

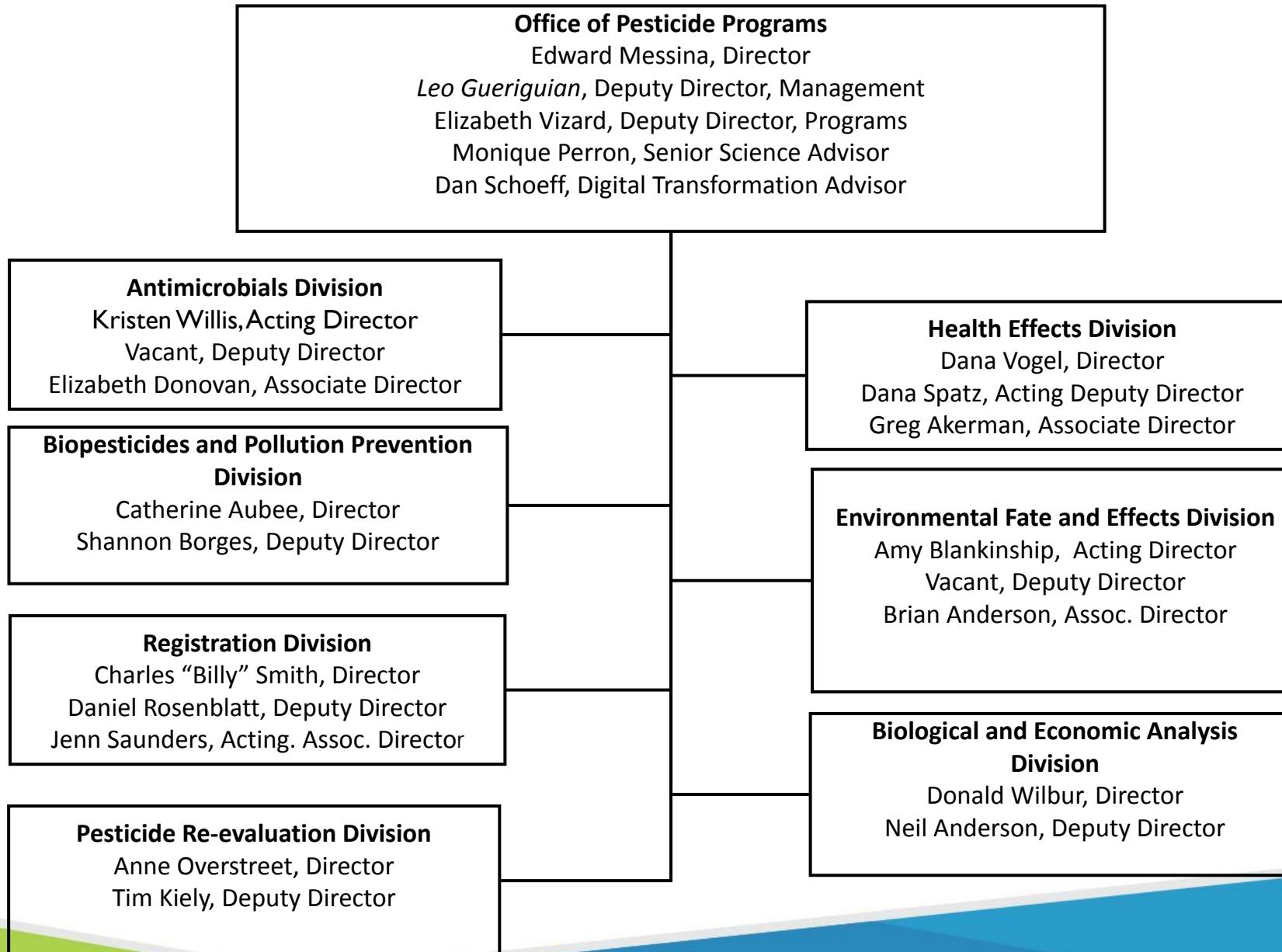
Office of Pesticide Programs Updates

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Discussion Topics

- OPP Goals and Status
 - Tolerance overview
 - Mechanisms to establish tolerances and harmonize MRLs
 - IR-4 and EPA
 - Policy and Rule development
 - Cross-agency collaboration
 - Minor Use team and other OPP updates
 - Public interest finding and the Stoplight Analysis
- 



OPP Completed Cases and Backlog FY26

Trend to Goal Green 100%+, Yellow 80-99%, Red <80%

Total Completions (PRIAs and non-PRIAs)
Goal: 9,120 (Stretch 10,014)



PRIA Completions
Goal 2,015 (Stretch 2,155)



Non-PRIA Completions
Goal 7,105 (Stretch 7,859)



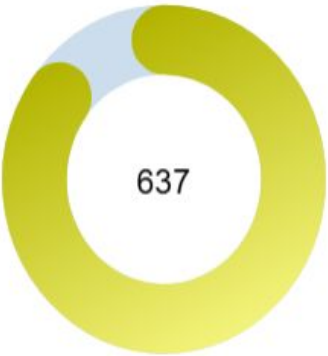
FTAs & Notifications
Goal: 4,005 (Stretch 4,560)



