sulfoxaflor as a pilot and established an ADI and recommended MRLs considering both regional zones (the method historically used) as well as the global dataset method for estimating MRLs.
- In 2013 Both the United States and Canada registered sulfoxaflor.



CCPR Initiatives

- At the 2013 CCPR the US Delegation reported on the outcome of the pilot project and the national global joint review associated with the pilot.
- The US Delegation reported that not all commodities were registered at the same GAP considered by the JMPR.
- MRLs for commodities where the GAP is the same or within 25% of the GAP JMPR considered were advance to Step 5/8. However, the Committee advanced the MRLs using the regional data set.
- Provided the CAC adopts these MRLs during the next session, this will result in Codex MRLs being established within 4 months of the national registration.



Bilateral Initiatives

- Japan:
 - Sharing of US EPA reviews to support MRLs on Positive List
 - Global joint review partner
- Brazil:
 - Participation in global joint reviews
- China:
 - ICAMA and EPA continue cooperation workshops and high level delegation meetings.



Bilateral Initiatives

- Taiwan:
 - Sharing of reviews that support MRLs
- Korea:
 - Minor Use Symposium in November
 - Cooperation with KFDA
- European Union:
 - Quarterly conference calls with European Food Safety Authority (EFSA)



Other Initiatives

- Work closely with USDA /FAS on chemical/commodity/country issues that arise and provide technical support.
- Work with commodity groups on chemical/commodity issues.



EPA's Minor Use Webpage

- www.epa.gov/pesticides/minoruse/
- Page provides practical and useful information for growers and other interested parties regarding ongoing activities that impact the minor use community.
- Activities include ongoing crop grouping project; how to obtain a Codex MRL; MRL data base; activities regarding NAFTA and cooperation on MRL alignment.
- Webpage provides easy one-stop access to multiple useful links including the workplan for registration of new actives and uses, guidance on PRIA fee waivers, joint reviews, crop grouping tables, Codex MRLs and Canadian MRLs.



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Minor Uses and Grower Resources

Current as of May 2012

This web page provides growers, registrants and other interested parties with information on the programs EPA is implementing to ensure safe pesticide tools are available, particularly for those involved in the minor uses of pesticides. A major part of this effort involves the partnerships with other organizations and stakeholders.

On this page:

- [Minor Use Crops and Pesticides](#)
- [Codex MRL Nominations](#)
- [NAFTA](#)
- [MRL Database](#)
- [Crop Group Revisions](#)
- [Exclusive Use Periods](#)
- [Definition of a Minor Use](#)
- [Related Information](#)

Minor Use Crops and Pesticides

Minor use crops have fewer than 300,000 acres in production in the United States. The small acreage may provide insufficient economic incentive for pesticide companies (i.e., registrants) to keep their products registered for use on these crops, or to register new

Resources

- [Workplan for Registration](#)
- [Guidance on PRIA Fee Waivers](#)
- [Nominate a Codex MRL](#)
- [Pesticides Registered via Joint Review \(PDF\) \(3pp, 42k, PDF\)](#)
- [Index to Tolerance Information](#)
- [Crop Group Tables](#)
- [US Tolerances \(40 CFR Part 180\)](#)
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Pesticides
HomeRegulating
Pesticides
Home

Registration

Reevaluation:
Pesticide
ReviewPesticide
Product
LabelsPesticide-
Producing
EstablishmentsLaws and
RegulationsInternational
ActivitiesAdverse
Effects
Reporting

Storage &



Summary

- Much progress made on international harmonization initiatives.
- Individual initiatives all have same goal and build on each other.
- Multiple initiatives pursued.
- Success depends on coordination across various US Federal Agencies, other national authorities, international organizations, and stakeholders.
- Stakeholder initiatives compliment government initiatives.



- Questions?
- Thank you.