STATE OF MAINE
DEPARTMENT OF AGRICULTURE, CONSERVATION AND FORESTRY
BOARD OF PESTICIDES CONTROL
28 STATE HOUSE STATION
AUGUSTA, MAINE 04333

JANET T. MILLS
GOVERNOR

AMANDA E. BEAL
COMMISSIONER

# BOARD OF PESTICIDES CONTROL

**October 13, 2023**

**9:00 AM Board Meeting**

**MINUTES**

1. Introductions of Board and Staff

   - Adams, Carlton, Ianni, Jemison, Lajoie, Neavyn
   - Assistant Attorney General Carey Gustanski and Staff introduced themselves

2. Minutes of the September 1, 2023 Board Meeting

   Presentation By: John Pietroski, Acting Director
   Action Needed: Amend and/or approve

   - **Jemison/Carlton: Moved and seconded to accept minutes as amended**
   - **In Favor: Unanimous**

3. Workshop Session to Review the Rulemaking Record on the Proposed Amendments to Chapters 20, 31, 32, and 41

   *(Note: No additional public comments may be accepted at this time.)*

   On August 9, 2023 a Notice of Agency Rulemaking Proposal was published in Maine's daily newspapers, opening the comment period on the proposed amendments to Chapters 20, 31, 32, and 41. A public hearing was held on September 1, 2023 by a hybrid meeting in Deering Building 101 at 90 Blossom Lane, Augusta and on the Microsoft Teams platform. The written comment period closed at 5:00 PM on September 11, 2023. Nine people spoke at the public hearing and six written comments were received by the close of the comment period. One additional comment was received after the close of the comment period. The Board will now review the rulemaking comments and determine how it wishes to proceed with the rulemaking proposals.

   Presentation By: Karla Boyd, Policy & Regulations Specialist

Action Needed: Discussion and determination on how the Board wishes to proceed with the rulemaking proposals

- Boyd explained the amendments in the chapters involved and told the Board the rulemaking packet also included public comments summarized with responses, the basis statement and impact on small business. She stated that Chapter 41 was major substantive. Boyd noted that there were three versions of proposed language for Chapter 20 incorporating suggestions relating to comments received regarding the proper identification of treatment sites.
- Adams asked for input from the Board regarding Chapter 20 language and if it should be specific to an individual applicator who continued to make mistakes or to companies that manage the applicators.
- Jemison stated that an individual making applications to an incorrect site was the problem but companies needed to train the applicator and the BPC needed to train the companies. He added that he appreciated that this change could be more difficult for larger companies to oversee but that the companies still had some responsibility.
- Carlton stated this became an issue because the Board had received many consent agreements regarding improper identification of the application site. He added that he was of the opinion that the violation needed to follow the employee and was leaning towards version two of the amended rule.
- Ianni stated that she would support version three of the proposed amendment which put the onus on the master applicator and the firm. She stated that regardless of the number of employees the businesses needed to have enough commercial master applicators to supervise those employees just like having managers for any business.
- Lajoie stated that shutting down a company because of one individual's mistakes seemed severe. He supported version two of the proposed rule.
- There was discussion about the process of inspections, consent agreements and steps in making a determination of whether a suspension would be in order.
- Boyd stated that Title 22 §1471-D outlined the process for applicator license suspension. The Board would be the entity to suspend a license temporarily and the individual would have the opportunity for a hearing.
- Carey said discretion was up to the Board on whether or not to impose a temporary suspension.
- There was discussion about the length of time it would take to impose a suspension after an offense and if a company would need to provide a plan to address errors moving forward. There was consensus that version two followed the applicator, which was what the Board was setting out to do initially, and it would eventually affect the company.
- Chapter 31 was a housekeeping change to consolidate category 7C. Boyd explained that the change in Chapter 32 was to incorporate federal rule by reference.
- There was Board discussion on the wording in Chapter 41 mandating seed sales of *Bt* corn must be in quantities large enough to plant one acre or more. The Board decided to remove the acreage requirement.
- Carey stated that if there were a change in the acreage requirement, the rule would need to go back to public comment. The basis statement would need to be amended so the other chapters could proceed in the rulemaking process.

- **Neavyn/Lajoie: Motioned and seconded to adopt version two of Chapter 20 as amended, the Basis Statement, the Impact on Small Business, and the Summary of Comments and Responses as written.**
- **In Favor: Unanimous**

- **Lajoie/Carlton: Motioned and seconded to adopt Chapter 31, the Basis Statement, the Impact on Small Business, and the Summary of Comments and Responses as written.**
- **In Favor: Unanimous**

- **Ianni/Lajoie: Motioned and seconded to adopt Chapter 32, the Basis Statement, the Impact on Small Business, and the Summary of Comments and Responses as written.**
- **In Favor: Unanimous**

- **Jemison/Neavyn: Motioned and seconded to table Chapter 41 and reinvite additional public comment.**
- **In Favor: Unanimous**

4. LD 1770 Sales & Use Reporting

At the September 1, 2023 Board meeting, staff brought forward a memo regarding the implementation of LD 1770. Bohlen agreed to join staff for a meeting with developers and licensed applicators/dealers that use Maine Pesticide Enforcement, Registration, and Licensing Software (MEPERLS) to discuss changes that would be needed to simplify the data entry process for annual reports. Staff will provide an update from that meeting. In addition, the Board discussed potential rulemaking to require electronic submissions of records. Staff have provided potential amendments to Chapter 50: Recordkeeping that would implement these requirements. A report on the implementation of LD 1770 is due to the legislature by March 1, 2024.

Presentation By: John Pietroski, Acting Director
Action Needed: Discussion

- Pietroski summarized the meeting that staff, Bohlen and stakeholders held reviewing what was currently in place for electronic annual use and sales summary reporting in MePERLS. It was decided at the meeting to update the current system to include a preliminary review process before an individual submitted a final report and to include the ability to enter adjuvants. There was discussion about the quality of the data. The group plans to have a subsequent meeting.
- Bryer stated this had been an issue to present quality data in a format the legislature would find useful. She added that staff could not get to fine details easily but with these records they could get to pesticide use trends that could assist in answering whether or not the state was reducing its reliance on pesticides. Bryer summarized what data had been collected and what could be gleaned from that. There was further discussion about what other entities would like from the data and the resource limitations on collecting that data. Bryer noted that the sales data seemed more reliable than the use data but gave less information on who was using it and why.
- There was Board discussion about exactly where the request for data was coming from and how data could be used to help the Board make decisions.
- Adams commented the Board could spend more money to update the software but that would only change what was reported, not the data quality.

- Bryer said it would be great to see some changes in the requirements for the form because recording the category an application is made under may be an improvement that would make the end data more useful.
- There was discussion about how 'application site' is recorded and if refining that could improve the data.
- Jemison suggested asking Representative Osher to attend the next meeting to hear the details about collecting this data.
- Ianni agreed that Osher and a data analytics person should be involved.
- There was a discussion about the reporting of adjuvants. The Board will discuss this further at the next meeting.

5. Revised BPC Budget Review

Staff have prepared the budget for fiscal years 2024, 2025, and 2026 for the Board to review. Staff is requesting the Board's guidance on adjustments to the budget including adding funding to additional programs.

Presentation By: John Pietroski, Acting Director
Action Needed: Review and Discussion

- Pietroski stated that FY '24, '25, and '26 revenue was projected to be higher than expenditures. Pietroski mentioned the previous approval from the Board for allocating funds towards outreach.

6. Discussion About Registration of Repellent Clothing

At the September 1, 2023 meeting, the Board discussed potentially adding repellent clothing to registration requirements. Staff had requested the Board's guidance in developing a policy for registering or exempting pesticide-impregnated clothing and gear. During the discussion, Board members asked for additional information describing the greater context of this issue. Staff will present assembled documents, sample labels, and feedback from other states regarding impregnated clothing and gear.