10/01/2025 Total Backlog Completed
Goal 6,380 of 10,633



10/01/2025 PRIA Backlog Completed
Goal 749 of 1,247



10/01/2025 non-PRIA Backlog Completed
Goal 5,632 of 9,386



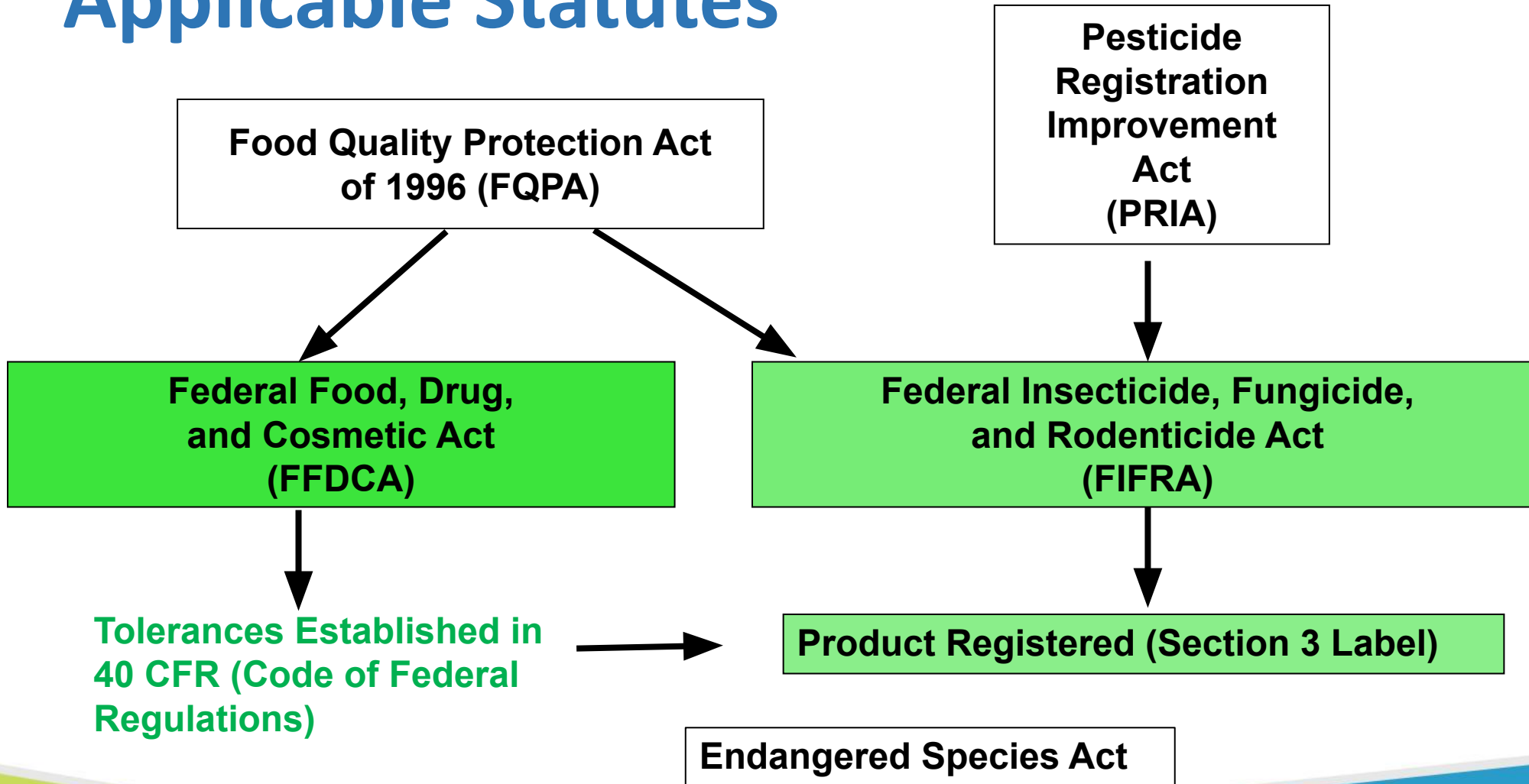
Conventional Registration Review Status - September 2026 Deadline

- There are 799 registration review cases due by October 1, 2026
 - 734 cases registered prior to FY 2007 that carried forward, and 65 new active ingredients registered after FY 2007 with registration review due dates that fall before October 2026.
- Of the 799, as of the end of FY 2026 Q2 there were
 - 733 cases (or 98%) for which draft risk assessments are completed (66 remain).
 - 639 cases (or 83%) for which final or interim decisions are completed (160 remain).

Applicable Statutes

- **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**
 - Registration/Licensing, registration review
- **Food Quality Protection Act (FQPA)**
 - Amended FFDCA and FIFRA
- **Federal Food, Drug, and Cosmetic Act (FFDCA)**
 - Tolerances/maximum residue levels (MRLs) for residues in food
- **Pesticide Registration Improvement Act (PRIA 1, 2, 3, 4 & 5)**
 - Amended FIFRA by adding registration fees and decision review periods
- **Endangered Species Act**
 - Protect threatened and endangered wildlife and plants

Applicable Statutes



Pesticide Registration Improvement Act (PRIA)

- The Pesticide Registration Improvement Act and its four reauthorizations provide a fee-for-service structure for EPA review of pesticide applications and set statutory decision time frames for review of those applications.
- PRIA provides two funding sources to EPA's pesticide program:
 - One-time registration service fees (i.e., PRIA fees) for the evaluation of new applications submitted to the EPA; and
 - Annual FIFRA maintenance fees
- Both PRIA registration service fees and maintenance fees are meant to supplement appropriations in funding these activities, and do not represent the total costs for EPA to conduct these activities.

