Update on EPA's Pesticide Program Activities

20th Annual Pesticide Stewardship Conference

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Office of Pesticide Programs - Update

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Discussion Topics

- FY19-20 Highlights and Priorities
- Chemical Updates
- UAVs

U.S. Pesticide Legislation

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
  - Registration/Licensing, registration review
- Federal Food, Drug, and Cosmetic Act (FFDCA)
  - Tolerances/maximum residue levels (MRLs) for residues in food
- Food Quality Protection Act (FQPA)
  - Safety standards
- Pesticide Registration Improvement and Renewal Act (PRIA 1, 2, 3, & 4)
  - Registration fees and decision review periods
- Endangered Species Act
  - Protect sensitive wildlife

Pesticide Use in the U.S.

- Scope of U.S. Pesticide Registrations
  - Over 1,200 active ingredients, over 16,800 pesticide products, over 16,300 tolerances (maximum allowable pesticide residue on food)
- Production & Formulation
  - 18 major producers, 100 other producers, 2,300 formulators, 20,000 distributors
- Agriculture Use
  - 2.2 million farms, 1 million certified applicators
- Residential Use
  - 105 million households, 33,000 pest control companies

Federal Partners

- U.S. Department of Agriculture (USDA)
- Department of Health and Human Services (DHHS)
- Food and Drug Administration (FDA)
- Department of the Interior (DOI)
- National Oceanic and Atmospheric Administration (NOAA)
- Center for Disease Control (CDC)
- Occupational Health and Safety Administration (OSHA)

Current OPP Priorities

- Meeting PRIA statutory deadlines
- Progressing the registration review program
- Advancing critical science and policy issues
- Working collaboratively with state partners and other stakeholders to implement program

FY 2019 Registration Highlights

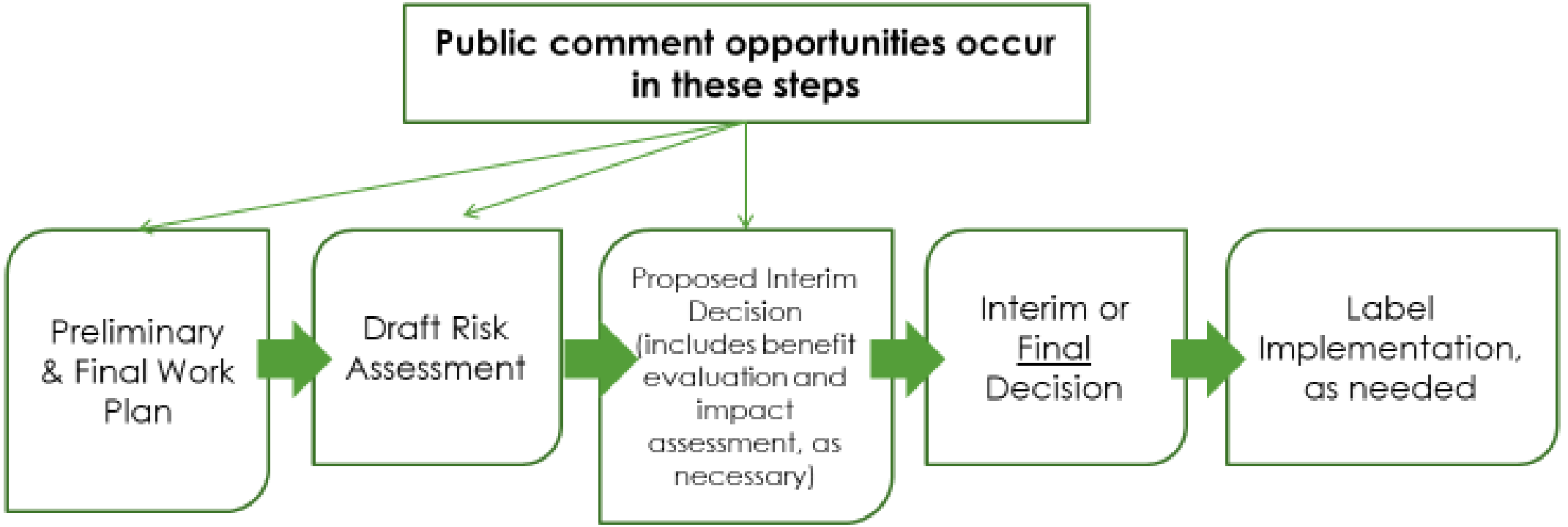
- 22 new active ingredients registered (9 biopesticides)

- 230 new uses for existing chemicals (3 new biopesticide uses) registered

What is Registration Review?