Presentation By: Pamela Bryer, PhD, Pesticides Toxicologist
Action Needed: Discussion

- Bryer stated that the EPA website described regulation of these types of articles. EPA only recognized permethrin-treated articles for ticks and mosquitoes. Board materials included three master labels that were currently registered. Bryer summarized the memo and described the current registration process for other treated articles. She explained how some of the other states handled these registrations and the max number that EPA registered.
- Adams stated that he felt like this proposed policy had a specific purpose to keep people safe.
- The Board directed staff to reach out to manufacturers of the cloth to inform them that moving forward each brand would require separate registration and to add explanatory language to the registration webpage.

7. Update on Agricultural Container Recycling in Maine

At the last Board meeting members expressed interest in receiving an update regarding the current landscape of agricultural container recycling in Maine. In response, staff spoke with Mark Hudson, Executive Director, of the Ag Container Recycling Council (ACRC). Hudson offered to attend the following Board meeting to give an update on agricultural container recycling. Additionally, material describing changes to state law regarding the new extended producer responsibility (EPR) container recycling program has been included in the board packet. The Department of Environmental Protection facilitates the EPR program. This new program may affect pesticide manufacturers depending on several criteria as described in the included material. Successful implementation of the ACRC (or similar) recycling program has the potential to provide an exemption for pesticide manufacturers from EPR participation.

Presentation By: Staff
Action Needed: Discussion

- Pietroski stated that Mark Hudson would address the Board at the next meeting. He added that BPC staff would be assisting Hudson with presentations for recertification and working with the regulated community.

8. Other Old and New Business

a. EEE Press Release
b. Press Release on Drone Use in Herbicide Applications in Maine
c. Variance Permit for CMR01-26 Chapter 29, RCL Services, LLC
d. Variance Permit for CMR01-26 Chapter 29, Midcoast Conservancy
e. EPA Update: DCPA (Dacthal) Technical Product Suspended
f. EPA Update: New Active Ingredient Fluazaindolizine Registered
g. EPA Update: Proposes New Mitigations for TCVP
h. EPA Update: Upcoming Webinar on Understanding Bulletins Live! Two November 9, 2023
i. EPA Update: Approves New Mitigations for Cyantraniliprole as Part of ESA Protections
j. EPA Update: Public Comment Period on Proposal to Register Novel Pesticide Technology for Potato Crops

9. Schedule of Future Meetings

December 1, 2023, January 10, 2024, February 23, 2024 and April 5, 2024 are the next scheduled Board meeting dates. The Board will decide whether to change and/or add dates.

Staff reserved Deering Room 101 for December 1, 2023 and January 10, 2024; Marquardt Room 118 for February 23, 2024; and Deering Room 101 for April 5, 2024.

Adjustments and/or Additional Dates?

9. Adjourn

- **Jemison/Lajoie: Motioned and seconded to adjourn at 12:05 PM**
- **In Favor: Unanimous**

STATE OF MAINE
DEPARTMENT OF AGRICULTURE, CONSERVATION & FORESTRY
PLANT HEALTH PROGRAM
28 STATE HOUSE STATION
AUGUSTA, MAINE 04333

JANET T. MILLS
GOVERNOR

AMANDA E. BEAL
COMMISSIONER

To: Board of Pesticides Control
From: Hillary Peterson, Integrated Pest Management Specialist
Re: Request for Funding
Date: December 1, 2023

The Integrated Pest Management Program is requesting funds to assist with ongoing efforts for the advancement of IPM in Maine. The Maine IPM Program works closely with the BPC to educate and promote IPM across the entire State of Maine, including giving talks annually for applicator credits across several categories, updating the GotPests Website with new factsheets and research, and referring to the BPC website in all presentations and educational materials.

Over the past two years, the program has been funded through various means including some BPC funding, general plant health funding, and using only leftover materials from the past IPM program. Materials are running out, and to run a more consistent IPM program, funding needs to be secured for the 2024 calendar year. While the program has secured a total of $54,000 in grant funding for three new IPM programs (Biological Control of Black Swallowwort, $15,000, USDA NIFA; Biological Control of Spotted Wing Drosophila, $20,000, USDA NIFA; Augmentative Biological Control Working Group, NE IPM Center, $19,920), the full IPM program cannot function without additional funds for the other established programs. Other programs that require funding include: Greenhouse IPM (estimated at $1,110 annually), outreach specific to the IPM council and its mission (estimated at $2,550 annually), funds for travel to provide education and outreach on various IPM topics, often for CEU Credits (estimated at $9,471 annually), the School IPM Program (estimated at $1,500 annually), structural IPM programs (namely, the Rodent Academy, which maintains a relationship with the world-renowned Rodentologist Bobby Corrigan, estimated at $10,000 annually), and the mosquito monitoring program (estimated at $14,3000 annually). The IPM program is requesting a total budget of $38,911 for the 2024 program. Please see the following pages for a breakdown of costs, along with expenditures for the end of 2022 and 2023 as examples of program costs.

Sincerely,

**Hillary Peterson,**
IPM Entomologist
Maine Department of Agriculture, Conservation and Forestry

GARY FISH, STATE HORTICULTURIST
90 BLOSSOM LANE, DEERING BUILDING

PHONE: (207) 287-7545
WEB: WWW.MAINE.GOV/HORT

# 2024 Maine IPM Program Budget Breakdown

The following table demonstrates funding needed for the 2024 Maine IPM Program, broken down by month and sub-category (topic). This table does not include the entirety of the Maine IPM Program, which otherwise is funded by three grants (currently) and several virtual presentations which are anticipated but do not come at a travel cost. Materials are included in this budget as the IPM Program has now worked through a backlog of left-over materials left by the previous Maine IPM Specialist, Kathy Murray.

| Month | Topic | Program | Description of Needs | Cost Estimate |
|---|---|---|---|---|
| January | Outreach & Education | Entomological Society of Americal Annual Membership Fee | Membership Fee | $ 161.00 |
| January | Outreach & Education | Agricultural Trades Show | Materials, table fee | $ 500.00 |
| January | IPM Council | Grow ME Green Expo | Materials, table fee | $ 500.00 |
| January | Outreach & Education | Attending Tri-State Workshop | Hotel, per diem | $ 300.00 |
| January | Outreach & Education | Various Presentations & Workshops | Materials, hotel | $ 500.00 |
| February | School IPM | School IPM Comprehensive Training | Folders, printing, binders, items for hands-on activities, hotel if | $ 300.00 |
| February | Greenhouse IPM | Greenhouse Best Practices Workshop | Materials, catering, honorarium | $ 1,100.00 |
| February | Outreach & Education | Various Presentations & Workshops | Materials, hotel, per diem, travel | $ 500.00 |
| March | IPM Council | Ag Day in the Legislature | Materials, table fee | $ 50.00 |
| March | IPM Council | Maine Invasive Species Network Meeting | Materials, table fee | $ 50.00 |
| March | Outreach & Education | Various Presentations & Workshops | Materials, hotel, per diem, travel | $ 500.00 |
| April | School IPM | School IPM Comprehensive Training | Folders, printing, binders, items for hands-on activities, hotel if | $ 300.00 |
| April | IPM Council | Maine Arborist Association Meeting | Materials, table fee | $ 300.00 |
| April | Outreach & Education | Various Presentations & Workshops | Materials, hotel, per diem, travel | $ 500.00 |
| May | Outreach & Education | Various Presentations & Workshops | Materials, hotel, per diem, travel | $ 500.00 |
| June | Vector Responsibilities | Mosquito Monitoring Program (June through October) | Employee (30 hours per week), materials, fleet vehicle if needed, mileage | $ 14,300.00 |
| June | School IPM | School IPM Comprehensive Training (EPMA Conference) | Folders, printing, binders, items for hands-on activities, hotel if | $ 300.00 |
| June | Outreach & Education | Various Presentations & Workshops | Materials, hotel, per diem, travel | $ 500.00 |
| July | School IPM | School IPM Turfgrass Training | Folders, printing, binders, items for hands-on activities, hotel if | $ 300.00 |
| July | Outreach & Education | Various Presentations & Workshops | Materials, hotel, per diem, travel | $ 500.00 |
| August | Outreach & Education | Various Presentations & Workshops | Materials, hotel, per diem, travel | $ 500.00 |
| September | IPM Council | Common Ground Country Fair | Materials, table fee | $ 50.00 |