PRIA 5 Implementation

- EPA continues to make progress implementing requirements of PRIA 5
 - For example, OPP:
 - Continues outreach to a broad array of stakeholders regarding **bilingual labeling implementation**, including accessibility of labels to farmworkers; stakeholders include farmworkers and farmworker advocacy groups, industry, states, and EPA regions
 - Has made progress **reducing the backlog of non-PRIA actions** and implementing process changes to review these types of actions according to their timeframes
 - Continues **development of IT systems** for electronic registration submission and application tracking

PRIA 5 Implementation

- PRIA 5 Implementation:
<https://www.epa.gov/pria-fees/pria-5-implementation>
- PRIA Annual Report - FY25 report published to PRIA Annual Reports webpage:
<https://www.epa.gov/pria-fees/implementing-pesticide-registration-improvement-act-2022-pria-5-fiscal-year-2025>
- Bilingual labeling implementation - FAQs, translation guide, implementation plan, outreach:
<https://www.epa.gov/pesticide-labels/bilingual-labeling>

Pesticides on Food

- Before allowing the use of a pesticide on food crops, EPA sets a **tolerance**, or **maximum residue limit**, which is the amount of pesticide residue allowed to remain in or on each treated food commodity.
- Actual residues are unlikely to exceed this level when a pesticide is applied according to label directions. The tolerance is the residue level that triggers enforcement actions.
- In setting the tolerance, EPA must make a safety finding that the pesticide can be used with "**reasonable certainty of no harm.**"

What Is A Tolerance Or Exemption?

- A tolerance is a regulation that sets a legal limit for pesticide residues in food.
 - For example, 40 CFR 180.482 sets a tolerance for residues of tebufenazide in or on grape at 3.0 ppm.
- An exemption is also a regulation that does not set a numerical limit for pesticide residues in or on food. It may contain limitations or allow for unlimited residues.
 - For example, 40 CFR 180.1363 exempts from the requirement of a tolerance residues of *Beauveria bassiana* strain PPRI 5339 under good agricultural practices.
 - 40 CFR 180.940 exempts from the requirement of a tolerance for residues of acetic acid when used in antimicrobial formulations on food-contact surfaces as long as the end-use product concentration of acetic acid does not exceed 100 ppm.

Where can you find U.S. tolerances?

- 40 CFR Part 180
- [eCFR](#) – kept up to date
- Example: Section [180.661](#) Fluopyram; tolerances for residues

Environmental Protection Agency

Pt. 180

Rulemaking, and the information submitted as part of the comments, the Administrator's response to comments and the documents or information relied on by the Administrator in issuing the regulation or order.

(5) All other documents or information submitted to the docket for the rulemaking in question under parts 177 or part 180 of this chapter.

(6) The Notice of Hearing published under §179.20.

(7) All notices of participation filed under §179.42.

(8) Any FEDERAL REGISTER notice issued under this part that pertains to the proceeding.

(9) All submissions filed under §179.80.

(10) Any document of which official notice was taken under §179.95.

(b) The record of the administrative proceeding is closed:

(1) With respect to the taking of evidence, when specified by the presiding officer.

(2) With respect to pleadings, at the time specified in §179.98(a) for the filing of briefs.

(c) The presiding officer may reopen the record to receive further evidence at any time before the filing of the initial decision.

[55 FR 50293, Dec. 5, 1990, as amended at 70 FR 33360, June 8, 2005]

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

Subpart A—Definitions and Interpretative Regulations

Sec.

180.1 Definitions and interpretations.

180.3 Tolerances for related pesticide chemicals.

180.4 Exceptions.

180.5 Zero tolerances.

180.6 Pesticide tolerances regarding milk, eggs, meat, and/or poultry; statement of policy.

Subpart B—Procedural Regulations

180.7 Petitions proposing tolerances or exemptions for pesticide residues in or on raw agricultural commodities or processed foods.

180.8 Withdrawal of petitions without prejudice.

180.9 Substantive amendments to petitions.

180.29 Establishment, modification, and revocation of tolerance on initiative of Administrator.

180.30 Judicial review.

180.31 Temporary tolerances.

180.32 Procedure for modifying and revoking tolerances or exemptions from tolerances.

180.33 Fees.

180.34 Tests on the amount of residue remaining.

180.35 Tests for potentiation.

180.40 Tolerances for crop groups.

180.41 Crop group tables.

Subpart C—Specific Tolerances

180.101 Specific tolerances; general provisions.

180.103 Captan; tolerances for residues.

180.106 Diuron; tolerances for residues.

180.107 Triflumezopyrim; tolerance for residues.

180.108 Acephate; tolerances for residues.

180.109 Fenpicoxamid; Tolerances for residues.

180.111 Malathion; tolerances for residues.

180.114 Ferbam; tolerances for residues.

180.116 Ziram; tolerances for residues.

180.117 S-Ethyl dipropylthiocarbamate; tolerances for residues.

180.123 Inorganic bromide residues resulting from fumigation with methyl bromide; tolerances for residues.

180.123a Inorganic bromide residues in peanut hay and peanut hulls; statement of policy.

