Updates from the EPA
Office of Pesticide Programs

2015 IR-4 Food Use Workshop
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What’s New Since September 2014

- Lois Rossi, Registration Division Director Retired on September 30, 2014.
- Susan Lewis, is now the Registration Division Director.
- Dana Vogel, was recently selected as the Health Effects Division Director.
- Laura Nollen is on a detail in the Health Effects Division and Nancy Keller from the Health Effects Division is on a detail to the Minor Use Team in the Registration Division.
Information on Exemptions from PRIA associated with IR-4 petition can be found at http://www2.epa.gov/pria-fees/factors-ir-4-public-interest-finding
IR-4 Request for Change in the Criteria

- In August of 2014, Jerry Baron requested that EPA revisit the Factors for IR-4 Public Interest Finding 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)”. 
Criteria for the Public Interest Finding for the IR-4 Fee Exemption under PRIA

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.
Revised Criteria for the Public Interest Finding for the IR-4 Fee Exemption

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
Criteria for the Public Interest Finding for the IR-4 Fee Exemption under PRIA

4. The use is for:

4.1 a minor crop (≤ 300,000 acres), or a specialty crop, which the 2004 Specialty Crop Competitiveness Act defines to include fruits; vegetables; tree nuts; dried fruits; and nursery crops (including floriculture); 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
Crop Grouping Activities

Information on all phases of the Crop Group Project can be found at regulations.gov in Docket #EPA-HQ-OPP-2006-0766
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.
Phase IV – Crop Group Project for NAFTA Countries

The following pending petitions were proposed in Federal Register on November 14, 2014 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

Anticipate Final Rule to Publish December 2015.
Phase IV – Crop Group Project for NAFTA Countries

- EPA did receive comments during the Proposed Rule for Phase IV. EPA was able to work with PMRA to reach agreement on proposed changes.

- EPA received a comment from IR-4 requesting reconsideration of a new crop definition for guava to include many of the closely related genus (Psidium), species and varieties.

- EPA received a comment requesting that Achachairú (Garcinia gardneriana (Planch. & Triana) Zappi) be added to the proposed Crop Subgroup 24B.

- EPA determined that it would be appropriate to include Achachairú in the Tropical and Subtropical Fruit, medium to large fruit, edible peel subgroup 23B.
Phase IV – Crop Group Project for NAFTA Countries

- EPA received a comment from the University of Hawaii, requesting removal of Longan from subgroup 24C and placing it in Crop subgroup 24A. The request is based on the size and texture of the fruit although it is similar to lychee, the adopted representative commodity for subgroup 24A.

- After consideration of the request, EPA agrees with the commenter to move Longan from Crop subgroup 24C to Crop subgroup 24A.

- As reported last year, the Proposed Rule included language 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.

- No comments were submitted objecting to the revised language for 180.40(f).
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 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.
Implementation of Phase IV

- Crop group conversions based upon Crop Group 4 and 5 tolerances will not be straightforward and may result in displaced individual commodities.

- For example, arugula, garden cress and upland cress were members of Subgroup 4A (represented by lettuces and spinach) will become members of Subgroup 4-15B (represented by mustard greens), and a conversion request to Crop Subgroup 4-15A would result in the displacement of those 3 commodities.

- Therefore, for Crop Groups 4 and 5 conversion requests, the EPA expects to allow the R175 PRIA fee request for the crop group conversion and the establishment of tolerances for those individual displaced commodities.

EPA has identified a plan for each individual chemical.
Phase IV Crop Group Changes

4A, Rep Commodity: Lettuces, Spinach
- Amaranth
- Arugula (to 4-15B)
- Chervil
- Chrysanthemum, Edible-leaved
- Chrysanthemum, Garland
- Corn Salad
- Cress, Garden (to 4-15B)
- Purslane, Garden
- Purslane, Winter
- Radicchio (Red Chicory)
- Spinach
- Spinach, New Zealand
- Spinach, Vine

4B, Rep Commodity: Celery
- Cardoon (to 22B)
- Celery (to 22B)
- Celery, Chinese (to 22B)
- Celtuce (to 22A)
- Fennel, Florence (to 22A)
- Rhubarb (to 22B)

5A, Rep Commodity: Cabbage; Broccoli or Cauliflower
- Broccoli
- Broccoli, Chinese (to 4-15B)
- Brussels Sprouts
- Endive
- Kohlrabi (to 22A)

5B, Rep Commodity: Mustard Greens
- Broccoli raab
- Cabbage, Chinese (bok choy)
- Collards
- Kale
- Mizuna
- Mustard greens
- Rape greens

4-15A, Rep Commodity: Lettuce, Spinach
- Amaranth, Chinese; Amaranth, leafy; Aster, Indian; Blackjack; Cat’s whiskers; Cervil, fresh leaves; Cham-chwi; Cham-na-mul; Chipilin; Chrysanthemum, garland; Cilantro, fresh leaves; Corn salad; Cosmos; Dandelion; Dang-gwi; Dillweed; Dock; Dol-nam-mul; Ebolo; Endive; Escarole;

