Updates from the EPA
Office of Pesticide Programs

2014 IR-4 Food Use Workshop
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What’s New Since September 2013

- The Office of Pesticide Programs has a new Office Director, Jack Housenger.
- Lois Rossi, Registration Division Director announced her retirement and will be leaving September 30, 2014.
Criteria for the Public Interest Finding for the IR-4 Fee Exemption under PRIA

- At the 2013 IR-4 Food Use Workshop Pete Caulkins from the Immediate Office in the Office of Pesticide Programs presented the revised Factors for the IR-4 Public Interest Finding.

- Under the Pesticide Registration Improvement Renewal Act (PRIA 3) (FIFRA Section 33(b)(7)(E)), the Administrator shall exempt an application from the registration service fee if the Administrator determines that
  - (i) the application is solely associated with a tolerance petition submitted in connection with the Inter-Regional Project Number 4 (IR–4) as described in section 2 of Public Law 89-106 (7 U.S.C. 450i(e)) and
  - (ii) the exemption is in the public interest.

- Thus, in order for EPA to grant an “IR-4 exemption,” the application must meet both criteria.
Criteria for the Public Interest Finding for the IR-4 Fee Exemption under PRIA

1. The data submitted have been developed by IR-4; and
2. The active ingredient, for which the data are developed, must have been already registered for use on a food commodity; and
3. The active ingredient/crop combination has been pre-screened by EPA prior to the Food Use Workshop, and EPA has discussed any risk concerns that might hinder registration or the establishment of tolerances with IR-4; and
4. The use is for:
   4.1 a minor crop (≤ 300,000 acres), or
   4.2 a major crop that is a representative commodity for a crop group/subgroup that is being submitted to establish tolerances for the minor uses in the crop group/subgroup, and where the accompanying label amendment adds at least one new minor use from that crop group to the label; or
IR-4 Request for Change in the Criteria

- In August of 2014 Jerry Baron requested that EPA revisit the existing criteria in light of the change in the 2014 Farm Bill that amended subsection (e) of the Competitive, Special, and Facilities Research Grant Act (7 U.S.C. 450i(e)).

- The Farm Bill modified the language authorizing the IR-4 Project to assist in the collection of residue and efficacy data in support of the registration or reregistration of minor agriculture uses and for use on specialty crops.

- The Specialty Crop Competitiveness Act of 2004 defined specialty crops as “fruits and vegetables, tree nuts, dried fruits, and nursery crops (including floriculture)".
IR-4 Request for Change in the Criteria

- Jerry Baron requested, that based on this new authorization, the EPA modify the Factors for IR-4 Public Interest Finding so Section 4.1 be changed from a minor crop (< 300,000 acres) and replaced with a specialty crop. Jerry also asked that Section 4.2 be modified to change minor use to minor use/specialty crop.

- The Office Director of the Office of Pesticide Programs is considering this request but has made no final determination.

- Currently, the labels submitted with IR-4 petitions will be considered under the existing criteria until a final decision is made.
Crop Grouping Activities

- Multiyear Joint Project involving NAFTA partners (EPA, IR-4, PMRA & PMC), the International Crop Grouping Consulting Committee (ICGCC) and Codex to evaluate crop (commodity) groups and extrapolation.

- NAFTA partners are working to revise existing crop groups (40 CFR 180.41) to add new crops and to create new groups/subgroups.

- Additionally the NAFTA partners are working with International stakeholders to modify Codex crop groups to better support global trade and use of extrapolation.
Submission to Crop Group Petitions to NAFTA and Codex

- The U.S. EPA and Canada’s PMRA review the crop group petitions submitted by IR-4 and make final recommendations as to what are the appropriate commodities for inclusion in a Crop Group.

- PMRA will adopt these recommendations and the EPA will publish a proposed rule and a final rule to establish crop groups.

- The petition submitted by IR-4 along with the EPA/PMRA recommendations are then submitted to the Chair of the Codex EWG for consideration.
Crop Group Revisions (40 CFR §180.41)

- At the 2013 IR-4 Food Use Workshop, I stated that the anticipated publication date of the Proposed Rule for Phase IV of the Crop Grouping was March of 2014 and the Final Rule to follow in Late 2014.

