

EPA's Pesticide Program Overview

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Office of Pesticide Program

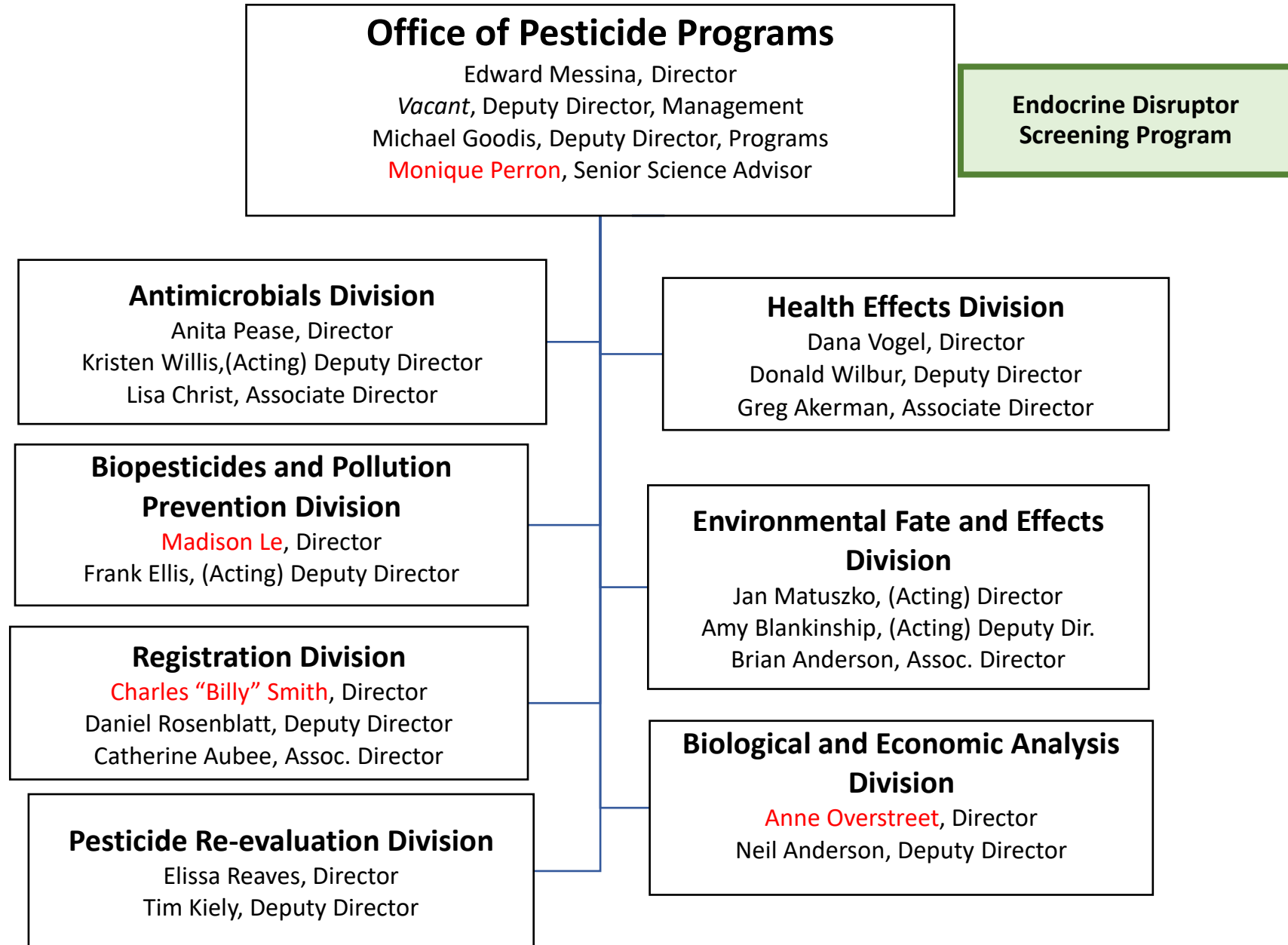
OPP Mission Statement:

To protect human health and the environment from unreasonable risks associated with pesticide use, and to ensure that pesticide residues in food present no undue risk

How Does OPP Accomplish This Mission?