2024 BPC Funding Request IPM Program Budget Breakdown

| Month | Topic | Program | Description of Needs | Cost Estimate |
|---|---|---|---|---|
| September | Outreach & Education | Various Presentations & Workshops | Materials, hotel, per diem, travel | $ 500.00 |
| October | School IPM | School Nurse Conference | Printing, handouts, hotel if needed | $ 300.00 |
| October | Structural IPM | Rodent Academy | Printing, handouts, honorarium, down payment for facility | $ 10,000.00 |
| October | IPM Council | NE International Society of Arboriculture ISA Annual Conference | Materials, table fee | $ 500.00 |
| October | IPM Council | Maine Municipal Association Convention | Materials, table fee | $ 500.00 |
| October | IPM Council | Coastal ME Botanical Garden Community Outreach | Materials, table fee | $ 100.00 |
| October | Outreach & Education | Various Presentations & Workshops | Materials, hotel, per diem, travel | $ 500.00 |
| November | Outreach & Education | ESA Meeting Attendance - Networking & Presentations | Flight, hotel, registration fee | $ 3,000.00 |
| November | Outreach & Education | Various Presentations & Workshops | Materials, hotel, per diem, travel | $ 500.00 |
| December | Outreach & Education | Various Presentations & Workshops | Materials, hotel, per diem, travel | $ 500.00 |
| | | | **Total** | **$ 38,911.00** |

# Previous Calendar Year - Maine IPM Program (September 2022 - October 2023)

The following table demonstrates funds incurred by the Maine IPM Program in the previous calendar year. This budget is estimated at a lower cost than the requested 2024 budget due to no material costs, as the IPM Program was working through a backlog of remaining materials from the previous Maine IPM Program (run by Kathy Murray). While it worked to rely on the materials at hand, these materials have now run out and need to be re-designed and replaced.

| Year | Month | Topic | Program | Description of Costs | Approx. Num Reach | Cost Estimate |
|---|---|---|---|---|---|---|
| 2023 | October | Structural IPM | Rodent Academy | Printing, handouts, mileage, honorarium, down payment for facility | 100 | $ 10,000.00 |
| 2023 | October | Vector Responsibilities | Managed Mosquito Program | Employee (20 hours per week), mileage, materials | 0 | $ 2,200.00 |
| 2023 | September | Vector IPM | Vector Control Districts USGS Trip | Mileage, per diem, flight. Partially funded program that covers lodging and per diem. | 100 | $ 620.00 |
| 2023 | August | Vector Responsibilities | Managed Mosquito Program | Employee (20 hours per week), mileage, materials | 0 | $ 2,200.00 |
| 2023 | August | IPM Research | Managed Spotted Wing Drosophila and Black Swallowwort Biocontrol Programs (funded by USDA NIFA) | Employee (20 hours per week), mileage, materials | 50 | $ - |
| 2023 | August | Outreach / Education | Maine Master Naturalist Program - Educated about insects including a 2hr presentation and a 5hr field day | Mileage | 50 | $ 31.08 |

| Year | Month | Topic | Program | Description of Costs | Approx. Num Reach | Cost Estimate |
|---|---|---|---|---|---|---|
| 2023 | July | Vector Responsibilities | Managed Mosquito Program | Employee (20 hours per week), mileage, materials | 0 | $ 2,200.00 |
| 2023 | July | IPM Research | Managed Spotted Wing Drosophila and Black Swallowwort Biocontrol Programs (funded by USDA NIFA) | Employee (20 hours per week), mileage, materials | 50 | $ - |
| 2023 | July | School IPM | School IPM Comprehensive Training (EPMA Conference) | Mileage, materials (using leftover materials from Kathy Murray) | 25 | $ 16.80 |
| 2023 | June | Vector Responsibilities | Managed Mosquito Program | Employee (20 hours per week), mileage, materials | 0 | $ 2,200.00 |
| 2023 | June | IPM Research | Managed Spotted Wing Drosophila and Black Swallowwort Biocontrol Programs (funded by USDA NIFA) | Employee (20 hours per week), mileage, materials | 50 | $ - |
| 2023 | May | Vector Responsibilities | Vector Biology Bootcamp (Fully funded program that covered all travel, food, and lodging costs). | | | |
| 2023 | April | School IPM | School IPM Comprehensive Training (Pittsfield) | Mileage, materials (using leftover materials from Kathy Murray, hosting school donated coffee and snacks) | 25 | $ 36.12 |

| Year | Month | Topic | Program | Description of Costs | Approx. Num Reach | Cost Estimate |
|---|---|---|---|---|---|---|
| 2023 | April | School IPM | School IPM Comprehensive Training (Lewiston) | Mileage, materials (using leftover materials from Kathy Murray, hosting school donated coffee and snacks) | 25 | $ 29.40 |
| 2023 | April | Outreach / Education | Preschool IPM Visit (Brunswick) | Mileage, materials (using leftover materials from Kathy Murray) | 10 | $ 29.40 |
| 2023 | March | Outreach / Education | Maine Invasive Species Network Tabling & Presentation | Mileage, materials | 100 | $ 123.08 |
| 2023 | March | IPM Council | Tabling: Agriculture Day at the Legislature | Mileage, materials | 100 | $ 52.10 |
| 2023 | March | IPM Council | March IPM Council Meeting | Food (paid out of pocket) | 0 | $ 50.00 |
| 2023 | March | Greenhouse IPM | Greenhouse Best Practices Workshop | Materials, mileage, catering, honorarium | 50 | $ 1,100.00 |
| 2023 | February | School IPM | School IPM Comprehensive Training (Nobleboro) | Mileage, materials (using leftover materials from Kathy Murray, hosting school donated coffee and snacks) | 25 | $ 25.20 |
| 2023 | January | Outreach / Education | Agricultural Trades Show | Mileage, materials | 300 | $ 65.12 |
| 2022 | December | IPM Council | December IPM Council Meeting | Food (paid out of pocket) | 0 | $ 50.00 |
| 2022 | September | IPM Council | Commonground Country Fair | Mileage, materials | 2000 | $ 327.68 |
| 2022 | September | Outreach / Education | Portland Sustainability & Landscape Education Event | Mileage, materials | 25 | $ 97.04 |
| | | | | | | **$ 21,453.02** |

# Rulemaking Cover Sheet

**MAPA-1**

**TO:** **Secretary of State**
**ATTN:** **Administrative Procedure Officer,**
**State House Station 101, Augusta, Maine 04333.**

**1. Agency:** Agriculture, Conservation and Forestry, Board of Pesticides Control

**2. Agency umbrella and unit number**:
(2 digit umbrella # and 3 digit unit #)

**3. Title of rule:** Special Restrictions on Pesticide Use

**4. Chapter number assigned to the rule:** 41
(must be 3 digits or less)

**5. Date(s)/method(s) of notice:**
Initial newspaper notice: August 9, 2023
Notice of extension of public comment period following Board amendments (5 MRS sec. 8052 sub-sec. 5(B)): October 25, 2023

**6. Date(s)/place(s) of hearing(s):** September 1, 2023

**7. Type:** ☐ new rule ☒ partial amendment(s) of existing rule

☐ suspension of existing rule ☐ repeal of rule ☐ emergency rule

☐ repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

**8. Name/phone of agency contact person:**
Karla Boyd
28 SHS
Augusta, ME 04333
(207) 287-2731

**9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following**

☒ **Provisional adoption** ☐ **Final adoption**
(prior to Legislative review)
☐ **emergency adoption of major-substantive rule**

**10. Certification Statement:** I, _____ hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by

_____ on _____.
(name of agency) (date)

I further certify that all portions of this rule are adopted in compliance with the requirements of the Maine Administrative Procedure Act.

