Update on EPA's Pesticide Program Activities

IR-4 Food Use Workshop

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Discussion Topics

- New Leadership
- Updates on Specific Chemicals
- COVID-19 Response
- Registration Division Accomplishments
- Crop Group Rulemaking
- Hemp

New Leadership

- On March 11, 2021, Michael S. Regan was sworn in as the 16th EPA Administrator
- President Biden has Nominated Michal Freedhoff to be the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention. Confirmation Hearing on May 12th. She was confirmed on June 14th.

Updates on Chemicals

Registration Review Update: Chlorpyrifos

- The comment period for the Chlorpyrifos Draft Risk Assessments and Proposed Interim Decision closed on March 7, 2021. EPA is currently reviewing those comments.
- The Court ordered EPA to, within a very short timeframe, revoke chlorpyrifos tolerances or modify them, provided that the Agency explain the safety finding supporting those modified tolerances in its final rule.
- The Court also ordered that EPA modify or cancel registrations for associated food uses of chlorpyrifos.
- On August 30, 2021, EPA issued a final rule revoking all tolerances for chlorpyrifos. This action will be incorporated into the ongoing registration review for chlorpyrifos.
- EPA is committed to helping to support and protect farmworkers and their families while making certain that pesticides are used appropriately among the nation's agriculture. EPA will ensure sound science leads the decision-making process under federal pesticide laws.

Registration Review Update: Glyphosate

- In early February 2020, EPA issued the Glyphosate Interim Decision, which included mitigation and label changes to target pesticide sprays on intended pests, protect pollinators, and reduce the problem of weeds becoming resistant to glyphosate.
- After a thorough review of the best available science, as required under FIFRA, EPA concluded that there are no risks of concern to human health when glyphosate is used in accordance with its current label and that glyphosate is not a carcinogen.
- In November 2020, EPA released its draft biological evaluation (BE) for glyphosate for public review and comment. The comment period closed on March 12, 2021.
- In November 2021, EPA expects to release the final BE for glyphosate and initiate consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service, if warranted.

Registration Review Update: Neonicotinoids

- In January 2020, EPA released the Proposed Interim Decisions for the neonicotinoids acetamiprid, clothianidin, dinotefuran, imidacloprid, and thiamethoxam with proposed new measures to reduce potential ecological risks, particularly to pollinators.
- The agency is also working with industry on developing and implementing stewardship and best management practices.
- Approximately 190,000 comments were received on the proposed interim decisions
- After reviewing public input, the agency anticipates issuing Interim Decisions in 2022.

Dicamba

- EPA issued its 2020 decision authorizing the use of dicamba on dicamba-tolerant crops after a court vacated an earlier 2018 decision, finding that EPA substantially understated the risks that it acknowledged, and that EPA entirely failed to acknowledge other risks.
- Key points of the new label are a calendar-based cut off date, the use of spray tank agents to control the pH of the mix, and bigger buffers for users in counties with endangered species.
- EPA is currently reviewing data on the effectiveness of the control measures that were implemented for the first time in the 2021 growing season, and looks forward to continuing to work with producers and our state partners to ensure that use of dicamba on dicamba-tolerant crops will not cause unreasonable adverse effects.

Antibiotics as Pesticides

- Antibiotics used on crops for purposes of pest control are pesticides under FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act).
- FIFRA requires EPA to determine that any registered pesticide is not expected to cause unreasonable adverse effects on human health or the environment.
- For antibiotic pesticides, antibiotic resistance is part of this determination.

COVID-19 Updates

EPA's COVID-19 Response

- List N weekly updates continue
  - 560 products on List N; 179 products w SARS-CoV-2 claims
- Processed 468 expedited List N submissions; approximately 1/3 did not pass the front-end screen
- Responded to >200 Congressional inquiries
- Participated in ~200 pre-submission meetings
- Responded to ~127 enforcement inquiries

Emergency Exemption for Antiviral Air Treatment for Grignard Pure

- In June 2021, EPA issued emergency exemptions for the states of Maryland, Nevada, Pennsylvania, and Texas allowing them to use Grignard Pure, an antiviral indoor air treatment.
- Previously, EPA issued emergency exemptions to Georgia and Tennessee allowing them to use Grignard Pure in:
  - health care facilities, intrastate transportation, food processing facilities, and indoor spaces within buildings—including government facilities—where people are conducting activity deemed essential by the state.

Disinfectant Policy Update

- Recent information from the Centers for Disease Control and Prevention (CDC) notes that the risk of being infected with COVID-19 by touching contaminated surfaces is considered low.
- Given this new information, EPA is no longer prioritizing Public Health Emergency requests for new products that address surface transmission of SARS-CoV-2.
- EPA is shifting resources to expedite applications for products with novel COVID-19 claims such as killing of airborne SARS-CoV-2 and surface residual efficacy.

