EPA's Pesticide Registration Review Process and Updates on the Neonicotinoids

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Outline for Discussion

- What is Registration Review for Pesticides?
- Pesticide Registration Review Process
- What goes into a Regulatory Decision for Pesticides?
- Risk Management through Pesticides Labels
- Neonicotinoids' Timeline
- Engaging with Pesticide Re-evaluation Division (PRD)
- Office of Pesticide Programs (OPP) Updates

Review of Registered Pesticides

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA): each pesticide is required to be reviewed every 15 years

- Intended to ensure that each pesticide's registration is based on current scientific and other knowledge regarding the pesticide


Photo courtesy of EPA

- Risk-benefit standard considers human and ecological risk and requires, for non-dietary risks, the consideration of the benefits from the use of the pesticide

Applicable Statutes

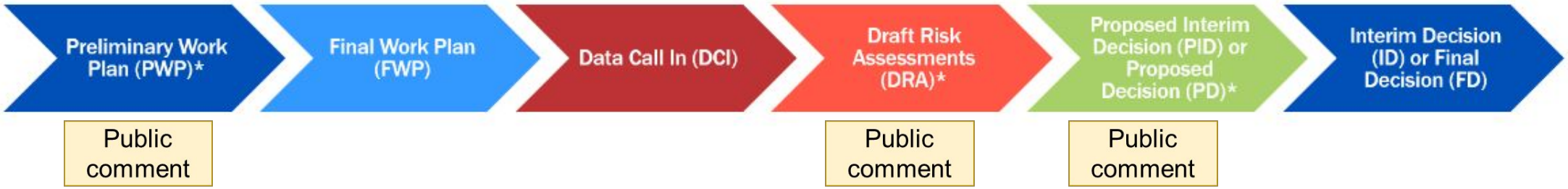
- **FIFRA**
  - Registration/licensing, registration review
- **Federal Food, Drug, and Cosmetic Act (FFDCA)**
  - Tolerances/maximum residue levels (MRLs) for residues on food
- **Food Quality Protection Act (FQPA)**
  - Safety standards
- **Pesticide Registration Improvement and Renewal Act**
  - Currently PRIA 5 (2022)
  - Registration fees and decision review periods
- **Endangered Species Act**
  - Protect sensitive wildlife

History of Pesticides Registration Review

- **Registration Review is the now!**
  - FQPA amendments to FIFRA require EPA to review each pesticide's registration at least every 15 years
    - Creation of the **registration review** program
  - Implementation began in 2007
  - Congressionally mandated deadline of October 1, 2022, for first review cycle
    - Deadline extended to October 1, 2026
  - Round 2 gearing up
- **Reregistration is the past…**
  - The process that preceded registration review
  - A one-time review of pesticides first registered before November 1984
  - Reregistration Eligibility Decisions (REDs) Often used as a baseline to inform registration review risk assessment and risk management decisions

Registration Review Process

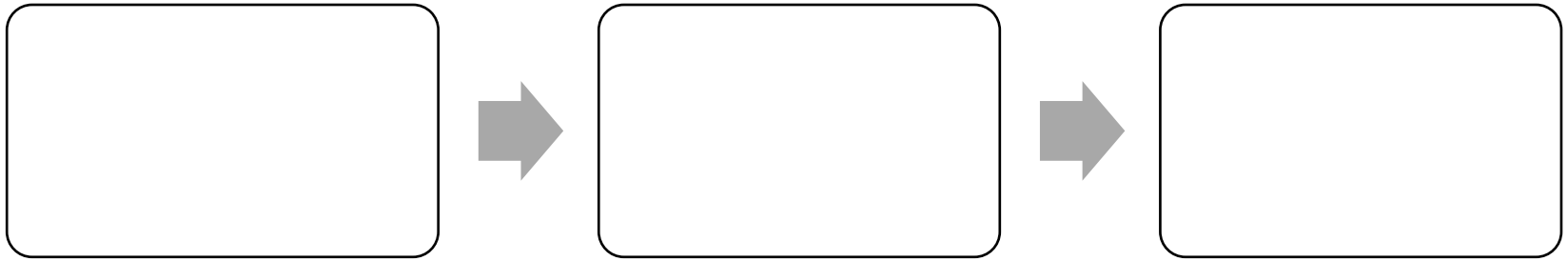
While each pesticide review is unique, all pesticides go through the same basic registration review process.