**Signature:** _____.
(original signature, personally signed by the head of agency)

**Printed name & title:** _____.

**11. Approved as to form and legality by the Attorney General on** _____.
(date)

**Signature** _____.
(original signature, personally signed by an Assistant Attorney General)

**Printed Name:** _____.

# Rulemaking Statement of Impact on Small Business
# 5 MRSA §8052, sub-§5-A

## Agency

Department of Agriculture, Conservation and Forestry—Maine Board of Pesticides Control

## Chapter Number and Title of Rule

CMR 01-026, Chapter 41—Special Restrictions on Pesticide Use

## Identification of the Types and an Estimate of the Number of the Small Businesses Subject to the Proposed Rule

Currently, there are 71 applicators that maintain certificates for Bt corn. These applicators would be affected, as they would not need to renew their trainings to receive certificates every three years.

## Projected Reporting, Record Keeping, and Other Administrative Costs Required for Compliance with the Proposed Rule, including the Type of Professional Skills Necessary for Preparation of the Report or Record

The changes to this rule reduce the burdens associated with reporting and recordkeeping. Applicators would only need trainings and would obtain a certificate once instead of renewing the certificate every three years.

## Brief Statement of the Probable Impact on Affected Small Businesses

The amendments to this chapter will modernize language to reflect planting practices currently in place. It will reduce the burden and cost for applicators to renew certificates by changing the requirement from every three years to one time. It changes the language from Bt corn to all plant-incorporated protectants, which will include more varieties of crops.

## Description of Any Less Intrusive or Less Costly, Reasonable Alternative Methods of Achieving the Purposes of the Proposed Rule

The Board could keep its current rules. However, the current version requires applicators to seek new certificates every three years. The Board could also choose to remove the plant-incorporated protectant portion and keep this section of the rule only to include corn crops, not all plant-incorporated protectants. Alternatively, the Board could strike this section of rule as was suggested by commenters.

**BASIS STATEMENT FOR ADOPTION OF**
**CMR 01-026, CHAPTER 41**

## Basis Statement

Chapter 41 – One amendment is proposed:

1. Amend grower requirements and product-specific requirements to broaden the scope from Bt corn to all plant-incorporated protectants and delete language regarding refuges that is not relevant to current plant-incorporated protectant growing practices.

The amendments to the proposed rule are in response to several needs BPC has identified in its rules. Amendments to Chapter 41 are in response to the need to modernize the language regarding Bt Corn in the current rule. The Board changed the language to reflect all plant-incorporated protectants (PIPs) that may be included in this chapter. Given that the training modules for PIPs do not significantly change over the three-year certificate period, the Board changed the requirements for training certificates, removing the requirement for new trainings every three years. After reviewing comments at the October 13, 2023 Board meeting, the Board removed section 5(E)(II) which requires dealers to sell in quantities of one acre or more. Since refuge-in-a-bag sells non-PIP refuge seeds mixed with PIP seeds, there is less need for larger plantings of PIP crops as the risk of resistance is reduced when planted together with refuge seeds.

Four comments were received during the initial comment period. Comments received for Chapter 41 included a detailed history of how Maine was the last state to allow the use of plant-incorporated protectants. Additionally, commenters agreed with the new amendments that only require training and a certificate issuance once for continued licensure. There were concerns regarding the requirement for dealers to sell at least one acre of product, as this could be difficult for small, diverse farms to adopt. X comments were received during the extended comment period.

## Impact on Small Business

In accordance with 5 MRSA §8052, sub-§5-A, a statement of the impact on small business has been prepared. Information is available upon request from the Maine Board of Pesticides Control office, State House Station #28, Augusta, Maine 04333-0028, telephone 207-287-2731.

**01 DEPARTMENT OF AGRICULTURE, CONSERVATION AND FORESTRY**

**026 BOARD OF PESTICIDES CONTROL**

**Chapter 41: SPECIAL RESTRICTIONS ON PESTICIDE USE**

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**SUMMARY**: This chapter describes special limitations placed upon the use of (1) aldicarb (Temik 15G) in proximity to potable water bodies; (2) trichlorfon (Dylox, Proxol); (3) hexazinone (Velpar, Pronone), (4) aquatic herbicides in the State of Maine; (5) plant-incorporated protectants; (6) neonicotinoids (dinotefuran, clothianidin, imidacloprid, thiamethoxam); and (7) chlorpyrifos (Dursban, Lorsban).

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## Section 1. ALDICARB (TEMIK®)

The registration of aldicarb (Temik 15G) is subject to the following buffer zone requirements:

A. Aldicarb (Temik 15G) shall not be applied within 50 feet of any potable water source if that water source has been tested and found to have an aldicarb concentration in the range of one to ten parts per billion (ppb). The 50 foot buffer would be mandatory for one year with a required retesting of the water at the end of the period.

B. Aldicarb (Temik 15G) shall not be applied within 100 feet of any potable water source if that water source has been tested and found to have an aldicarb concentration in excess of 10 ppb. The 100 foot buffer would be mandatory for one year with a required retesting of the water at the end of this period.

## Section 2. TRICHLORFON (DYLOX, PROXOL)

The registration of trichlorfon (Dylox, Proxol) is subject to the following requirements:

A. Trichlorfon shall only be used for control of subsurface insects on turf.

B. Prior to application the target pest must be identified and the severity of the infestation must be determined, including the extent of the damage.

C. Only infested areas shall be treated with trichlorfon. Broadcast treatments of the entire turf area are prohibited.

D. Following application, the trichlorfon must be watered into the soil with at least ½ inch of water and according to the label directions. The applicator must assure that the appropriate watering will take place prior to re-entry by any unprotected person.

## Section 3. HEXAZINONE (VELPAR, PRONONE)

The registration of hexazinone is subject to the following limitations and conditions.

A. **Licenses Required**

No person shall use or supervise the use of any pesticide containing the active ingredient hexazinone unless they have obtained an applicators license in accordance with 22 M.R.S. §1471-D.

## Section 4. AQUATIC HERBICIDES

The registration of pesticides for which there is an aquatic herbicide use on the product label shall be subject to the following limitations and conditions.

A. **Board Publication of List**

The Board of Pesticides Control will publish by May 23, 2003 and by March 15th of each year thereafter a list of herbicide products registered in Maine for which the manufacturer has verified that there is an aquatic use on the pesticide label. Based on available information, the Board may exempt from this list pesticides that it determines are not for use in the control of aquatic vegetation. Pesticides labeled solely for use in aquariums and antifouling paints, are specifically exempt from this list.

B. **Licenses Required**

I. Unless exempted under Chapter 41, Section 4 (B) (III), no person shall purchase, use or supervise the use of any aquatic herbicides identified on the Board's annual listing unless they have obtained a private or commercial pesticide applicator's license from the Board.