- Regulates the use of all pesticides in the United States
- Ensures any pesticide residues on food are safe
- Ensures pesticide users have information (e.g., clear label) that allows for proper use
- Ensures decisions reflect the best science and policy judgments
 - Evolving science
 - Endangered species, pollinators, endocrine disruption, human studies are important and challenging science and policy issues







OPP-wide Priorities

- PRIA 5 Implementation
- Registration and Registration Review
- ESA Implementation
- Implementation of Agency Priorities
 - Environmental Justice
 - Climate Change
- Advancing State of the Art Science
- Rule-Making, Guidance, Litigation, OIG, and Petition Responses
- Employee Experience/Organizational Development /Process and IT Improvements (GP2W)(People, Processes, and Technology)



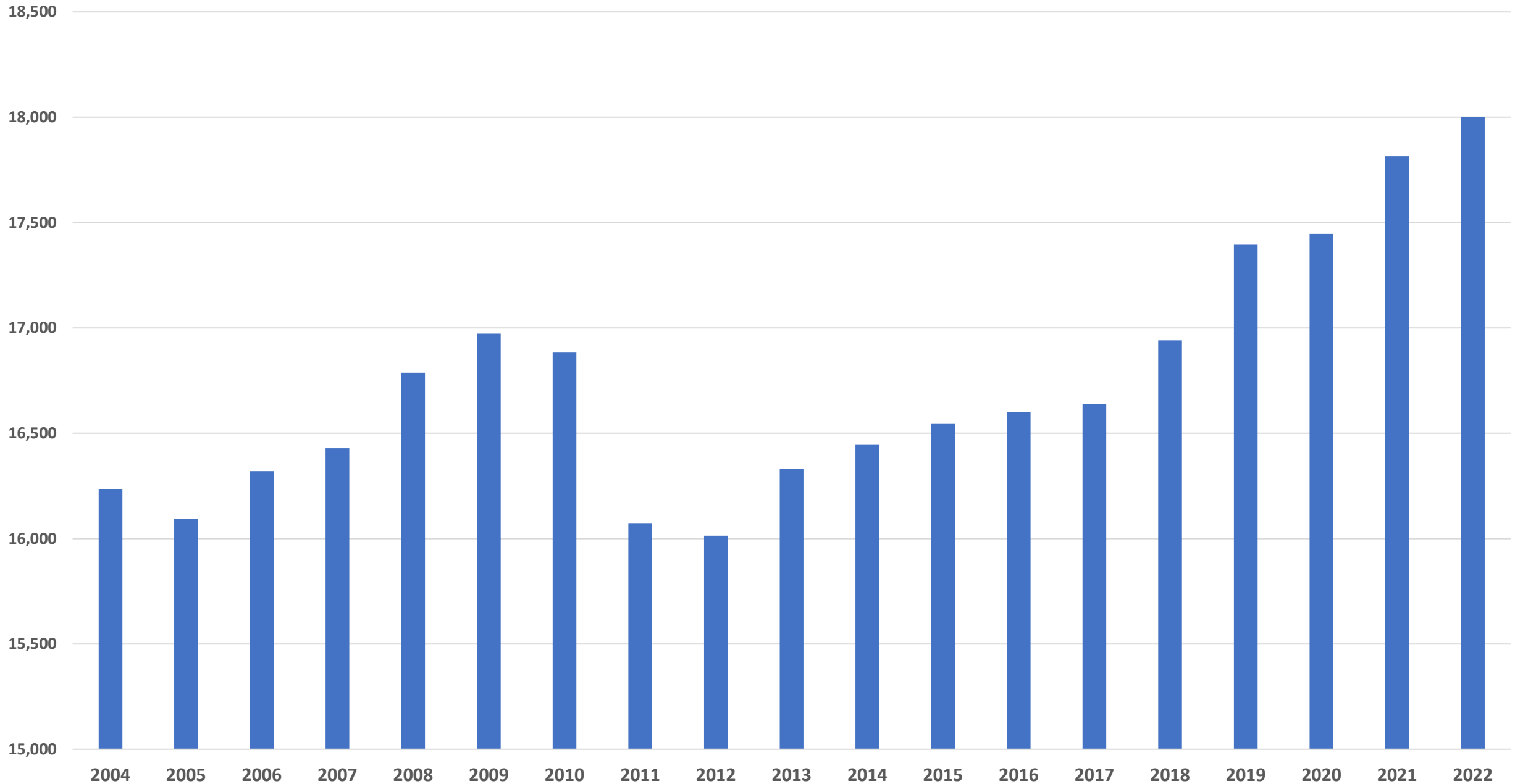


OPP FY22 Highlights



- Over **11,500 submissions** via Portal
- Over **7,700 PRIA and non-PRIA actions** completed
- Registered **13 new active** ingredients
- **38 Section 18** emergency exemption decisions (Covid-19, herbicide resistant amaranth species in peanuts and sugar beets, coffee leaf rust)
- OPP Ombudsman responded to approx. **2,700** (Jan-Sept) **messages from the public**
- Center for Integrated Pest Management hosted **10 IPM webinars (over 9,900 attendees)** and responded to over **2,800 public inquiries**
- Responded to a high volume of public health related inquiries: efficacy testing methods and claims for products intended to be effective against public health pathogens (**179**), **Monkeypox and COVID-19 (150)**, **pesticidal devices (360)**
- Reviewed labels and website materials for more than **40 products submitted** by EPA regional offices and state partners to ensure compliance **with device regulations**

Section 3 Product Registrations, 2004-2022





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 assessed to products currently in the marketplace, a significant portion of which are used to support the re-evaluation of pesticides in order to meet statutory deadlines, including the new deadline of **October 1, 2026**, for completing the first round of registration review.

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 and Appropriations

- **PRIA - Increase in fees and funding for OPP (+\$11m for maintenance; +\$6m for registration)**