4-15B, Rep Commodity: Mustard Greens
- Arugula; Broccoli raab; Broccoli, Chinese; Cabbage, Abyssinian; Cabbage, seakale; Chinese cabbage, bok choy; Collards; Cress, garden; Cress, upland; Hanover salad; Kale; Maca; Mizuna; Mustard greens; Radish; leaves; Rape greens; Rocket, wild; Shepherd’s purse; Turnip greens; Watercress

5-15, Rep Commodity: Cabbage; Broccoli or Cauliflower
- Broccoli; Brussels sprouts; Cabbage; Cabbage, Chinese, napa; Cauliflower

22A: Rep Commodity: Asparagus
- Agave; Aloe vera; Asparagus; Bamboo shoots; Celtuce; Fennel, Florence, fresh leaves and stalk; Fern, edible (fiddlehead); Kale, sea; Kohlrabi; Palm hearts; Prickly pear; pads; Prickly pear, Texas, pads

22B: Rep Commodity: Celery
- Cardoon; Celery; Celery, Chinese; Fuki; Rhubarb; Udo; Zuiki
Implementation of Phase IV

- Watercress will become a member of Crop Group 4-15, in Subgroup 4-15B.

- This use may result in the requirement of a chemical-specific aquatic dissipation study, under 40 CFR §180.158.1300- Environmental Fate.

- In the absence of the study, the Agency would entertain waiver requests for the study requirement. In waiver requests for specific chemicals, petitioners should address the potential for persistence, mobility, nontarget aquatic toxicity or bioaccumulation.

- EPA may conduct conservative screening-level assessments and model application scenarios to water such as the Tier I Rice Model (or Modified Cranberry Model), or the Tier II Pesticides in Flooded Application Model (PFAM).
Implementation of Phase IV

- 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.

- Tolerances should be recommended and established based only upon the available and appropriate residue data. For example, if a tolerance was previously established on passionfruit based upon the guava definition, the passionfruit tolerance may not be used to establish a tolerance on Subgroup 24B because there are no actual representative passionfruit data.

- The ChemSAC may use discretion to evaluate specific proposals for data extrapolations on a case-by-case basis.
Implementation of Phase IV

- Although EPA will no longer recommend or establish individual tropical and subtropical fruit commodity tolerances based on the Reviewer’s Guide, the Agency does not believe that the tolerances established based on the Guide underestimate potential residues.

- Therefore, those individual tolerances based on the Reviewer’s Guide will not be retroactively altered or removed.

- EPA has identified the existing tropical fruit tolerances that will remain without the need for additional data in the 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
- Crop Group for Cereal Grains and Forage, Fodder and Straw of Cereal
Petitions IR-4 Plans to Submit

- Crop Group for Grass Forage, Fodder & Hay
- Nongrass Animal Feeds
Codex Proposal for Cucurbit Group

- Group 011 for Fruiting vegetables, cucurbits was discussed again at the 2015 Codex Committee of Pesticide Residues.

- There were three options under consideration based on work by the eWG.

- The U.S. Delegation provided a justification as to why two subgroups, Cucurbits - melon and Cucurbits - squash/cucumber, were appropriate for Fruiting vegetables, cucurbits. However, other than Canada, there was little to no support from the other delegations for this Option.

- The Fruiting vegetables, cucurbits group will be discussed again by the EWG in preparation for the 2016 CCPR to determine if a compromise solution can be found.
Codex Proposal for Cucurbit Group

- Other options:

- Three subgroups with winter squash in a subgroup on its own including Casabanana; Chinese cucumber; Cucumber; African horned; Pumpkins; Wax gourd; Winter squash; or

- Two subgroups with winter squash represented by melon including Casabanana; Chinese cucumber; Cucumber; African horned; Melons; Melon, Nara; Pumpkins; Wax gourd; Winter squash; Watermelon.
Pollinators

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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Interim Position on New Outdoor Neonicotinoid Registrations
Joint Announcement with Canada  April 2, 2015

- Letters sent April 2, 2015 to registrants of neonicotinoid pesticides with new pending outdoor uses
  - EPA will likely not be in a position to approve new uses of these chemicals until new bee data are submitted and pollinator risk assessments are complete.

- Position permits EPA to focus on moving forward with Registration Review for Neonicotinoid class of chemicals.

- Activity coordinated with Canada’s Pesticide Management Regulatory Agency (PMRA).

- Interim Position – Next Step: Development of risk assessments
During this interim period, EPA is unlikely to grant the following affected actions:

- New or Modified Uses (including crop group expansion requests)
- Changes to Existing Use Patterns (ex. adding aerial or soil application or significant formulation changes)
- Experimental Use Permits
- New Special Local Needs Registrations
On Tuesday, May 19, the White House announced the National Strategy to Promote Pollinator Health. The strategy and its accompanying Pollinator Research Action Plan outline needs and priority actions to better understand pollinator losses, improve pollinator health, and to enhance pollinator habitat.

(https://www.whitehouse.gov/sites/default/files/microsites/ostp/Pollinator%20Health%20Strategy%202015.pdf)
Overarching Goals of the Pollinator Strategy:

- The strategy’s broad-reaching goals are to:
  
  - Restore colony health to sustainable levels by 2025.