- Statutory Mandate
  - FIFRA section 3(g).
  - Requires review of each registered pesticide every 15 years.
- Scope
  - ~725 "cases" encompassing over 1,100 pesticide active ingredients (A.I.s).
  - Conventional, antimicrobial, and biopesticides.
- Statutory Deadline
  - EPA must complete review of all pesticides by 10/1/2022.
- Future Scope
  - Chemicals need to go through the process again not later than 15 years after:
    - Date on which the initial registration review is completed
    - Date the chemical was registered

Registration Review Process and Public Participation



FY19 Registration Review Highlights

- ~ 85 Draft Risk Assessments completed
- ~76 Proposed interim Decisions completed
- ~79 Final or Interim Decisions completed

Registration Review Progress

Conventionals

- 374 draft risk assessments completed (~19% remaining)
- 291 proposed interim decisions complete (~37% remaining)
- 261 final or interim decisions complete (~43% remaining)

Antimicrobials

- 80 draft risk assessments completed (~42% remaining)
- 68 proposed interim decisions complete (~51% remaining)
- 59 final or interim decisions complete (~57% remaining)

Biopesticides

- 103 draft risk assessments completed (~18% remaining)
- 103 proposed interim decisions complete (~18% remaining)
- 89 final or interim decisions complete (~29% remaining)

FY20 Registration Review Focus

- Conventional Pesticide Registration Review Deliverables:
  - ~60-70 Draft Risk Assessments anticipated
  - ~60-70 Proposed Interim Decisions anticipated
  - ~75-80 Interim Decisions anticipated
- Registration Review Deliverables include:
  - Structural/commodity fumigants
  - Rodenticides
  - Pyrethroids
  - Neonicotinoids

ESA

- In early 2019, EPA released, for public comment, the revised proposed methods for evaluating the potential effects of pesticides on endangered and threatened species, based on experience gained from the first three pilot assessments on chlorpyrifos, diazinon, and malathion.
- These draft revisions to the framework are intended to streamline the process to a point where it is protective of species, timely for FIFRA registration review decisions, feasible within the agencies' resource constraints, and transparent to the public.
- The public comment period closed on August 15. EPA expects to complete its review of the public comments by early 2020.
- EPA delivered its first Report to Congress on ESA implementation on December 20, 2019.

EPA Biotechnology

- The June 2019 Executive Order *Modernizing the Regulatory Framework for Agricultural Biotechnology Products* directs EPA to use existing statutory authority, as appropriate, to exempt low-risk products of agricultural biotechnology from undue regulation to the extent consistent with law and the executive order.
- On January 9, 2020, EPA, USDA, and FDA launched a unified website that provides a one-stop-shop for information about the actions the federal government is taking to oversee the development of agricultural biotechnology products. This new website is a key accomplishment under the June 2019 Executive Order.

Pollinators

- Pollinator protection is a priority for EPA. Pollinator species are important to our ecological systems and successful food production.
- EPA conducts insect pollinator risk assessments to support regulatory decisions for new and existing pesticides using the best available science. To ensure that it has the best available science for these assessments, the agency has worked collaboratively with regulatory counterparts, academia, and industry to develop guidance on exposure and effects testing for assessing risks to bees.
- In response and with the goal of supporting pollinators broadly, EPA's pesticide office is addressing this issue on two fronts: (1) improving the science for bee risk assessment (which primarily relies on honey bees as a surrogate), and (2) advancing management initiatives to achieve pollinator protection and sustainability.