II. No person shall:

a. Distribute any aquatic herbicides identified on the Board's annual listing without a restricted use pesticide dealer's license from the Board; or

b. Unless exempted under Chapter 41, Section 4 (B) (III), distribute any aquatic herbicides identified on the Board's annual listing to any person who is not licensed as a private or commercial applicator by the Board.

III. Registered herbicides containing only the active ingredients erioglaucine (Acid Blue 9 or FD&C Number 1, CAS Registry No. 1934-21-0) and/or tartrazine (Acid Yellow 23 or FD&C Yellow Number 5, CAS Registry No. 2650-18-2 (trisodium salt) or 3844-45-9 (triammonium salt)) are exempt from the applicator licensing requirements described in Chapter 41, Section 4 (B) (I) and Chapter 41, Section 4 (B) (II) (b).

C. **Disclosure**

The Board will make a disclosure form available to dealers distributing any aquatic herbicides identified on the Board's annual listing. The Board requests that dealers present to customers the disclosure form that advises purchasers that, (1) an aquatic discharge license must be obtained from the Maine Department of Environmental Protection before any application may be made to any surface waters of the State as defined in 38 M.R.S.A. Section 361-A(7) including any private ponds that may flow into such a body of water at any time of year, (2) that Best Management Practices developed jointly by the Board and the Maine Department of Environmental Protection on the use of aquatic herbicides are available.

D. **Records and Reporting**

Dealers distributing any aquatic herbicides identified on the Board's annual listing shall keep records of such sales and provide reports to the Board as described for restricted use pesticides in Chapter 50, "Record Keeping and Reporting Requirements."

E. **Use of Best Management Practices**

Aquatic herbicides applied to private ponds and not subject to an aquatic discharge permit may only be applied consistent with Best Management Practices developed jointly by the Board and the Maine Department of Environmental Protection.

## Section 5. PLANT-INCORPORATED PROTECTANTS

The registration, distribution and use of plant-incorporated protectants are subject to the following limitations and conditions:

A. **Definitions**

"Plant-incorporated protectant" means a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for the production of such a pesticidal substance.

B. **License Required**

No person shall distribute any plant-incorporated protectant without either a general use pesticide dealer license or a (restricted or limited use) pesticide dealer license from the Board.

C. **Dealer Requirements**

Dealers distributing plant-incorporated protectants are subject to the following requirements:

I. General use and (restricted or limited use) pesticide dealers shall notify the Board of their intent to distribute plant-incorporated protectants on all initial license and license renewal application forms provided by the Board.

II. General use and (restricted or limited use) pesticide dealers shall maintain sales records showing the list of the names and addresses of all purchasers of plants, plant parts or seeds containing plant-incorporated protectants. These records must be made available to representatives of the Board for inspection at reasonable times, upon request, and must be maintained for two calendar years from the date of sale.

III. Any general use and (restricted or limited use) pesticide dealer who discontinues the sale of plant-incorporated protectants shall notify the Board in writing and shall provide the Board, upon request, with all records required by Section 5(C)II of this chapter.

D. **Grower Requirements**

I. All users of plant-incorporated protectants shall maintain the records listed below for a period of two years from the date of planting. Such records shall be kept current by recording all the required information on the same day the crop is planted. These records shall be maintained at the primary place of business and shall be available for inspection by representatives of the Board at reasonable times, upon request.

a. Site and planting information, including town and field location, a map showing crop location and refuge configuration in relation to adjacent crops within 500 feet that may be susceptible to cross-pollination;

b. Total acres planted with the plant-incorporated protectant and seeding rate;

c. Total acres planted as refuge and seeding rate;

d. Detailed application information on any pesticide applied to the refuge as described in Section 1(A) of Chapter 50, "Record Keeping and Reporting Requirements"; and

e. Planting information for each distinct site including:

i. date and time of planting; and

ii. brand name of the plant-incorporated protectant used.

II. There are no annual reporting requirements for growers.

E. **Product-Specific Requirements**

I. Requirements for plant-incorporated protectants ~~corn containing Bacillus thuringiensis (Bt) protein and the genetic material necessary for its production~~.

a. Prior to planting plant-incorporated protectants ~~corn containing any Bacillus thuringiensis (Bt) protein and the genetic material necessary for~~

~~its production~~, the grower must have completed a Board-approved training course available on-line, pass an exam, and acquire an appropriate ~~and possess a valid product-specific~~ training certificate.

~~b.~~ ~~Product-specific training certificates shall be issued following each Board-approved session. The certificates will remain valid until December 31 of the third year after issuance.~~

~~c~~b. Non-~~Bt corn~~ plant-incorporated protectant growers whose crops are or will be located within 500 feet of a prospective ~~Bt corn~~plant-incorporated protectant planting site can request that the ~~Bt corn~~plant-incorporated protectant grower protect the non-~~Bt corn~~plant-incorporated protectant crop from pollen drift.

i. the request must be made prior to planting of the ~~Bt corn~~plant-incorporated protectant crop;

ii. the request must identify the non-~~Bt corn~~plant-incorporated protectant crop to be protected; and

iii. the growers may agree on any method for protection but, if an agreement cannot be reached,

1. If a refuge is required, the ~~Bt corn~~plant-incorporated protectant grower must plant ~~any~~ refuge required by the ~~Bt corn~~plant-incorporated protectant grower agreement, grower guide or product label in a configuration that provides maximum protection from pollen drift onto the adjacent non-~~Bt corn~~plant-incorporated protectant crop; or

2. if no refuge is required, the ~~Bt corn~~plant-incorporated protectant grower shall maintain at least a 300-foot ~~Bt~~ plant-incorporated protectant~~corn~~-free buffer to non-~~Bt corn~~plant-incorporated protectant crops.

~~d~~c. ~~Bt corn~~Plant-incorporated protectant growers are encouraged to follow all best management practices developed by the Board or the Department of Agriculture, Conservation and Forestry.

~~II.~~ ~~Dealers distributing Bt plant-incorporated protectant sweet corn shall only sell the seed in quantities large enough to plant one acre or more.~~

F. **Confidentiality**

Any person providing information to the Board in connection with the record-keeping and reporting requirements of Section 5 of this chapter may designate that information as confidential in accordance with 7 M.R.S.A. §20.

## Section 6. NEONICOTINOIDS (DINOTEFURAN, CLOTHIANIDIN, IMIDACLOPRID, OR THIAMETHOXAM )

The registration of pesticides containing dinotefuran, clothianidin, imidacloprid, or thiamethoxam for which there is an outdoor ornamental plant or turf use on the product label shall be subject to the following limitations and conditions.

### A. Definitions

I. "Emerging Invasive Invertebrate Pests" means any invertebrate, including its eggs or other biological material capable of propagating that species that occurs outside of its eco-region and its introduction causes or is likely to cause economic or environmental harm, or harm to human, animal, or plant health, to include:

a. Species both known now and unknown now but showing up at a later date;

b. Species that occur outside of their eco-region (level III) as defined by EPA; and

c. Species on a Board approved list.

II. "Ornamental Plants" means shrubs, trees and related vegetation excluding turf and lawn, in and around residences.

### B. Board Publication of Product List

The Board of Pesticides Control will publish within 30 days of adoption and by March 15th of each year thereafter a list of insecticide products containing dinotefuran, clothianidin, imidacloprid, or thiamethoxam registered in Maine for which the manufacturer has verified that there is an outdoor ornamental plant or turf use on the pesticide label. Based on available information, the Board may exempt from this list pesticides that it determines are not for use in the control of invertebrate pests on outdoor ornamental plants or turf. Pesticides labeled solely for use in preserving wood, managing indoor pests, managing structural pests within five (5) feet of a human dwelling, and treating pets are specifically exempt from this list.