180.124 Methyl bromide; tolerances for residues.

180.127 Piperonyl butoxide; tolerances for residues.

180.128 Pyrethrins; tolerances for residues.

180.129 o-Phenylphenol and its sodium salt; tolerances for residues.

180.130 Hydrogen Cyanide; tolerances for residues.

180.132 Thiram; tolerances for residues.

180.142 2,4-D; tolerances for residues.

180.145 Fluorine compounds; tolerances for residues.

180.151 Ethylene oxide; tolerances for residues.

180.153 Diazinon; tolerances for residues.

180.155 1-Naphthaleneacetic acid; tolerances for residues.

180.163 Dicofof; tolerances for residues.

180.169 Carbaryl; tolerances for residues.

180.172 Dodine; tolerances for residues.

180.175 Maleic hydrazide; tolerances for residues.

180.176 Mancozeb; tolerances for residues.

180.178 Ethoxyquin; tolerances for residues.

180.181 Chlorpropham; tolerances for residues.

180.182 Endosulfan; tolerances for residues.

180.183 Disulfoton; tolerances for residues.

Why Do We Need Tolerances/Exemptions?

- The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that pesticide chemical residues in or on food be covered by a tolerance (or an exemption from the requirement of a tolerance).
- Residues in or on food that are not covered by a tolerance or exemption render a food **adulterated**.
 - Cannot be sold in interstate commerce
 - Subject to seizure by U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), or a state enforcement agency
- **EPA does not register pesticide products that result in residues in or on food unless necessary tolerances or exemptions are in place.**

Types of Tolerances

- ▶ Permanent Tolerance
 - ▶ The legally established maximum residue limit (MRL) for a pesticide that may be present in or on food or feed commodities
- ▶ Temporary Tolerance
 - ▶ Time-limited allowance for pesticide residues in food or feed crops that are grown under experimental use permits (EUPs)
- ▶ Time-Limited-Tolerance
 - ▶ FIFRA Section 18 emergency exemptions
 - ▶ Usually set for a maximum of 3 years
 - ▶ Allows time for a permanent tolerance to be established with a related Section 3 registration
- ▶ Import Tolerance*
 - ▶ * Tolerance in absence of a US registration (no related Section 3 product)
 - ▶ Related to imported commodities
- ▶ Regional Tolerance
 - ▶ Related to established tolerance on food crops within specific geographic areas.

Sources of Pesticide Residues

- ▶ Direct treatment of target crop
 - ▶ Treatment to seed stock
 - ▶ Inadvertent carryover of residues in the soil to rotational or replacement crops
 - ▶ Runoff and spray drift
 - ▶ Consumption of treated commodities by livestock
 - ▶ Post-harvest applications
- 

Process for establishing tolerances

FFDCA 408(d)

- Allows submission of a petition requesting that the Agency establish a tolerance.
- Petitioners must submit supporting documentation listed in FFDCA.
- EPA publishes a notice of receipt (NOR) of the petition and reviews all available scientific information.
- EPA also publishes a Notice of Filing (NOF) of the pesticide tolerance petition which provides the proposed commodities and associated tolerances.
- EPA issues a final rule if it's determined that the tolerance is safe.

FFDCA 408(e)

- EPA can initiate the process to establish a tolerance on its own.
 - Usually during registration review.
- EPA determines tolerances are necessary and evaluates the science to ensure the tolerances are safe.
- EPA issues a proposed rule and provides an opportunity for public comment.
- After considering the comments, EPA publishes a final rule.

Safety Standard For Establishing Tolerances

- “The Administrator may establish ... a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the tolerance is safe.” FFDCA § 408(b)(2)(A)(i).
- Safe is defined as “a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” § 408(b)(2)(A)(ii).
- Risk-only standard; not risk-benefit balancing, as under FIFRA.
- Standard is the same for exemptions. § 408(c)(2)(A)(i) and (ii).

Assessing Safety

- Human health risks only, not environmental risks
 - Dietary (food and drinking water) and residential (non-occupational and non-dietary) exposures □ aggregate exposure