Neonicotinoids Registration Review

- **2010-2011:** Imidacloprid, thiamethoxam, clothianidin, and dinotefuran
- **2014:** Published a benefits assessment on the treatment of soybean seeds with neonicotinoids
- **2016-2017:** Published the preliminary pollinator assessments
- **2017:** Published draft human health risk assessment
- **2017:** Published additional benefits assessments on cotton and citrus, along with a revised seed treatment assessment
- **2017-2018:** Received new pollinator toxicity and exposure data
- **Regulatory Updates**
  - EPA's preliminary pollinator assessments noted the potential for on-field risk from some uses. However, risk was considered to be low for other uses such as seed treatments.
  - EPA's draft ecological risk assessments noted potential risk to aquatic invertebrates from drift and run-off, as well as to birds and mammals from potential exposure to treated seed.
  - **January 30, 2020, EPA published the Proposed Interim Decisions for acetamiprid, clothianidin, dinotefuran, imidacloprid, and thiamethoxam with new measures to reduce potential ecological risks, particularly to pollinators, and protect public health.**

Neonicotinoids Registration Review

- EPA is proposing:
  - Management measures to help keep pesticides on the intended target and reduce the amount used on crops associated with potential ecological risks;
  - Requiring the use of additional personal protective equipment to address potential occupational risks;
  - Restrictions on when pesticides can be applied to blooming crops in order to limit exposure to bees;
  - Language on the label that advises homeowners not to use neonicotinoid products; and
  - Cancelling spray uses of imidacloprid on residential turf under the Food Quality Protection Act (FQPA) due to health concerns.
- Additionally, the agency is working with industry on developing and implementing stewardship and best management practices.

Animal Testing

- In September 2019, EPA Administrator Andrew Wheeler signed a directive to prioritize EPA efforts to reduce animal testing including reducing mammal study requests and funding 30 percent by 2025 and eliminating them by 2035.
- In December 2019, EPA hosted its first annual conference on the State of the Science on Development and Use of New Approach Methods (NAMs) for Chemical Safety Testing. The one-day conference, which attracted more than 600 participants, including those on the phone and in person, focused on New Approach Methods (NAMs) for achieving reductions in animal testing.

Worker Protection Standard Application Exclusion Zone

- In November 2019, EPA proposed updates to the Worker Protection Standard pesticide regulation to improve the Application Exclusion Zone (AEZ) requirements. The updates would:
  - improve enforceability for state regulators and reduce regulatory burdens for farmers
  - maintain public health protections for farm workers and other individuals near agricultural establishments that could be exposed to agricultural pesticide applications
- The agency held a **90-day public comment period** seeking input on select updates that were publicly suggested to EPA by state pesticide agencies.
- The public comment period closed January 30, 2020.

Worker Protection Standard Application Exclusion Zone

- EPA is proposing to:
  - Modify the AEZ so it is applicable and enforceable only on a farm owner's property, where a farm owner can lawfully exercise control over employees and bystanders who could fall within the AEZ
  - Exempt immediate family members of farm owners from the AEZ requirements
  - Add clarifying language that pesticide applications suspended due to individuals entering an AEZ may be resumed after those individuals have left the AEZ
  - Simplify the criteria for deciding whether pesticide applications are subject to the 25- or 100-foot AEZ

CPA Rule - Certification Plan Implementation Timeline

- Certifying authorities have until **March 4, 2020,** to submit modified certification plans **(which may include provisions contingent upon legislative/regulatory action, etc.**) to EPA.

- **Existing plans remain in effect** until EPA approves or rejects the revised plan or **March 4, 2022**, whichever is earlier.

- Timeframe for implementation/compliance with revised certification plan will be decided on a **case-by-case basis** as part of EPA's review and approval of each revised certification plan.

Glyphosate Registration Review

- In April 2019, EPA released the Glyphosate Proposed Interim Decision for public comment
  - EPA continues to find that there are no risks to public health when glyphosate is used in accordance with its current label and that glyphosate is not a carcinogen
  - EPA proposed management measures to help farmers target pesticide sprays on intended pests, protect pollinators, and reduce the problem of weeds becoming resistant to glyphosate
- **On January 30, 2020, EPA released its Interim Decision.**

C. Auris and Other Emerging Pathogens

- EPA is announcing the availability of the first products registered for use against the emerging fungal pathogen *Candida auris* (*C. auris*).
- *C. auris* is an emerging fungal pathogen that poses a global health threat and often causes serious and sometimes fatal fungal infections.
- *C. auris* infections tend to occur in hospitalized patients and can be resistant to antifungal drugs.
- In response to recent confirmation of the first U.S. case of the novel coronavirus (2019-nCoV), EPA has activated its Emerging Viral Pathogens Guidance for Antimicrobial Pesticides. Under this guidance, EPA is providing pesticide registrants with a voluntary, two-stage process to enable the use of certain EPA-registered disinfectant products against this emerging viral pathogen.