### C. Licenses Required

I. No person shall purchase, use, or supervise the use of any pesticides containing dinotefuran, clothianidin, imidacloprid, or thiamethoxam identified on the Board's annual listing unless they have obtained a private or commercial pesticide applicator's license from the Board.

II. Unless exempted under Chapter 41, Section 6 (C) (IV) no person shall purchase, use or supervise the use of any pesticides containing dinotefuran, clothianidin, imidacloprid, or thiamethoxam in outdoor residential landscapes to include ornamental plants and turf.

III. No person shall distribute any pesticides containing dinotefuran, clothianidin, imidacloprid, or thiamethoxam identified on the Board's annual listing without a restricted use pesticide dealer's license from the Board.

IV. Registered pesticides containing dinotefuran, clothianidin, imidacloprid, or thiamethoxam and identified on the Board's annual listing are exempt from the prohibition of use described in Chapter 41, Section 6 (C) (II) where by:

a. The applicator obtains an emergency permit from the Board; or

b. The use of these products is for management of emerging invasive invertebrate pests on ornamental plants in outdoor residential landscapes.

V. No person shall use any pesticides containing dinotefuran, clothianidin, imidacloprid, or thiamethoxam identified on the Board's annual listing for the purposes of managing turf and lawn in outdoor residential landscapes.

D. **Records and Reporting**

Dealers distributing any pesticides containing dinotefuran, clothianidin, imidacloprid or thiamethoxam identified on the Board's annual listing shall keep records of such sales and provide reports to the Board as described for restricted use pesticides in Chapter 50, "Record Keeping and Reporting Requirements."

E. **Emergencies**

The Board's staff may grant an emergency permit authorizing neonicotinoid use in compliance with Sections 6(C) of this chapter if the restrictions in this chapter prevent efficacious application of pesticide(s) and the staff determines that an emergency situation exists as outlined in Chapter 51(VII)(B)(1).

I. No variance may be granted if the emergency is the result of an unjustifiable delay created by the person seeking the variance or the person requesting the pesticide application.

II. If the staff does not grant the variance, the applicator or the person requesting the pesticide application may petition the Board for exemption following the requirements set forth in 22 M.R.S.A. §1471-T, "Exemption".

F. **Emergency Use Permits**

Emergency use permit applications shall be made on such forms as the Board provides and shall include at least the following information:

I. The name, address and telephone number of the applicant;

II. The area(s) where pesticides will be applied;

IV. The purpose for which the pesticide application(s) will be made;

V. The approximate application date(s);

VI. The type(s) of application equipment to be employed;

VII. The approved pest species for which the application is being made as defined in policy or by the board; and

VIII. The particular reasons why the applicant seeks a variance from the requirements of this section, including a detailed description of the techniques to be employed to assure that a reasonably equivalent degree of protection of surrounding nontarget vegetation will be obtained.

Within 30 days after a complete application is submitted, the Board or its staff shall issue a permit if it finds that the application meets requirements of Section 6 (E). The Board may place conditions on any such permit, and the applicant shall comply with such conditions. Except as required by the permit, the applicant shall undertake the application in accordance with all of the conditions described in their request and all other applicable legal standards. Permits issued by the Board under this section shall not be transferable or assignable except with further written approval of the Board and shall be valid only for the period specified in the permit.

**Section 7. CHLORPYRIFOS (DURSBAN, LORSBAN)**

The registration of chlorpyrifos (Dursban, Lorsban) is subject to the following limitations and conditions.

A. No person shall use or supervise the use of any pesticide containing the active ingredient chlorpyrifos unless they have obtained a private or commercial applicator's license from the Board, possess the pesticide in the State before January 1, 2022, and obtain a temporary use authorization permit from the Board.

B. Permit applications shall be made on such forms as the Board provides and shall include at least the following information:

I. The name, address and telephone number of the applicant;

II. The brand name of the pesticides to be applied;

III. The date on which the pesticides were purchased;

IV. The approximate quantity of the pesticides possessed;

V. The purpose for which the pesticide application(s) will be made; and

VI. The duration for which the applications will take place or until the product is gone.

C. Within 30 days after a complete application is submitted, the Board or its staff shall issue a permit if:

I. The permit application is received prior to December 31, 2022;

II. The applicant possesses a valid pesticide applicator license issued by the State;

III. The pesticides proposed for use were purchased prior to January 1, 2022;

The Board may place conditions on any such permit, and the applicant shall comply with such conditions. Except as required by the permit, the applicant shall undertake the application in accordance with all of the conditions described in their request and all other applicable legal standards. Permits issued by the Board under this section shall not be transferable or assignable except with further written approval of the Board and shall be valid only for the period specified in the permit.

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STATUTORY AUTHORITY:
5 M.R.S.A. §§ 8051 *et seq*.
7 M.R.S.A. §§ 601-610
22 M.R.S.A. §§ 1471-A, 1471-B, 1471-C, 1471-D, 1471-M

EFFECTIVE DATE:
March 8, 1981 (Captan)

AMENDED:
May 7, 1981 (Trichlorfon)
January 2, 1984 (Aldicarb)
May 8, 1988 (Trichlorfon)
August 5, 1990 (Captan)
August 17, 1996 (Hexazinone)
October 2, 1996

EFFECTIVE DATE (ELECTRONIC CONVERSION):
March 1, 1997

AMENDED:
May 7, 1997 - Section 3(B)(II)

CONVERTED TO MS WORD:
March 11, 2003

AMENDED:
May 12, 2003 - Section 4 added

NON-SUBSTANTIVE CORRECTIONS:
June 24, 2003 - summary only

AMENDED:
February 2, 2004 - Section 4, 1st paragraph and sub-section A, filing 2004-31
April 30, 2007 – filing 2007-154
February 3, 2008 – filing 2008-36
July 16, 2009 – filing 2009-253 (final adoption, major substantive)
May 3, 2012 – filing 2012-99 (final adoption, major substantive)

CORRECTIONS:
February, 2014 – agency names, formatting

AMENDED:
December 9, 2014 – Section 3, filing 2014-283
September 20, 2022 – filing 2022-181

APPROVED
JUNE 23, 2023
BY GOVERNOR

CHAPTER
71
RESOLVES

**STATE OF MAINE**

**5**

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**IN THE YEAR OF OUR LORD**

**TWO THOUSAND TWENTY-THREE**

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**H.P. 1134 - L.D. 1770**

# Resolve, Directing the Board of Pesticides Control to Transition to Electronic Submission of Pesticides Sales and Use Data

**Sec. 1. Board of Pesticides Control; pesticides sales and use data. Resolved:** That, pursuant to the Maine Revised Statutes, Title 22, section 1471-M, subsection 2, paragraph D, the Department of Agriculture, Conservation and Forestry, Board of Pesticides Control shall adopt any rules necessary to implement the transition from paper to electronic format of reports required to be submitted to the board as required by Title 22, section 1471-G. The board shall implement a system of electronic data collection that is efficient for those required to submit reports to the board under Title 22, section 1471-G and useful to the board and members of the public. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

**Sec. 2. Report. Resolved:** That, no later than March 1, 2024, the director of the Board of Pesticides Control within the Department of Agriculture, Conservation and Forestry shall submit a report regarding rulemaking and implementation of electronic reporting under section 1 to the Joint Standing Committee on Agriculture, Conservation and Forestry, which may report out a bill to the Second Regular Session of the 131st Legislature based on the report.