Dietary exposure



Residential exposure



Assessing Safety

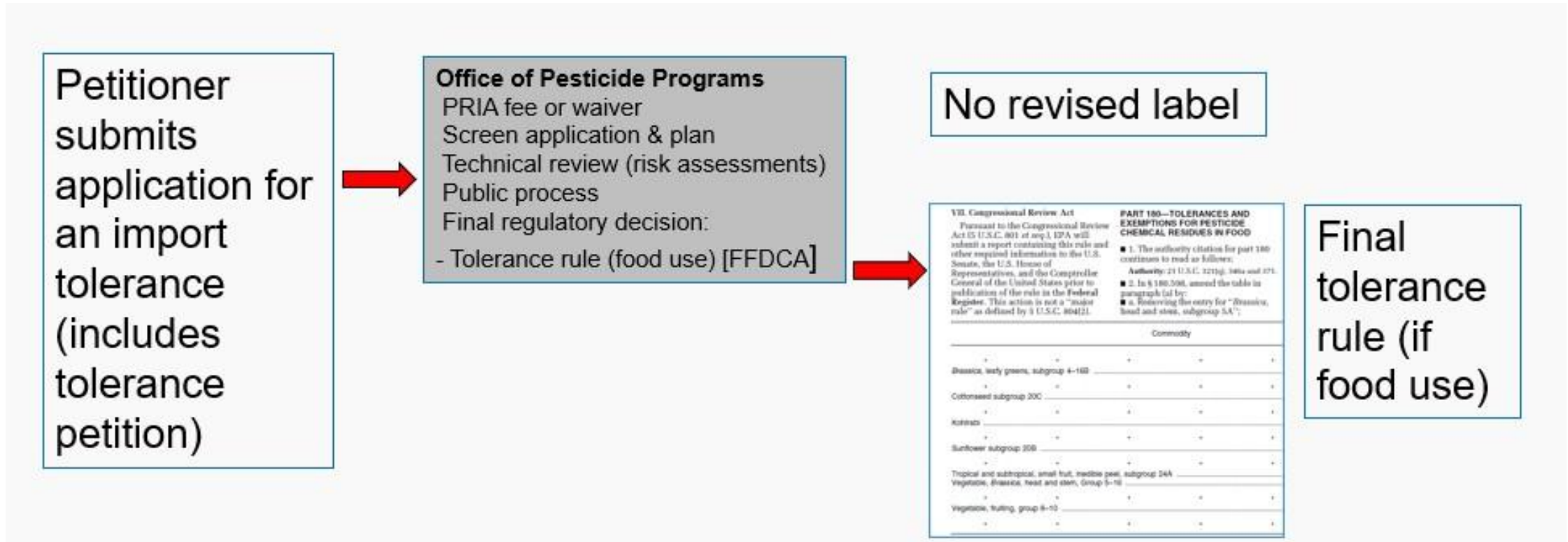
- FFDCA § 408(b)(2)(D): In establishing tolerances, the Administrator shall consider multiple factors, including
 - Information on toxicity, exposure, and consumption patterns
 - Cumulative exposure with other of chemicals that have a common mechanism of toxicity
 - Available information concerning aggregate exposure
- FFDCA § 408(b)(2)(C): Requires special consideration of the risks to infants and children
 - Disproportionately high consumption of foods, special susceptibility to the pesticide, any cumulative effects on children
 - Make a specific determination of safety for children
 - Requires application of additional safety factor unless reliable data shows a lower factor is safe

So, it's important to set a tolerance for pesticide uses in the U.S.; how does it affect trade and commerce?

What is an Import Tolerance?

- “**Import tolerance**” = a tolerance that exists in the U.S. for which there is no accompanying U.S. registration
- Import tolerances are based on the **same safety standards** as “regular” U.S. tolerances.
- Import tolerances generally require the same types of data as are needed to establish tolerances associated with U.S. registrations.

Process for establishing import tolerances (no U.S. domestic use)



Mechanisms to establish tolerances and harmonize MRLs

- Tolerance petitions from pesticide companies and IR-4, petitioning for the MRLs to be harmonized with international standards
- Policy and Rule development
 - Inter-governmental effort to develop a pilot program, resulting in a new category of tolerance petition submissions which rely on data reviews conducted by international entities (e.g. JMPR, EFSA)
 - Guidance development to harmonize MRLs
 - Incentives to register minor crop and specialty crop uses
 - Crop group rule and updates
- Cross-agency collaboration
 - USDA (Foreign Ag Service, OPMP), IR-4, Minor Use foundation, grower groups, Canada PRD (formerly PMRA), PMC

Tolerance Petitions to the Agency

- Petitions from pesticide companies, also known as “registrants”.
 - Submits petitions for major crop and minor/specialty crop uses
 - Conventional chemicals and biopesticides; the goal is to register new products
- IR-4 tolerance petitions
 - Submits petitions for minor crop/specialty crop uses, as well as crop group expansions/conversions
 - Registration fees are waived if the submission satisfies the Public Interest Finding (PIF) criteria <https://www.epa.gov/pria-fees/factors-ir-4-public-interest-finding>
 - Works closely with grower groups and supports harmonizing MRLs
 - US EPA, IR-4, Canada PRD (formerly PMRA), and PMC conduct joint reviews and work shares

IR-4 and EPA Office of Pesticide Programs

- The IR-4 Project was established in 1963 by the USDA to ensure that specialty crop farmers have legal access to safe and effective crop protection products
- IR-4 works with grower groups, registrants, extension programs and other stakeholders
- Generates data for regulatory compliance (residue trials, product performance, etc.)
- OPP supports IR-4 and the minor use community by the following:
 - Registration fee waivers for applications satisfying the Public Interest Finding criteria
 - Annual 'Stoplight Analysis' of prospective IR-4 residue projects that informs the IR-4 portfolio
 - Regular meetings, quarterly technical work groups, yearly crop tour
 - Crop group rule updates