Chlorpyrifos

- Pesticide Action Network North America and the Natural Resources Defense Council filed a petition, requesting that EPA revoke all tolerances for chlorpyrifos under FFDCA and cancel all chlorpyrifos registrations under FIFRA.
- In 2017, EPA issued an order denying the petition, and in June 2017, the petitioners and others filed objections.
- In July 2019, EPA denied the objections because the data available are not sufficiently valid, complete or reliable to meet petitioners' burden to present evidence demonstrating that the tolerances are not safe.
- Although EPA has concluded that the petitioners had not satisfied their burden under the FFDCA, the issues petitioners raised are being evaluated through the EPA's ongoing registration review of chlorpyrifos.

Chlorpyrifos Registration Review

- The 2019 objection denial is being challenged in the Ninth Circuit, but EPA will not answer questions about pending litigation.
- EPA is expediting the agency's review of chlorpyrifos. The proposed interim decision incorporating updated chlorpyrifos assessments is anticipated for public availability and comment by October 2020.
- EPA has also been engaged in discussions with the chlorpyrifos registrants that could result in further use limitations affecting the outcome of the EPA's assessment.

Pyrethroids Registration Review

- In 2016/2017, published draft risk assessments for public comment.
- In 2018, considered public comments submitted and revised risk assessments based on new data and comments.
- The Proposed Interim Decisions for five pyrethroids were released for public comment in November 2019.
- The Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal (applicable to all the pyrethroids), which primarily addresses the potential risks to aquatic invertebrates, was released for public comment in November 2019.
- The public comment period ended January 13, 2020.
- EPA plans to publish interim decisions for two pyrethroids (prallethrin and tefluthrin) for public comment in January 2020.

Dicamba Label Changes: 2019/2020 Seasons

- Extensive adjustments made to labels for 2019 season
- Use Limited to Certified Applicators Only and Special Training for Use
- Detailed Label Information on Application Practices, Acceptable Nozzles, Tank Clean Out, Tank Mixing, and Wind Speed
- Unique Terms to Protect Against Application During Temperature Inversions and Specific Field Buffers including in counties with endangered species habitat
- Going forward - Continuing to work with registrants and also review new regulatory data
- Active engagement with both states and academia
- Current label expires in December 2020

Sulfoxaflor

- July 12, 2019 EPA issued approval for sulfoxaflor for use on variety of crops
- Poses no significant risk to human health and lower risk to non-target wildlife
- Expected to provides significant benefits to growers as an effective tool against difficult pests, such as sugarcane aphids and tarnished plant bugs (Lygus)
- Registration negates a large number of emergency use requests
- Supported by strong science that shows minimal risks for pollinators; included review of one of the Agency's largest datasets on effects of pesticides on bees
- End use label includes certain crop bloom time restrictions and bee safety advisory statements

Sulfoxaflor Uses

EPA issued approval for sulfoxaflor use on:

- Alfalfa
- Corn
- Cacao
- Grains (millet, oats)
- Pineapple
- Sorghum
- Teff
- Teosinte
- Tree plantations
- Citrus
- Cotton
- Cucurbits (squash, cucumbers, watermelons, some gourds)
- Soybeans
- Strawberries

Atrazine Registration Review

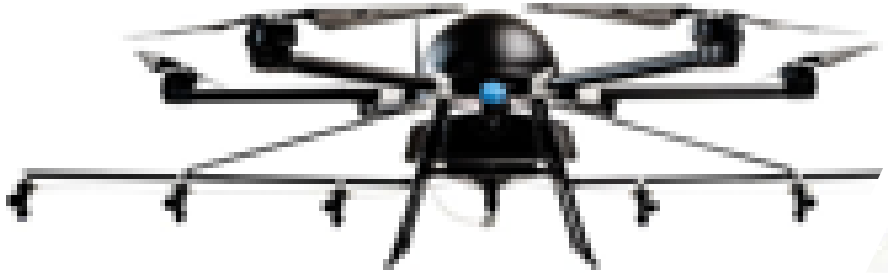
- On December 19, 2020, EPA published the Atrazine Proposed Interim Decision for a 90-day public comment.
- EPA is proposing to:
  - reduce the maximum application rate for turf to protect children who crawl or play on atrazine-treated grass
  - add personal protective equipment to protect workers
  - add mandatory label directions for spray drift management to minimize pesticide drift into non-target areas to protect the environment
  - add new label language to reduce the problem of weeds becoming resistant to atrazine
- After reviewing the comments received, EPA anticipates publishing a final registration review decision in late 2020.