OPP Front End Processing Backlog

21-Day Backlog - How We Got There

- Early 2020, ISB began experiencing a backlog in the initial step of in-processing submission submitted via the Pesticide Submission Portal (PSP);
  - OPP prioritized COVID-19 actions;
  - PSP backlog and COVID-19 prioritization impacted the 21-day review process;
- To date there is no backlog of 21-day review;
  - Major backlog of over 500(+) submissions addressed as of April 30, 2021;

Actions to Date to decrease backlog reoccurrence

- Process improvements implemented within Front-end;
- Additional contract resources added for 21-day review.

Registration Division Accomplishments

Registration Division FY2021

- Registered:
  - 7 new active ingredients
  - 126 new uses for existing chemicals
  - 675 new products (or label amendments)
- Completed:
  - 563 fast track label amendments
  - 911 notifications of label changes
  - 104 minor formulation amendments
- Issued:
  - 56 emergency use exemptions (Section 18s)

Minor Use Completions

- EPA completed work on 20 IR-4 petitions in FY 2021, registering 58 minor uses and 225 crop group expansions requested by Interregional Research Project #4 (IR-4).
  - Includes new tolerances and crop group expansions
- EPA completed 34 crop group conversions requested by IR-4 in 2021.
- Includes 5 joint reviews with Canada and two workshares with California

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 Criterion #4: The use is for:

- 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; or
- A major crop that is a **representative commodity** for a crop group/subgroup that is being submitted to establish tolerances for the minor uses/specialty crops in the group/subgroup; or
- Control of a **niche pest** on a major crop (where the most likely number of acres treated is ≤ 300,000 acres when submitted); or
- Control of a public health pest on the List of Pests of Significant Public Health Importance; or
- Control of a pest identified as critical by the federal government National Plant Disease Recovery System; or
- Control of a pest identified as critical by the USDA OPMP or APHIS Plan Protection and Quarantine Program Pests; or
- Associated with a Section 18 and there is likely insufficient economic incentive for the registrant to generate the data

USDA Specialty Crops

- https://www.ams.usda.gov/services/grants/scbgp/specialty-crop
- List of Ineligible Commodities identifies 49 commodities including some included on this year's stoplight analysis: buckwheat, camelina (gold-of-pleasure), oats, peanut, potato, rice, rye, sugar beets
- Also flaxseed, hemp, sugarcane
- If acreage > 300,000, these would not meet the four basic PIF criteria.

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

Other Topics

Crop Group Rulemaking

Crop Grouping Phase V final rule was published November 6, 2020.

Previous Crop Group: §180.41(c)(28)	New Crop Groups §180.41(c)(34) & (35)
Crop Group 19: Herbs and Spices Group • 68 commodities • Rep crops: basil (fresh & dried); black pepper; chive; celery seed or dill seed	No equivalent
Herb Subgroup 19A • 36 commodities • Rep crops: basil (fresh & dried); chive	Crop Group 25: Herb Group • 418 commodities • Rep crops: basil, dried leaves; basil, fresh leaves; mint, dried leaves; mint, fresh leaves
Spice Subgroup 19B • 32 commodities • Rep crops: black pepper; celery seed or dill seed	Crop Group 26: Spice Group • 209 commodities • Rep crops: Dill seed or celery seed

Monitoring Data for Import Tolerances on Spices

- Policy of establishing “import tolerances” for pesticide residues in spices based on monitoring data
- See November 6, 2020 Crop Grouping Phase V rule
- Only applies to spices and “import tolerances”
  - Residue data on the representative commodities is still needed to establish a domestic tolerance (and register the use) on spices

Hemp Registrations

- EPA has committed to a timely review of any pesticide registration action for use on hemp.
- Since December 2019, EPA has approved adding hemp to the use sites of nearly 60 pesticides.
  - Nearly all are biopesticide products
- As EPA receives additional applications to amend product labels to add use on hemp, the agency will process those applications on an ongoing basis.
- https://www.epa.gov/pesticide-registration/pesticide-products-registered-use-hemp

Hemp Regulatory Activities

- Legislative changes now make hemp regulatory approvals under FIFRA much more viable.
- EPA is evaluating proposals for data generation or data translation on a case-by-case basis.
- Registrants should consider human exposure profiles and test guidelines when developing proposals on generating residue data or translating data from similar crops.
- Registrants are encouraged to contact their product managers if they want to discuss data development or translation proposals.

Thank You

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