Policy and Rule Development

- A relatively new PRIA fee category for a tolerance petition to be supported by “a comprehensive residue chemistry data review conducted by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) to support a Codex maximum residue limit (MRL), another supranational advisory body such as the European Food Safety Authority or a national regulatory authority rather than de novo review of raw residue data from field trials (e.g., a Magnitude of the Residue study).”
 - Pilot program development, following 2015 APEC workshops on Harmonization of Pesticide Maximum Residue Limits, including evaluations from Brazil, Canada, Japan, JMPR, and EFSA
 - Test streamlined approach based on acceptance of residue chemistry data review by national or supranational authority (e.g., EFSA, JMPR)
 - Minimize additional data generation and data review
 - Maximize opportunities for harmonized regulatory levels
 - Maintain confidence in MRL/tolerance levels and risk assessment outcomes

Policy and Rule Development

- Updating EPA OPP internal guidance to meet evolving needs, while keeping up with developments in pesticide science
- Continuous updates to testing guidelines (multi-year projects, ongoing)
- Crop Group Rule updates –
 - Crop groups are established when residue data for certain representative crops are used to establish pesticide tolerances for a group of crops that are botanically or taxonomically related.
 - Crop groups are an important tool for growers, especially those who need pesticide options for minor uses.
 - A multi-year joint project with international partners to revise the existing crop groups in 40 CFR 180.41, to add new crops and create new groups and subgroups.
 - Petitions are submitted by IR-4 to the EPA for joint review by U.S. and Canadian regulatory agencies. Approved revisions to crop group regulations are formalized in the U.S. by publication in the Federal Register.
 - Simultaneous efforts to update the CODEX crop groups will help to standardize commodity terminology and crop groupings within the global context.

Crop Group Ruling

- Next CG to be added to the CFR: Root and Tuber Vegetables
 - Future initiatives:
 - Sweet sorghum/ sugar cane/ grasses used for syrup production
 - Grasses and non-grasses for forage, fodder, and hay
 - Cucurbit vegetables
- 

Policy and Rule Development

- Incentives to register minor uses, crop group expansions/conversions
 - PRIA exempts certain pesticide applications from registration service fees, including:
 - Tolerance petition submitted by IR-4 (full exemption)
 - Application for minor uses of a pesticide (partial or full exemption)
 - FIFRA provides data protection incentives to register pesticides on minor uses:
 - Initial exclusive use period for a new chemical can be extended by registering minor uses
 - After the exclusive use period ends, registrant data to support a minor use are protected for 10 years

Exclusive Use Data Protection for Minor Use Registrations

- FIFRA exclusive use provisions for minor use registrations provide incentives to pesticide companies **to register minor uses of pesticides**. Registrants submit studies to EPA when registering a pesticide. FIFRA authorizes a period of time for “exclusive use” of the studies by the company after they register a new pesticide or add a new use for an existing pesticide
- During **the period of exclusive use (10 years)**, no other registrant can use the same data in support of registration of another product unless they have the written permission of the original registrant
- Extension of **one additional year for each 3 minor uses** registered; up to a total of **three additional years for all minor uses registered**

Cross-Agency Collaboration

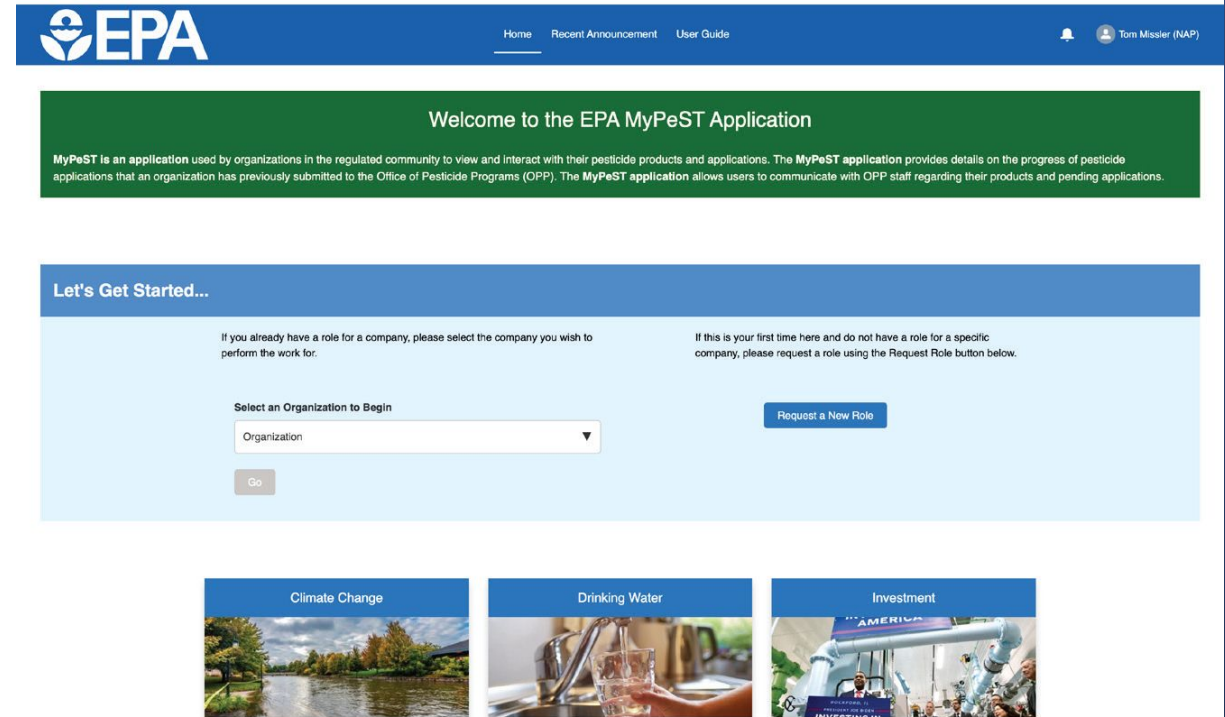
- Joint reviews and workshares with Canada PRD (formerly PMRA). IR-4 and/or PMC generates data that can be evaluated by U.S. or Canada
- Collaboration with USDA Foreign Agricultural Service and Office of Pest Management Policy
- Regular interactions with IR-4, Minor Use foundation, grower groups, and registrants
- Crop group rule development between EPA, IR-4, and other stakeholders
- FDA to enforce EPA tolerances for domestic foods shipped in interstate commerce and foods offered for import into the U.S., except for meat, poultry, catfish and certain egg products that are regulated by the USDA Food Safety and Inspection Service (FSIS)