  - Increase Eastern monarch butterfly populations to 225 million butterflies by year 2020.

  - Restore or enhance seven million acres of land for pollinators over the next five years.
Proposal to Mitigate Acute Risk to Bees

Proposal was released for public comment on May 29, 2015 and the comment period closed August 28, 2015.

Addressed acute contact exposure to foliar pesticide applications.

Two Mitigation Strategies
1. Label Restrictions for Contract Pollination Services
2. State and Tribal Managed Pollinator Protection Plans for Bee Colonies Not under Contract Pollination Services

Will not supersede existing chemical-specific restrictions

Chemical-specific risk assessments to address other routes of exposure and effects (seed treatments, chronic, whole hive)
Identified 76 active ingredients that are acutely toxic to bees including most insecticides and some herbicides.

Refer to regulations.gov – Docket # EPA–HQ–OPP–2014–0818

EPA is considering the comments received and anticipates a roll out of new policy for the chemicals acutely toxic to bees in 2016.

One of the biggest challenges is mitigation measures for indeterminate blooming crops.
Pollinator Concerns

- EPA is 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 is also considering additional data requirements regarding the exposures of pesticides to pollinators.
Proposed Data Requirements

- EPA intends to expedite the proposal to revise the data requirements regarding exposures to pollinators.

- This will impact all outdoor field uses – not just insecticides.

- Once these data requirements are final the goal is that there will be no phase in period and the requirements will be effective immediately for any new action.

- EPA is encouraging registrants to develop these data now to support new actives. New active ingredients, new uses as well as chemicals being assessed under registration review will be considered under this framework.
Pollinator Stewardship Council V. U.S. EPA

- On September 10, 2015, The United States District Court for the Central District of California vacated the Environmental Protection Agency’s registration of sulfoxaflor, and remanded the registration decision to EPA.

- EPA is reviewing the opinion in consultation with the Department of Justice to determine the next steps.

- The Court's decision won't take effect until it issues its mandate, which will not happen before November 1.

- Until the mandate issues, all activities that were previously authorized under the registration remain lawful, and we do not know what the court’s mandate will say.
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.

- Projects discussed today may be impacted by the new data requirements by the time submissions are made to the EPA.
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

- The Public Process for the IR-4 submission for PP# 4E8236 for use of streptomycin on tomato, grapefruit and Pome Fruit Group 11-10 will begin in the next few months.

- Sign up to be notified at regulations.gov - Docket #EPA-HQ-OPP-2014-0134.
Minor Use Joint Reviews

- Joint Reviews completed since September, 2014 between PMRA/EPA:
  - Metrafenone on cherry, hops, cantaloupe, squash and peach.
  - Sethoxydim on blueberry.
  - Metconazole on sunflower.
  - Prohexadione Calcium on strawberry.
  - S-metolachlor on cantaloupe and summer squash.
Minor Use Joint Reviews

Joint Reviews currently pending:

- Pyrimethanil on GH cucumber
- Fluazifop-p-butyl on lettuce (head and leaf), caneberry, green onion and rhubarb.
- Clethodim on cherry.
- Cyazofamid – GH tomato and GH pepper.
- Abamectin on GH tomato joint review.
- Penflufen on onion (CG 3-07 dry and green)
- Fomesafen – dry pea and perennial strawberry.
- Flumioxazin on broccoli and caneberry.
- Clomazone – asparagus.
Codex MRLs

- Codex Electronic Working Group on Priorities for 2015/2016 sent 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 Laura Nollen (nollen.laura@epa.gov) no later than Thursday, October 15.

- Though Laura Nollen is on a detail in the Health Effects Division she will still be the primary contact for nominations.
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 2017, at the earliest.
Pesticide Cumulative Risk Assessment: Framework for Screening Analysis


- Comment period closes September 28, 2015. EPA invites stakeholders to comment on this document at regulations.gov in Docket# EPA-HQ-OPP-2015-0422.

- This document provides guidance on how EPA will screen available information to identify groups of pesticides that may have a common mechanism of toxicity.

- As an example of how the EPA would implement the guidance, a draft copy of the human health risk assessment for abamectin and emamectin benzoate, considering both cumulative and aggregate risks.
Preliminary Risk Assessment and Interim Decision for Registration Review

- EPA will be publishing numerous preliminary risk assessments and interim decision documents on or around September 30, 2015 for all of the sulfonyl urea pesticides and a few organophosphates (OPs).

- Stakeholders are encouraged to comment if they are using any of these compounds.

- Please especially comment if growers are using any of these compounds in a manner different than that evaluated in the risk assessment.

- It is useful for EPA to hear from growers and extension agents to submit comments on things like application rates and use practices.
OPP Minor Use Web Page

- EPA Minor Use webpage is a good resource - http://www2.epa.gov/pesticide-registration/minor-uses-and-grower-resources

- Can find links to the Grower Priority Database, USDA International Maximum Residue Level Database, Crop Grouping Docket, Information on Joint Reviews, and EPA Workplan.
Pesticide Registration

You are here: EPA Home » Pesticide Registration » Minor Uses and Grower Resources

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