- There has been a delay in the publication of this Proposed Rule while the EPA worked through issues regarding proposals to amend the language under 40 CFR 180.40 (f).

- The current language prevents the EPA from establishing tolerances for processed commodities on a group basis.

- Language will be included in the Proposed Rule of Phase IV to amend this language to allow for group tolerances on processed commodities.
Phase IV – Crop Group Project for NAFTA Countries

- The following pending petitions have been reviewed by the HED ChemSAC and PMRA and will be proposed in the Federal Register under Phase IV of the Crop Grouping Project:
  - Crop Group for Leafy Vegetables
  - Crop Group for *Brassica* Head and Stem Vegetables
  - Crop Group for Stalk and Stem Vegetables
  - Crop Group for Tropical Fruits - Edible peel
  - Crop Group for Tropical Fruits - Inedible peel

Extrapolations Based on Reviewers Guide are Superseded by Phase IV Proposal

- With the publication of the Proposed Rule as we transition to the new crop groups for the tropical fruits, the 2013 HED ChemSAC decisions for the tropical fruit groups will supersede the tropical fruit extrapolations that have been allowed based on the 2008 Guide Reviewer’s.

- OPP will provide a memo documenting this decision in the near future.
Petitions Pending for Future Phase

- Crop Group for Herbs and Spices (likely be two groups)
- Crop Group for Root and Tuber Vegetables
- Crop Group for Leaves of Root and Tuber Vegetables
- Crop Group for Legume Vegetables
- Crop Group for Foliage of Legume Vegetables
- Crop Group for Cucurbit Vegetables
Petitions IR-4 Plans to Submit

- Crop Group for Cereal Grains
- Crop Group for Forage, Fodder & Grasses
- Crop Group for Aquatic Vegetables
- Crop Group for Teas
Implementation

- EPA cannot allow additional exposures to pesticides until the potential risks have been assessed.

- When a crop group is amended to expand its coverage of commodities, EPA must retain the pre-existing crop group in § 180.41 and create a new crop group with a title that clearly differentiates it from the pre-existing crop group.

- EPA will initially retain pre-existing crop groups that have been superseded by revised crop groups however, EPA will not establish new tolerances under the pre-existing groups once a new group is created.

- EPA plans to eventually convert tolerances for any pre-existing crop group to tolerances with coverage of the revised crop group.
Questions?
Pollinator Concerns

- At the 2013 IR-4 Food Use Workshop it was reported that EPA was taking immediate steps to change pesticide labels for the neonicotinoid pesticides so they better protected bees by being clearer and more precise in their directions for pesticide application.

- The revised labels include specific limits such as “Do not apply this product while bees are foraging. Do not apply this product until flowering is complete and all petals have fallen ....”

- All product labels for registered pesticides containing imidaclorpid, dinotefuran, clothianidin or thiamethoxam with use directions for all foliar applications are now in compliance with these changes.
THE NEW EPA BEE ADVISORY BOX
On EPA’s new and strengthened pesticide label to protect pollinators

PROTECTION OF POLLINATORS

APPLICATION RESTRICTIONS EXIST FOR THIS PRODUCT BECAUSE OF RISK TO BEES AND OTHER INSECT POLLINATORS. FOLLOW APPLICATION RESTRICTIONS FOUND IN THE DIRECTIONS FOR USE TO PROTECT POLLINATORS.

Look for the bee hazard icon application site for specific use restrictions and instructions to protect bees and other insect pollinators.

This product can kill bees and other insect pollinators. Bees and other insect pollinators will forage on plants when they flower, shed pollen, or produce nectar.

Bees and other insect pollinators can be exposed to this pesticide from:
- Direct contact during foliar applications, or contact with residues on plant surfaces after foliar applications
- Ingestion of residues in nectar and pollen when the pesticide is applied as a seed treatment, soil, tree injection, as well as foliar applications.