STATE OF MAINE
DEPARTMENT OF AGRICULTURE, CONSERVATION & FORESTRY
DIVISION OF ANIMAL AND PLANT HEALTH
28 STATE HOUSE STATION
AUGUSTA, MAINE 04333-0028

JANET T. MILLS
GOVERNOR

AMANDA E. BEAL
COMMISSIONER

# MAINE BOARD OF PESTICIDES CONTROL POLICY REGARDING THE TREATMENT OF ADJUVANTS AS PESTICIDES

Adopted XXXX

## BACKGROUND

Recently, LD 2019 "An Act To Require the Registration of Adjuvants in the State and To Regulate the Distribution of Pesticides with Perfluoroalkyl and Polyfluoroalkyl Substances" (PL 2022 c.673) was approved by the 130th Maine Legislature in 2022. Under this law, adjuvants were added to the definition of pesticides and must now be registered within the State of Maine. The Board has discussed several policies related to spray adjuvants, which have been consolidated below. The purpose of this policy is to clarify the Board's decisions regarding the treatment of "spray adjuvants" in the state of Maine. This policy clarification incorporates three topics:

Inclusion of Colorants: At the February 24, 2023 Board meeting, the Board discussed a staff memo regarding added colorants and if they are considered pesticides under the new state definition. An informal vote was taken, and the majority of Board members stated that colorants did not fit into the definition of adjuvants given that they do not increase the efficacy of the applied product.

Currently held stock: At the July 21, 2023 Board meeting, the Board discussed a staff memo regarding the distribution of spray adjuvant products. The Board voted to adopt the proposed policy that would treat adjuvant products in possession of dealers, distributors, and end users the same as pesticides in Chapter 20, Section 1. D.

Recordkeeping: There is also a need to review recordkeeping and reporting requirements for adjuvants. Staff have included proposed language for this section of the policy below.

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## POLICY

### Definition
Under state law, “spray adjuvants” are included in the definition of “pesticide” and are defined under Title 7 §604(31-A) as:

31-A. Spray adjuvant. "Spray adjuvant" means any wetting agent, spreading agent, sticker, deposit builder, adhesive, emulsifying agent, deflocculating agent, water modifier or similar agent that is intended to be used with any other pesticide as an aid to the application or the effect of it and that is in a package or container separate from that of the other pesticide.

### Colorants and Water
Adjuvants that are labeled as added colorants for pesticides are not considered spray adjuvants in Maine.

### Distribution
Spray adjuvant products that were in the possession of dealers, distributors, and end users when PL 2022 c. 673 became effective on August 8, 2022 will be included as “pesticides no longer registered in Maine” under Chapter 20, Section 1(D).

> **Chapter 20, Section 1. D.**
> *Retailers and end users of pesticides no longer registered in Maine may continue to sell and use those items provided they were properly registered when obtained and such distribution and use is not prohibited by FIFRA or other Federal law.*

### Recordkeeping
Spray adjuvants considered to be pesticides in the State of Maine must be included in recordkeeping and reporting requirements as stated in Chapter 50. In records and reports, the term “Primary Functioning Agent (PFA)” will be used in place of “active ingredient” on records where the active ingredient is required. Likewise, for recordkeeping activities, the term “Constituents Ineffective As Spray Adjuvants (CIASA)” will be used in spray adjuvants to replace of the terms “Other” or “Inert” typically used in pesticides.

LAW WITHOUT GOVERNOR'S SIGNATURE

APRIL 28, 2022

CHAPTER

673

PUBLIC LAW

**STATE OF MAINE**

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**IN THE YEAR OF OUR LORD**

**TWO THOUSAND TWENTY-TWO**

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**H.P. 1501 - L.D. 2019**

# An Act To Require the Registration of Adjuvants in the State and To Regulate the Distribution of Pesticides with Perfluoroalkyl and Polyfluoroalkyl Substances

**Be it enacted by the People of the State of Maine as follows:**

**Sec. 1. 7 MRSA §604, sub-§22-A** is enacted to read:

**22-A. Perfluoroalkyl and polyfluoroalkyl substances or PFAS.** "Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" has the same meaning as in Title 32, section 1732, subsection 5-A.

**Sec. 2. 7 MRSA §604, sub-§25,** as amended by PL 2005, c. 620, §3, is repealed and the following enacted in its place:

**25. Pesticide.** "Pesticide" means:

A. Any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pests;

B. Any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant; and

C. Any substance or mixture of substances intended to be used as a spray adjuvant.

"Pesticide" includes a highly toxic pesticide.

**Sec. 3. 7 MRSA §604, sub-§31-A** is enacted to read:

**31-A. Spray adjuvant.** "Spray adjuvant" means any wetting agent, spreading agent, sticker, deposit builder, adhesive, emulsifying agent, deflocculating agent, water modifier or similar agent that is intended to be used with any other pesticide as an aid to the application or the effect of it and that is in a package or container separate from that of the other pesticide.

**Sec. 4. 7 MRSA §606, sub-§1,** as amended by PL 2021, c. 105, §§1 to 3, is further amended to read:

**1. Unlawful distribution.** A person may not distribute in the State any of the following:

A. A pesticide that has not been registered pursuant to the provisions of this subchapter;

B. A pesticide if any of the claims made for it or any of the directions for its use or other labeling differs from the representations made in connection with its registration, or if the composition of a pesticide differs from its composition as represented in connection with its registration; a change in the labeling or formulation of a pesticide may be made within a registration period without requiring reregistration of the product if the registration is amended to reflect that change and if that change will not violate any provision of FIFRA or this subchapter;

C. A pesticide unless it is in the registrant's or the manufacturer's unbroken immediate container and there is affixed to the container, and to the outside container or wrapper of the retail package, if there is one, through which the required information on the immediate container cannot be clearly read, a label bearing the information required in this subchapter and rules adopted under this subchapter;

D. A pesticide that has not been colored or discolored pursuant to section 610, subsection 1, paragraph D;

E. A pesticide that is adulterated or misbranded or any device that is misbranded;

F. A pesticide in containers that are unsafe due to damage; ~~or~~

G. Beginning January 1, 2022, a pesticide containing chlorpyrifos as an active ingredient~~.~~;

H. A pesticide that has been contaminated by perfluoroalkyl and polyfluoroalkyl substances; or

I. Beginning January 1, 2030, a pesticide that contains intentionally added PFAS that may not be sold or distributed pursuant to Title 38, section 1614, subsection 5, paragraph D.

**Sec. 5. 7 MRSA §606, sub-§2,** as amended by PL 2005, c. 620, §5, is further amended to read:

**2. Unlawful alteration, misuse, divulging of formulas, transportation, disposal and noncompliance.** A person may not:

A. Detach, alter, deface or destroy, wholly or in part, any label or labeling provided for in this subchapter or rules adopted under this subchapter;

A-1. Add any substance to or take any substance from a pesticide in a manner that may defeat the purpose of this subchapter or rules adopted under this subchapter;

B. Use or cause to be used any pesticide in a manner inconsistent with its labeling or with rules of the board, if those rules further restrict the uses provided on the labeling;

C. Use for that person's own advantage or reveal, other than to the board or proper officials or employees of the state or federal executive agencies, to the courts of this State or of the United States in response to a subpoena, to physicians, or in emergencies to pharmacists and other qualified persons for use in the preparation of antidotes, any information relative to formulas of products acquired by authority of section 607 or any information judged by the board to contain or relate to trade secrets or commercial

or financial information obtained by authority of this subchapter and marked as privileged or confidential by the registrant;

D. Handle, transport, store, display or distribute pesticides in such a manner as to endanger human beings or their environment or to endanger food, feed or any other products that may be transported, stored, displayed or distributed with such pesticides;

E. Dispose of, discard or store any pesticides or pesticide containers in such a manner as may cause injury to humans, vegetation, crops, livestock, wildlife or beneficial insects or pollute any water supply or waterway;

F. Refuse or otherwise fail to comply with the provisions of this subchapter, the rules adopted under this subchapter~~,~~ or any lawful order of the board; ~~or~~

G. Apply pesticides in a manner inconsistent with rules for pesticide application adopted by the board~~.~~; or

H. Use or cause to be used any pesticide container inconsistent with rules for pesticide containers adopted by the board.