*After publication EPA generally holds a 60-day public comment period.

https://www.epa.gov/pesticide-reevaluation/registration-review-process

Pesticide Registration Review Timeline



*Open for public comment

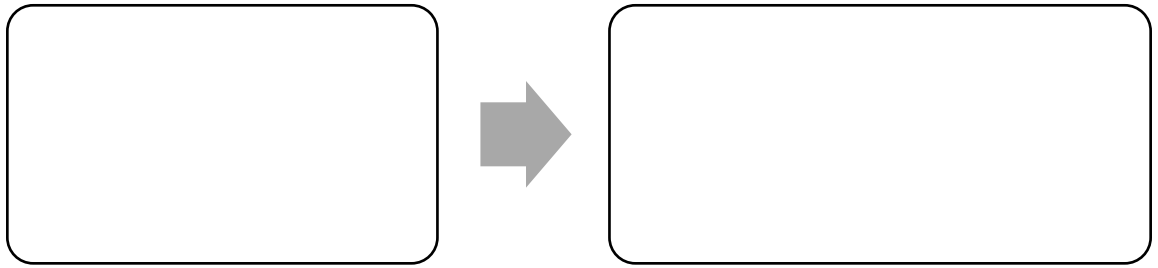
Preliminary Work Plan

- EPA initiates registration review by establishing a public docket for a registration review case and opens public comment period
- Summarizes information on the pesticide active ingredient and its anticipated path forward, including facts about the pesticide and its current use and usage, anticipated risk assessment and data needs, and timeline for review

Final Work Plan

- EPA considers information received during the comment period and develops a Final Work Plan

Pesticide Registration Review Timeline



*Open for public comment

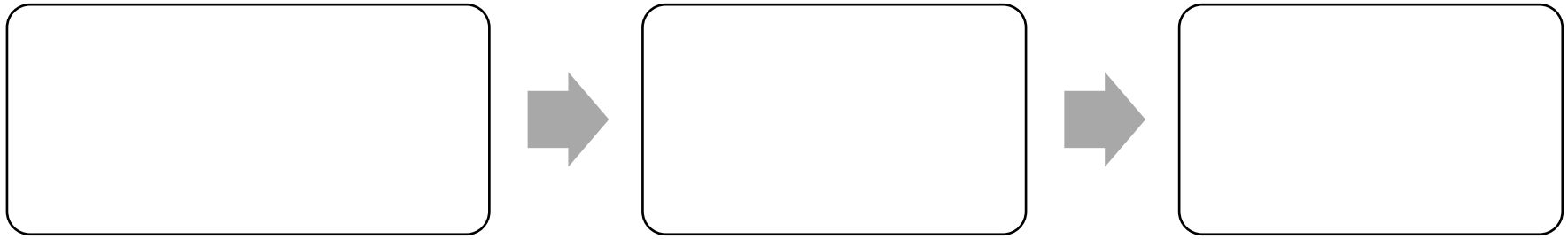
Data Call In

- If additional data or information are needed to conduct review, EPA issues a Data Call In (DCI) notice to registrants
- Discuss data and information for chemical cases

Risk Assessments

- Data incorporated from DCI and other sources into human health and ecological draft risk assessments
- Discuss the assumptions used to generate assessments and resulting risk estimates