- **FY23 appropriations - \$11m increase, targeted at ESA**
- Omnibus - October 1, 2026, deadline extension (IDs with measures to reduce)
- Spanish Labeling for Pesticides
- ESA Guidance to Registrants
- Renegotiation Provisions for submissions
- Grants for Pesticide Safety including Farmworker Training and Health Care Provide Training
- Testing Protocols for Devices
- Vector Expedited Review Voucher program
- Pesticide Surveillance Program
- Audit of OPP Processes and IT Upgrades
- Government Shutdown Provisions
- Reports to Congress
- <https://www.congress.gov/bill/117th-congress/house-bill/2617/text> (CTRL F “pesticide)



Endangered Species Act

- Under Section 7(a)(2) of the ESA, Federal agencies must ensure that the “actions” they authorize will not result in jeopardy or adversely modify designated critical habitat for species listed as endangered or threatened by the U.S. Fish and Wildlife Service (FWS) and/or the National Marine Fisheries Service (NMFS) (jointly the Services).
- For the Office of Pesticide Programs, the “actions” we authorize are the sale, distribution, and use of pesticides according to the product labeling.



Courts Increasingly Impatient with EPA's Non-Compliance

It's déjà vu all over again. EPA comes before this court once more because of its failure to abide by the law....EPA cannot flout the will of Congress—and of the people—just because it thinks it is too busy or understaffed.

Center for Food Safety v. Regan, Dec. 2022, 9th Circuit

“Before registering a pesticide, EPA must consult with the statutorily specified agencies that have expertise on risks to species’ survival. But for decades EPA routinely skipped that step when it registered pesticides....”

Center for Biological Diversity v. EPA, Dec. 2022, DC Circuit

EPA has long had a fraught relationship with the ESA. It has made a habit of registering pesticides without making the required effects determination.

In re: Center for Biological Diversity and Center for Food Safety, Nov. 2022, DC Circuit

Over 57 Pesticides with Current or Upcoming ESA Commitments *Through 2030*



2021

Methomyl
Carbaryl
Atrazine
Simazine
Glyphosate

2022

Enlist One
Enlist Duo
Imidacloprid
Clothianidin
Thiamethoxam
Sulfoxaflor

2023

Inpyrfluxam
Cyantraniliprole
~ 10 new Als

2024

Dinotefuran
Acetamiprid
Brodifacoum
Warfarin
Bromadiolone
Zinc phosphide
Chlorophacinone
Diphacinone