When Using This Product Take Steps To:
- Minimize exposure of this product to bees and other insect pollinators when they are foraging on pollinator attractive plants around the application site.
- Minimize drift of this product onto beeshives or to off-site pollinator attractive habitat. Drift of this product onto beeshives can result in bee kills.

Information on protecting bees and other insect pollinators may be found at the Pesticide Environmental Stewardship website at: http://pesticidestewardship.org/pollinatorprotection/Pages/default.aspx

Pesticide incidents (for example, bee kills) should immediately be reported to the state/local lead agency. For contact information for your state/lbe, go to: www.aapco.org. Pesticide incidents can also be reported to the National Pesticide Information Center at: www.npmic.oregonstate.edu or directly to EPA at: beeskill@epa.gov

Alerts users to separate restrictions on the label. These prohibit certain pesticide use when bees are present.

The new bee icon helps signal the pesticide’s potential hazard to bees.

Makes clear that pesticide products can kill bees and pollinators.

Bees are often present and foraging when plants and trees flower. EPA’s new label makes it clear that pesticides cannot be applied until all petals have fallen.

 Warns users that direct contact and ingestion could harm pollinators. EPA is working with beekeepers, growers, pesticide companies, and others to advance pesticide management practices.

Highlights the importance of avoiding drift. Sometimes, wind can cause pesticides to drift to new areas and can cause bee kills.

The science says that there are many causes for a decline in pollinator health, including pesticide exposure. EPA’s new label will help protect pollinators.

Read EPA’s new and strengthened label requirements: http://go.usa.gov/jHHH4
What is New Regarding Pollinators

- Presidential Memorandum on Pollinator Health released June 20, 2014

- Goal is to create a federal strategy to promote the health of honey bees and other pollinators

- The memorandum established a Pollinator Health Task Force. The Task Force will be co-chaired by the Secretary of Agriculture and the Administrator of the Environmental Protection Agency.
Presidential Memorandum on Pollinator Health

- The EPA has been directed to assess the effect of pesticides, including neonicotinoids, on bee and other pollinator health and take action, as appropriate, to protect pollinators.

- EPA was also directed to engage State and tribal environmental, agricultural, and wildlife agencies in the development of State and tribal pollinator protection plans.

- EPA is working with Tribal Pesticide Program Council (TTPC), Association of American Pesticide Control Officials (AAPCO), State FIFRA Issues Research and Evaluation Group (SFIREG) to develop guidance on core elements for the pollinator protection plans.

Several states already have developed plans (Florida and North Dakota).
Pollinator Concerns

- EPA was also directed to expedite review of registration applications for new products targeting pests harmful to pollinators.

- EPA has developed a risk assessment framework for pollinators in cooperation with PMRA and CDPR. New active ingredients, new uses as well as chemicals being assessed under registration review will now be considered under this framework.

- EPA has updated its webpage and is a good source for the latest information on pollinator activities
  http://www2.epa.gov/pollinator-protection
Protecting Bees and Other Pollinators from Pesticides

New risk assessment guidance for pollinators

Pollinator risk assessment guidance

Pollinator Health

Importance of pollinators
Factors affecting pollinator health
Colony Collapse Disorder

What EPA is Doing

Risk assessment
Risk management: EPA actions to protect pollinators
Pollinator health resources

How You Can Help

What you can do
Report bee kills
Use best management practices

Past Meetings on Pollinator Issues

Pollinator Summit on Dust from Treated Seed

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How Does it Impact the Food Use Workshop

- In the stop light analysis of potential projects for discussion at the Food Use Workshop, EPA classified chemistries with potential bee concerns yellow.

- If these projects are chosen, consideration should be given to minimizing pesticide exposure to bees. This includes post bloom applications for foliar applications, reduction in use rates or other possible ways to mitigate exposures.

- There is pending litigation for sulfloxaflor, clothianidin and thiamethoxam.
Antibiotics

- Risk assessment process will involve evaluation of hazard and risks of bacterial resistance.