Other EPA OPP Updates

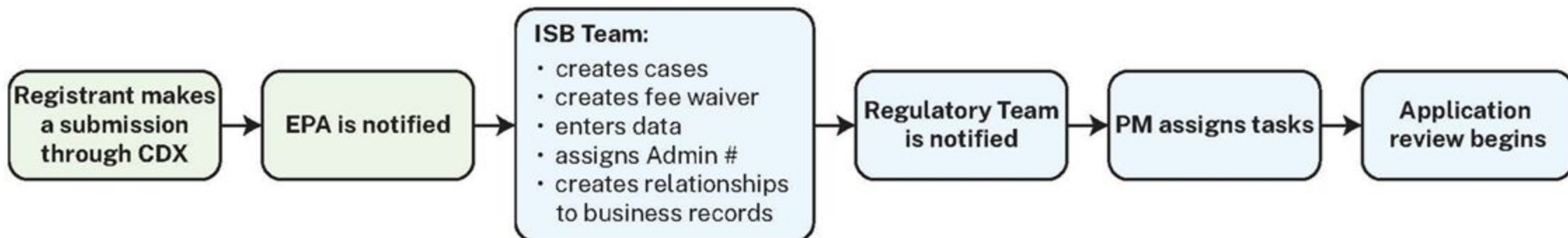
- Program updates that support the pesticide registration framework
 - Digital Transformation (IT build out, bulletins for ESA compliance, MyPest)
 - Endangered Species Act compliance
 - Consultation process with the Services
 - Herbicide, Insecticide, and Rodenticide Strategies
 - Systems support for ESA strategies include Pesticide Use Limitation Areas (PULAs) found in Bulletins Live! Two and the Pesticide App for Label Mitigations (PALM)
 - Minor Use coordination team
 - Point of contact for insecticides, herbicides, and fungicides
 - Expands the minor use registration expertise across the OPP Registration Division