Difenacoum

Bromethalin
Difethialone
Cholecalciferol

2025

Flupyradifurone
Bicyclopyrone

2026

Streptomycin
Acephate
Dimethoate
Naled
Tribufos

2027

Benzovindiflupyr
Halauxifen-methyl
Bensulide
Ethoprop
Phorate
Phosmet

In Pending Litigation

1,3-D (Telone)
2,4-D
Captan
Chlorothalonil
Dicamba
Diuron

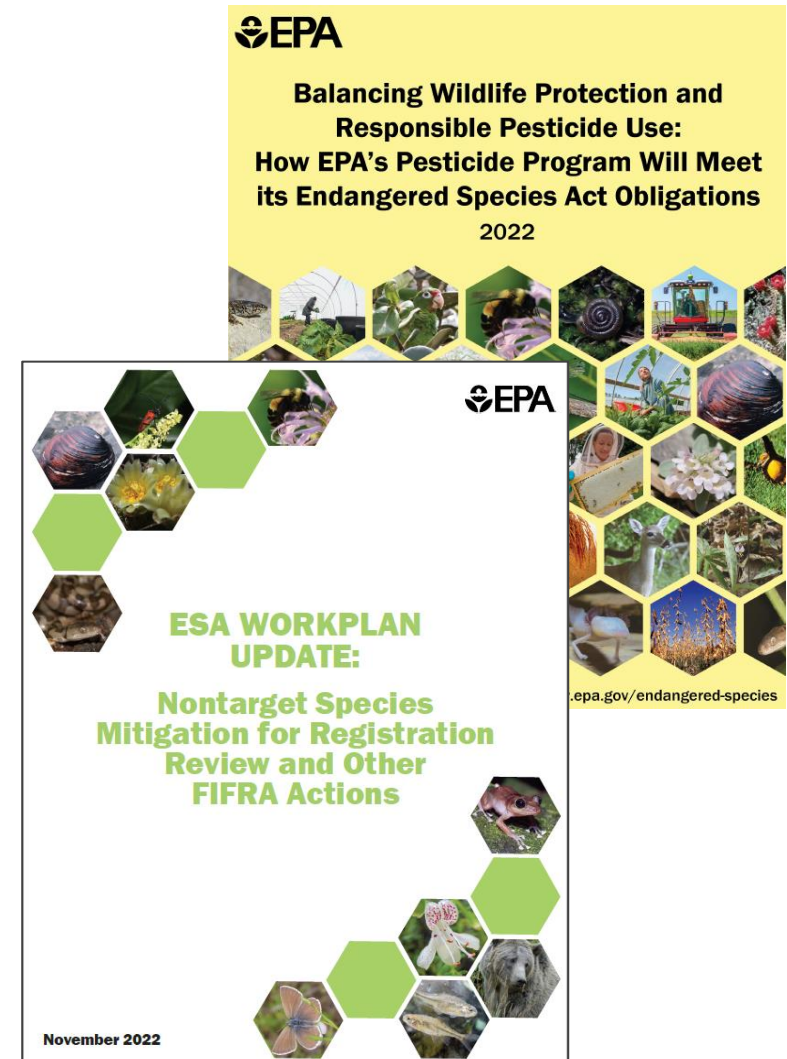
MCPA

Mancozeb
Metolachlor
Metribuzin
Oxyfluorfen
Paraquat
Pendimethalin
Propanil
Propargite
Phosphorotrithioate
Thiobencarb
Trifluralin



ESA Highlights

- **January 2022- ESA Policy for New Conventional Als**
 - Only for new conventional AI registrations
 - must comply with ESA
 - Does not cover non-conventionals or new uses of conventionals – case by case analysis based on ecological and legal risks
- **April 2022 – ESA Workplan**
 - Prioritize FIFRA actions for ESA compliance
 - Early mitigation
 - More efficient approaches
- **November 2022 – ESA Workplan Update**
 - First workplan update
 - Focus on early mitigation
 - Greater efficiency and address litigation risk





EPA Crop Group Rulemaking

EPA actively working on Rulemakings to update Crop Groups

Recent Rules

- November 2020: Final rule establishing new crop groups for herbs and spices
- September 2022: Final rule updating four crop groups:
 - CG 6-22: Legume vegetables and CG 7-22: Forage and hay of legume vegetables
 - CG 15-22: Cereal grains and CG 16-22: Forage, hay, stover and straw of cereal grains