Pesticide Registration Review Timeline



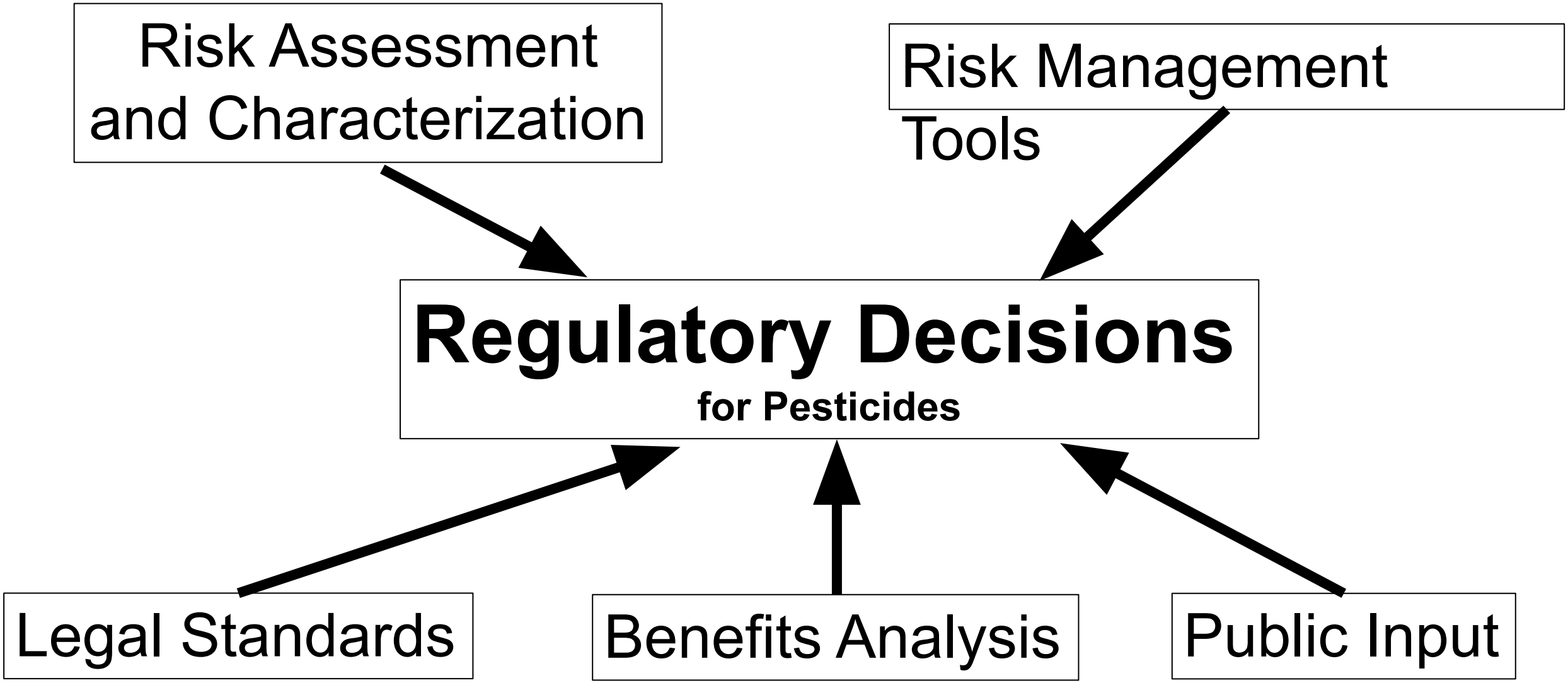
*Open for public comment *Open for public comment

<u>Proposed Interim Decision</u>

- Proposed mitigations if risks of concern are identified in the draft risk assessments with specific label changes

<u>Interim or Final Decision and Next Steps</u>

- Interim Decision may be issued and require the submission of updated labels
- Final Decision issued once all portions of assessments are completed including the Endangered Species Act (ESA) and Endocrine Disruptor Screening Program (EDSP)
- Label implementation process and tolerance rulemaking


Risk Assessment and Characterization
Risk Management Tools
Regulatory Decisions
for Pesticides
Legal Standards
Benefits Analysis
Public Input

Pesticide Labels

- Critical information about how to handle and safely use the pesticide and avoid harm to human health and the environment
- Interim or Final Registration Review Decision requires registrants submit amended labels within 60 days
- Pesticide Re-evaluation Division ensures consistency between labels and decision and coordinates with Registration Division to amend the labels

Photo courtesy of EPA

Example label table published in a PID/ID

- Section IV of a PID/ID/FD contains the Risk Mitigation and Rationale narrative
- Appendix B contains the actual updated language that will appear on labels

Appendix B: Proposed Labeling Changes for Clothianidin and Thiamethoxam Products

Table 1: Proposed Labeling Changes for Clothianidin Products

Description	Proposed Label Language for Clothianidin Products	Placement on Label
Technical Products		
For any product that allows use on bulb vegetables	Delete foliar and soil use on bulbs.	Directions for Use
End Use Products		
Mode/Mechanism of Action Group Number	**Note to registrant:** • Include the name of the **ACTIVE INGREDIENT** in the first column • Include the word "**GROUP**" in the second column • Include the **MODE/MECHANISM OF ACTION CODE** in the third column (for herbicides this is the Mechanism of Action, for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action) • Include the type of pesticide in the fourth column. **CLOTHIANIDIN** | **GROUP** | **4A** | **INSECTICIDE**	Front Panel, upper right quadrant. All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.
Updated Gloves Statement	Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA's chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Cotton, set maximum annual rate	Regardless of application method, apply no more than 0.15 lbs. a.i./A per year, including seed treatment, soil drench and foliar sprays.	Directions for Use
Fruiting Vegetables, set maximum annual rate for foliar spray	For foliar spray only: maximum annual application rate is not to exceed 0.17 lbs. a.i./A per year.	Directions for Use