- EPA is working closely with FDA and CDC on pending cases and follows the general FDA process for evaluating bacterial resistance.

- EPA is looking to registrants to develop strong stewardship and resistance management program on these uses.
Antibiotics

- Benefits and pest management alternatives also key consideration

- Actions for any submitted FIFRA antibiotics expected to be taken through EPA's public process
  http://www.epa.gov/pesticides/regulating/registration-public-involvement.html

- Attend the Antibiotic Summit on Thursday to learn more about this issue
Questions?
Minor Use Joint Reviews

- Joint Reviews completed since September, 2013 between PMRA/EPA:
  - Fomesafen on cucumber
  - Methoxyfenozide on basil and caneberry
  - Flonicamid on tomato
  - Mandipropamid on basil, ginseng, snap bean and greenhouse tomato
  - Fenamidone on ginseng and succulent bean
  - Chlorantraniliprole on green onion, peanuts, and artichoke
Minor Use Joint Reviews

Joint Reviews currently pending:

- Metrafenone on cherry, hops, cantaloupe, squash and peach
- Sethoxydim on blueberry
- Metconazole on sunflower
- S-metolachlor on cantaloupe and summer squash
- Pyrimethanil on GH cucumber
U.S.-Canada Regulatory Cooperation Council

- As per the Regulatory Cooperation Council (RCC) pilot for spirotetramat, under joint review and workshare submissions, crop group updates will be considered if requested by the petitioner provided the original crop group is already registered on the label.

- Additionally, import MRLs for crops that are not grown in each country but are being submitted by either PMC or IR-4 with the joint review petition will be considered under the joint review provided the appropriate data are submitted for review by the registrant.
Codex MRLs

- Codex Electronic Working Group on Priorities for 2014/2015 will send out call for additional nominations to the Priority List of Pesticides to be considered at the next Codex Committee on Pesticide Residues (CCPR) meeting.

- If you would like to submit a nomination for consideration by the U.S. Delegation to CCPR, please e-mail Barbara Madden (madden.barbara@epa.gov) no later than Friday, October 10.

- Laura Nollen will be on a detail beginning September 21, 2014 so I will be the primary contact for now.
Codex MRLs

- If you are a commodity representative/grower, please provide the following information:
  - Contact information,
  - Chemical requested,
  - Commodity(ies), and
  - Pest problem

- The U.S. Delegation will work with registrants/IR-4 to determine if there are available data and support for your nominations.

- Note, that supported nominations (not previously reviewed by Codex or not currently scheduled) are not likely to be reviewed until 2016, at the earliest.
The Grower Priority Database was launched on 9/1/13. Funded by USDA Technical Assistance for Specialty Crop (TASC) Grant.

Can be found at www.mrlpriority.com

Tool for US grower groups to identify their MRL needs in major export markets to registrants and government agencies.

Markets included initially are: Japan, China, South Korea, Taiwan, Canada, and Codex. Additional markets to be added in coming years.
Grower Priority Database

- All grower groups are encouraged to enter their priorities. Currently 32 commodity groups have priorities entered.

- Growers can enter MRL priorities in each market and can make comments on needs.

- Registrants can review grower priorities and add own comments.

- Goal of database is to provide US government and registrants one spot to find US grower MRL needs abroad.

- Database used extensively to determine US Taiwan priorities submitted in June 2014. Focus now on Korean priorities for upcoming MRL transition.
Grower Priority Database

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OPP Minor Use Web Page

- EPA has updated the Minor Use webpage - http://www2.epa.gov/pesticide-registration/minor-uses-and-grower-resources

- Can find links to the Grower Priority Database, Crop Grouping Docket, Information on Joint Reviews, and EPA Workplan.

- There is also a link to Indexes to Part 180 Tolerance Information – this index was just recently updated so is fairly current.
Minor Uses and Grower Resources

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

On this page:

- Minor Use Crops and Pesticides
- International MRLs
- NAFTA Minor Use Joint Reviews
- Crop Grouping
- 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 minor use pesticides. Many fruits and vegetables qualify as minor crops.
Questions?

Thank You