Future Rules

- Proposed and final rules for the remaining crop groups

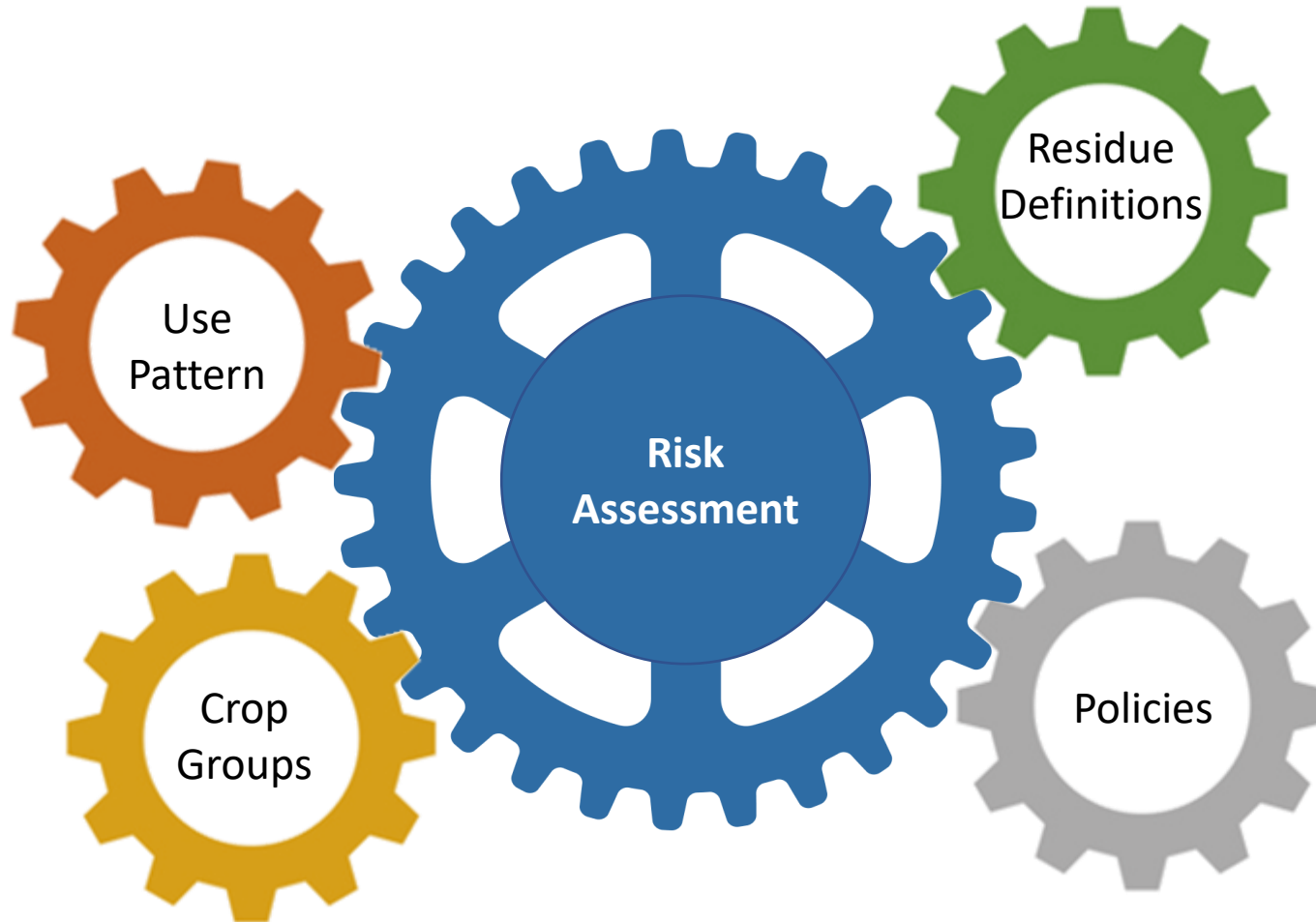


OPP's International Efforts Supporting Pesticide MRLs





International MRL Harmonization



Work is ongoing in these areas:

- OECD Harmonized Test Guidelines and Guidance documents
- Developing tolerance/MRL practices in cooperation with Health Canada PMRA
- Harmonization with Codex crop groups
- Joint-review program



Harmonized MRLs

Science Input

Compliance

Stakeholder
Input

Risk Assessment

Risk Management



International Efforts Supporting Pesticide MRLs

- Ensure U.S. engagement on international issues is consistent with EPA regulations
- Support the Office of the United States Trade Representative's (USTR) engagement at the World Trade Organization (WTO) and U.S. Department of Agriculture with Codex.
- Develop policy and negotiating direction for EPA to ensure pesticide and chemical interests are reflected in international fora
- Respond to urgent requests to assist with trade barriers
- Recent conversation with the EU on channels of trade revised/revoked EU MRLs.