Recent Neonicotinoid Regulatory Actions

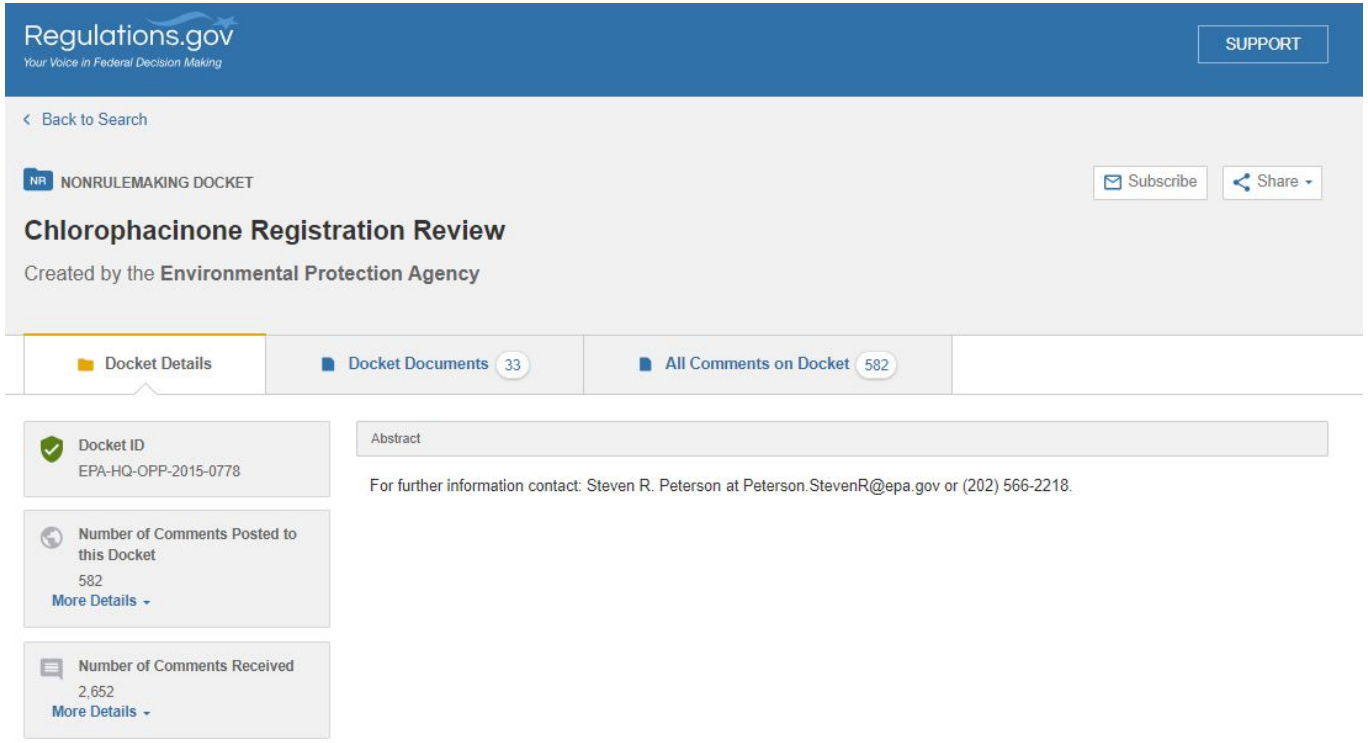
- January 2020 – Proposed Interim Decisions (PIDs)
- August 2021 – Draft Biological Evaluations (BEs)
- June 2022 – Final BEs
- April 2023 – Jeopardy and Adverse Modifications Analyses (J/AMs)
- July 2024 – Draft Insecticide Strategy (IS) and Updated Occupational Exposure Assessments

Upcoming Neonicotinoid Actions

- 2024
  - Final BEs for Acetamiprid and Dinotefuran
- 2025
  - Final IS
  - Amendments to the PIDs
  - Interim Decisions