Digital transformation MyPest app

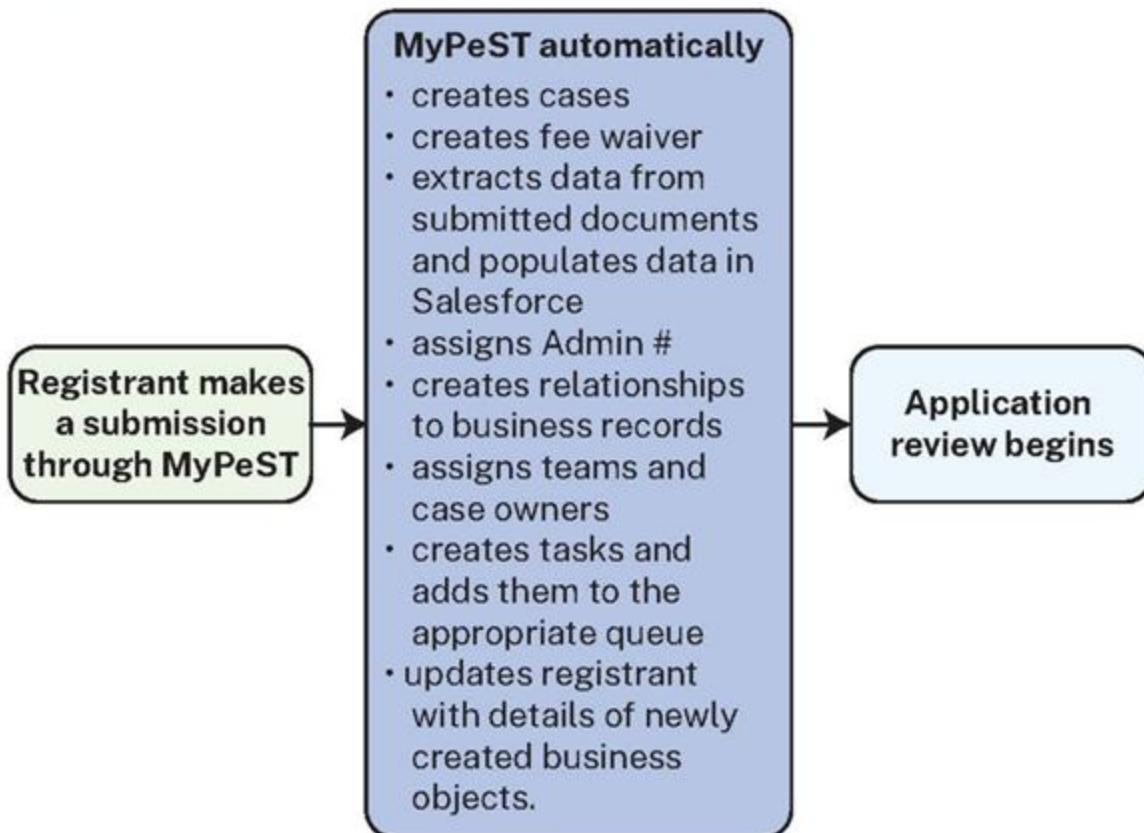
- Allows registrants of pesticide products to monitor the status of their pesticide registration submissions in real-time
 - Dashboard page with cases and products under review
 - Projected completion dates
 - Capability to communicate with EPA staff directly
- Makes the regulatory process more efficient and transparent
- Updates can be implemented over time; updates planned include enhancements to user experience, details on reg review cases, and data call-ins



Current Process



New Process

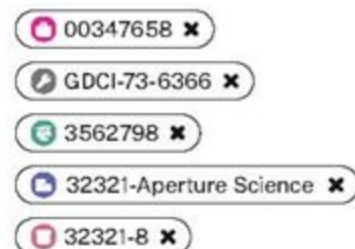


Other New Features

Document Upload—you are now able to upload documents directly to cases, products, ingredients, companies, or DCIs.



Document Linking—instead of creating multiple copies of a document that reside on individual hard drives all relevant documents are linked to that object and easily accessible to everyone.



Document Search—the interface stays the same but the functionality has improved. The full text of every document is fully searchable. You can access Document Search more easily and when you have found what you were searching for, can easily link the document and return to exactly where you were before your search.



Launched: Mon, July 6, 2026

IR-4 Minor Use actions – FY 2025 to 2026

- EPA completed work on **four IR-4 petitions** in FY 2026, establishing tolerances to support **11 new or revised uses** and **21 crop group expansions/conversions** requested by IR-4
- 2 ChemSAC proposal decisions delivered to IR-4

IR-4 Public Interest Finding (PIF)

An application will be presumed to be in the public interest if it is for a **biopesticide** or if the **following criteria** are met:

- 1) The data submitted have been developed by IR-4;
- 2) The active ingredient is already registered for use on a food commodity;
- 3) The active ingredient/crop combination has been pre-screened by EPA prior to the Food Use Workshop and EPA has discussed risk concerns that might hinder registration or the establishment of a tolerance with IR-4 [“stoplight analysis”]; and
- 4) The use is for a minor crop, specialty crop, etc.

<https://www.epa.gov/pria-fees/factors-ir-4-public-interest-finding>

PIF Weight of Evidence Approach

For actions that do not meet the criteria above, EPA will determine if a fee exemption is warranted on a **case-by-case** basis using a **weight-of-evidence** approach considering:

- Insufficient economic incentive for registrant to support the use
- Pesticide provides new mode of action
- Pesticide plays a significant role in IPM program
- Pesticide has characteristics that other registered alternatives do not have
- Insufficient efficacious alternatives
- Reduced risk compared to existing alternatives

Stoplight Analysis

- Green: No risks that would impact our ability to register the use and establish the corresponding tolerance(s)
- Yellow: There are some risks that could impact our ability to register the use and/or establish the corresponding tolerance(s)
- Orange: There are significant risks that could impact our ability to register the use and/or establish the corresponding tolerance(s) but it's not quite red OR there are additional steps/processes needed that will likely slow down the registration and establishment of the corresponding tolerances
- Blue: Neutral response for chemicals that are not registered yet and for new active ingredients that we are actively reviewing. Blue indicates a neutral response; we do not have enough information about the chemical or are conducting our initial FIFRA/FFDCA/ESA assessments and are not ready to assign a color
- Red: There are significant risks or unknowns that would prevent us from being able to register the use and/or establish the corresponding tolerance(s); these chemicals were removed from the nomination list

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- Wheeler.Maya.B@epa.gov – herbicides
- Swinger.Carmen@epa.gov – fungicides

- <https://www.epa.gov/pesticide-reevaluation>
- <https://www.epa.gov/pria-fees/guidance-ir-4-exemptions>
- <https://www.epa.gov/pesticide-registration/minor-uses-and-grower-resources>