Sodium Cyanide (M-44)

- USDA is the primary registrant, along with South Dakota, Texas, Montana, Wyoming, and New Mexico departments of agriculture (which are responsible for training certified applicators on using M-44 devices).
- On August 6, 2019, EPA released the interim decision for sodium cyanide, including M-44 devices. This decision was withdrawn shortly afterward.
- On December 5, EPA issued a revised interim decision on sodium cyanide as part of the registration review process.
- EPA's new restrictions:
  - A 600-foot buffer around residences where M-44s cannot be applied (except for cooperating landowners who have given written permission for placement of the devices on their property).
  - Increasing the distance where M-44s cannot be used from 100 feet to 300 feet surrounding public paths and roads.

PESTICIDE APPLICATION BY UAVS

Not an Endorsement



EPA'S OFFICE OF PESTICIDE PROGRAMS INVOLVEMENT IN UAVS

EPA receives questions requesting agency's position on Unmanned Aerial Vehicle uses and compliance with product labels

- UAV companies seek regulatory approval in coordination with FAA
- Chemical companies need guidance to incorporate UAVs in aerial applications
- States/tribes and EPA regional offices seek regulatory guidance on acceptability

Benefits: reduction in worker exposure, targeted applications, reduce environmental loading

Uncertainties: safety, implementation, regulatory compliance

BENEFITS & OPPORTUNITIES

Precision agriculture

- Control invasive weeds and target applications in tough and difficult conditions (e.g., cliff sides)
- Reduce environmental loading through GPS-initiated applications

Potentially faster and cheaper than traditional aerial applications

Potentially less worker exposure to pesticides particularly in areas where hand application is needed

Potential increased pilot safety in difficult terrain

Applications can be made closer to crop canopy, reducing spray drift

Spot or partial field applications become more viable

Night time application can feasibly occur

CHALLENGES & ISSUES

Does “Aerial application” incorporate UAVs?
FIFRA-labeling compliance issues?
Uncertainties in modeling and assessments?
Data needs and requirements?
Agency policies/decisions?
Operator definitions?
Drift/safety?
Change in technology impacts and assessments?

EPA COMMUNICATIONS TO DATE

Fact finding meetings with states/tribes, FAA, EPA regions revealed opportunities collaborate in August 2017

Recent presentations:

- AAPCO (March 2019)
- PPDC (May 2019)
- SFIREG (June 2019)

States and EPA regions have sought clarification on labeling requirements of pesticide products applied by UAV

EPA COMMUNICATIONS TO DATE

Organization for Economic Cooperation and Development (OECD)

AAPCO Technology Workgroup

Conversations with Registrants and Equipment Manufacturers

Conversations with National Agricultural Aviation Association

PPDC sessions

QUESTIONS FOR CONSIDERATION

- What are the important trends and developments regarding UAV technology that EPA needs to understand?
- What are the most viable ways for EPA to both account for chemical exposures and risk assessments, and support user needs in the adoption of UAV technologies?
- What data sources are available that can assist EPA in developing appropriate risk assessments and regulatory positions for UAV technologies?

NEXT STEPS

- Develop official EPA position on UAVs' equivalence to "aerial" application
- Address label interpretation concerns from stakeholders (e.g., boom length to rotor specifications, fixed wing and helicopter application methods)
- Identify data gaps and uncertainties posed by UAVs in risk assessments and FIFRA decision making
- Understand scope of products and use patterns that may benefit from UAV applications
- Develop regulatory structure in parallel with FAA that aligns with any agency-wide drone policies
- Create an OPP strategy that coincides with the evolution of UAV technology (as opposed to hindering it)
- Issue agency policy outlining acceptable UAV use patterns that covers: labeling, regulatory clarity, safety, and enforcement issues

Thank You!