Engaging with PRD

- PRD Contacts
- Bookmark Registration Review Schedule
- Subscribe to specific dockets on www.regulations.gov
- Subscribe to the Federal Register for EPA updates



Registration Review Schedules

Filters

Division

Action

Year

Quarter

Status

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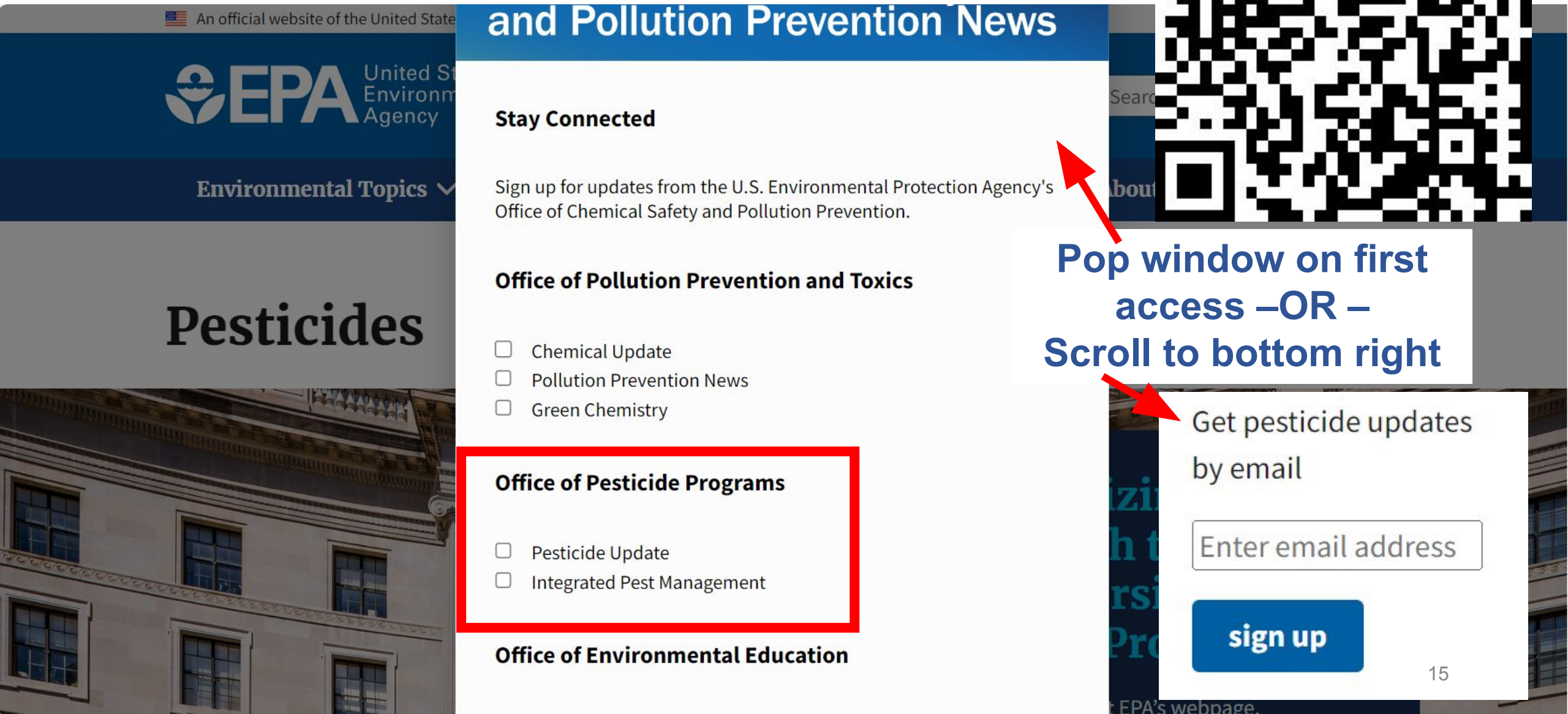
Show 10 entries | Export to PDF | Export to CSV | Search:

Case Name	Case Number	Division	Action	Year	Quarter	Docket Number	Status
Acrolein	2005	Pesticide Reevaluation Division; Antimicrobials Division	Interim Decision	24	4	EPA-HQ-OPP-2015-0571	Upcoming
Chlorothalonil	97	Pesticide Reevaluation Division; Antimicrobials Division	Interim Decision	24	3	EPA-HQ-OPP-2011-0840	Upcoming

Sign Up for OPP Updates



Thank you!

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