World Trade Organization's Sanitary and Phytosanitary Agreement (WTO SPS)

- Use risk-based decision making to establish our MRLs
- Notify the WTO SPS members of our MRL actions
 - New notifications on Crop Groupings
- Share our technical expertise and U.S. perspective during SPS Committee events



United States-Mexico-Canada Free Trade Agreement (USMCA)

Technical Working Group on Pesticides

- Canada to host the 2023 meeting in-person
- Tentatively scheduled for November 7-8, 2023 - in Ottawa
- The agenda is in the process of being finalized

OPP and PMRA also have regular engagements on various science and regulatory actions



Asia Pacific Economic Forum (APEC) Food Safety Cooperation Forum

EPA's APEC Import Tolerance Pilot Project

- EPA relies on residue chemistry data reviews from a National Authority, JMPR or EFSA rather than a standard U.S. review
- EPA reviews the in-depth report from the competent authority.
- U.S. tolerance = MRL from Codex, European Union or exporting country
- Only applies to crop residue data. All other data requirements must be met.



Asia Pacific Economic Forum (APEC) Food Safety Cooperation Forum

EPA's APEC Import Tolerance Pilot Project

- Consideration of more than 30 pesticide/crop combinations covering a range of crop commodities (including crop subgroups)
- Residue chemistry data reviews from Brazil, Canada, Japan, JMPR, and EFSA
- High percentage of “successful” outcomes
 - Suitable external review
 - No risk issue identified
 - Tolerances established



Asia Pacific Economic Forum (APEC) Food Safety Cooperation Forum

APEC IT Pilot Project – Transition to Standard Practice

- Implement the new PRIA code for petitions using the import tolerance pilot approach
 - Standard import tolerance petition (R290): 16 months; \$91,465
 - “Pilot approach” import tolerance petition (R281): 12 months; \$68,599
- Document the change from pilot process to standard practice
 - Criteria for acceptable external data review
 - Guidance for Registration and Health Effects Divisions on implementation
- Publish updated approach for residue chemistry (target 2023; pathway TBD)



Organization for Economic Co-operation and Development (OECD)

Chemicals and Biotechnology Committee

- Mutual Acceptance of Data (MAD) framework
- Inter-Organization Program for the Sound Management of Chemicals (IOMC) Toolbox case studies

Working Party on Pesticides

- Initiating international discussion of data requirements
- Exposure models used in regulatory context and for children's health assessment



Organization for Economic Co-operation and Development (OECD)

Working Group of National Coordinators of the Test Guidelines Program

- Harmonization of test guidelines for pesticides and toxic substances
- Guideline on Defined Approaches for Skin Sensitization
- New Approach Methodologies (NAMs) webinars
- Residue chemistry harmonization – guidelines, definitions, honey, stability



Global Joint Reviews

- What is a Joint Review?
 - A Joint Review is a cooperative effort by two or more regulatory authorities to review data/information provided to support the registration of a new active ingredient
- Joint Review Objectives
 - MRL Harmonization; minimize trade barriers
 - International Collaboration
 - Resource Savings
 - Aligned Market Entry – generally safer pesticides
- Moving Forward
 - The US sees value and is committed to the Joint Review process
 - Exploring ways to increase efficiency and effectiveness of these reviews
 - Tailored approach – focused on MRL harmonization and other key science issues
 - The US is open to wider participation and having more countries in Joint Reviews



Codex Committee on Pesticide Residues (CCPR)

- CCPR establishes food safety standards for food and feed commodities that are traded globally.
- CCPR is held annually in China, attended by 80+ Member Countries, and typically sets > 300 new pesticide MRLs each year.
 - Promotes fair global trade practices through harmonization of food standards worldwide
 - Protects consumer health through establishment of science-based public health and food safety standards
- OPP leads the U.S. Delegation to CCPR and is responsible for planning, coordination with U.S. stakeholders, and development of strategies to advance U.S. priorities
- After holding two virtual meetings during the Covid Pandemic, CCPR will physically hold its next committee meeting in Beijing, China on June 26 – July 1, 2023.



Joint Meeting on Pesticide Residues (JMPR)

OPP is continuing to support the JMPR by providing expertise

- 1 Residue Chemist with 2 in training
- 1 Toxicologist with 1 in training

Aware of the backlog in JMPR work exacerbated by Covid-19

- Working with the JMPR, the CCPR, and Industry to explore ways to improve the evaluation process and maintain the independent nature of the JMPR



Take-home Messages



- Harmonization is important
- MRL heterogeneity has a real-world, negative impact on growers
- EPA default: Harmonize with Codex if possible
- Stakeholder input is crucial



Thank you

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