**Sec. 6. Board of Pesticides Control; rules.** The Department of Agriculture, Conservation and Forestry, Board of Pesticides Control shall adopt rules regulating pesticide containers as authorized in the Maine Revised Statutes, Title 7, section 606, subsection 2, paragraph H no later than January 1, 2023. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

**Sec. 7. Appropriations and allocations.** The following appropriations and allocations are made.

**AGRICULTURE, CONSERVATION AND FORESTRY, DEPARTMENT OF**

**Office of the Commissioner 0401**

Initiative: Provides allocations for position technology and STA-CAP costs.

| **OTHER SPECIAL REVENUE FUNDS** | **2021-22** | **2022-23** |
|---|---|---|
| All Other | $0 | $11,502 |
| OTHER SPECIAL REVENUE FUNDS TOTAL | $0 | $11,502 |

**Pesticides Control - Board of 0287**

Initiative: Provides allocations for one Environmental Specialist III position, one part-time Environmental Specialist II position, one part-time Office Associate II position and associated All Other costs.

| **OTHER SPECIAL REVENUE FUNDS** | **2021-22** | **2022-23** |
|---|---|---|
| POSITIONS - LEGISLATIVE COUNT | 0.000 | 1.000 |
| POSITIONS - FTE COUNT | 0.000 | 1.000 |
| Personal Services | $0 | $168,311 |
| All Other | $0 | $10,500 |
| OTHER SPECIAL REVENUE FUNDS TOTAL | $0 | $178,811 |

| AGRICULTURE, CONSERVATION AND FORESTRY, DEPARTMENT OF DEPARTMENT TOTALS | 2021-22 | 2022-23 |
|---|---|---|
| OTHER SPECIAL REVENUE FUNDS | $0 | $190,313 |
| DEPARTMENT TOTAL - ALL FUNDS | $0 | $190,313 |

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EPA

# Pesticide Update

EPA's Office of Chemical Safety and Pollution Prevention

## EPA Rebuilds Endocrine Disruptor Screening Program to Better Assess Human Endocrine Effects of Pesticides

**WASHINGTON** – Today, the U.S. Environmental Protection Agency (EPA) is announcing a strategic plan to ensure that its assessments of pesticides more closely, quickly, and effectively evaluate the potential for endocrine effects in humans. These strategies will also improve EPA's ability to protect against those effects as part of its pesticide decisions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and to implement the Endocrine Disruptor Screening Program (EDSP) under section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

"This plan is a major milestone in our efforts to ensure that pesticide decisions continue to protect human health," said **Deputy Assistant Administrator for Pesticide Programs for the Office of Chemical Safety and Pollution Prevention Jake Li.** "Starting with our highest priority chemicals, EPA will communicate more transparently our endocrine findings for humans, pulling from existing data when possible, and requesting new data when necessary to evaluate potential estrogen, androgen, and thyroid effects."

Endocrine systems, also referred to as hormone systems, are found in all mammals, birds, fish, and many other living organisms. The systems regulate many biological processes in the body from conception through adulthood and into old age, including the development of the brain and nervous system, the growth and function of the reproductive system, and metabolism and blood sugar levels.

Endocrine disruptors are chemicals that mimic, block, or disrupt the normal function of hormones. Following the 1996 amendment of FFDCA, EPA established EDSP to evaluate how pesticides and other chemicals may affect estrogen, androgen, and

thyroid systems. Since then, EPA has encountered several challenges with implementing EDSP. For example, the Agency has historically lacked scientific methods to rapidly and cost-effectively test thousands of chemicals for endocrine-disrupting effects. Further, EPA's FIFRA decisions rarely explained whether or how they fully obtained all needed endocrine data or complied with FFDCA by protecting humans from potential endocrine effects. EPA staff also received minimal support and direction from leadership in the last Administration to implement EDSP. Because of these and other issues, the Office of Inspector General issued a report in 2021 concluding that the Agency had made limited progress in implementing EDSP and recommending, among other things, that the Agency develop an EDSP strategic plan.

The strategic plan and supporting documents released today advance EDSP in several unprecedented ways.

**EPA will use its FIFRA process to obtain endocrine data and make endocrine decisions for human health**. Going forward, EPA will use its existing FIFRA data collection authorities to obtain the data it needs to make both FIFRA and EDSP decisions on whether the pesticide impacts the human estrogen, androgen, and thyroid systems, and will require any needed protections. Given the large number of pesticides awaiting these decisions, EPA is prioritizing the approximately 400 conventional pesticide active ingredients that are being registered for the first time or undergoing registration review.

**EPA will make endocrine decisions related to human health more expeditiously by using existing data when possible.** EPA routinely obtains data under FIFRA that are identical or comparable to data that EPA would have obtained through EDSP. Additionally, other existing studies may also inform EDSP findings. Where these data are sufficient to support EDSP findings under FFDCA, EPA will make those findings without seeking additional data. This minimizes duplicative and expensive animal testing and expedites EPA’s ability to make those findings without waiting for new studies. To support the strategic plan, EPA is releasing a science paper that addresses longstanding questions about which types of existing data can inform endocrine findings under FIFRA and FFDCA.

After evaluating available data for 403 conventional pesticides, EPA has determined it has adequate estrogen and androgen data for 86 of these chemicals. Thus, as part of registration review, after assessing for potential thyroid effects, EPA can make final EDSP decisions on the potential for these chemicals to impact the human estrogen, androgen, and thyroid systems. Similarly, EPA has determined it has sufficient data for 52 pesticide chemicals (50 conventional active ingredients and two inert ingredients) it prioritized in 2009 to assess the potential for these chemicals to impact the human estrogen, androgen, and thyroid systems. Now, as a supplement to the strategic plan, the Agency is communicating its final EDSP decisions relating to impacts on the human estrogen, androgen, and thyroid pathways for these 52 chemicals.

Because the science on the human endocrine system evolves constantly, especially for thyroid, EPA anticipates seeking in 2025 scientific peer review on scientific advancements and on its current approach to thyroid assessments. The Agency will then determine whether to update its approach.

**In the near-term, EPA will require additional endocrine data for human health for 30 pesticides.** EPA has identified 30 high-priority pesticides that require additional data on potential human estrogen and/or androgen effects. These pesticides are considered high priority because preliminary data indicate the chemicals may cause activity in the endocrine system. EPA is seeking available data or information on these chemicals for 60 days as part of a public comment period. Additionally, to fill any remaining data gaps, the Agency intends to issue FIFRA human health data requests for these chemicals in the spring of 2024. EPA is also seeking available data or other information to evaluate endocrine data needs for a second group of 126 conventional pesticides for which the Agency's initial analysis has found limited endocrine data. For 161 additional conventional pesticides, the Agency will determine which ones it needs to obtain updated endocrine data for in the coming years as part of registration review.

The comment period for this action will open Friday, October 27. Once available, interested parties can submit data or a comment in docket EPA-HQ-OPP-2023-0474 at www.regulations.gov.

Subscriber Services:

Pesticide Questions? Contact Us | TSCA Questions? Contact Us

Manage Preferences or Unsubscribe | Help

This email was sent to pamela.j.bryer@maine.gov using GovDelivery Communications Cloud on behalf of: U.S. EPA Office of Chemical Safety and Pollution Prevention · 707 17th St, Suite 4000 · Denver, CO 80202 · 1-800-439-1420

GOVDELIVERY

# Understanding Bulletins Live! Two

Original Webinar 2019: Steve Lennartz, BLT System Administrator

**This 2023 Webinar is an update of the 2019 webinar**

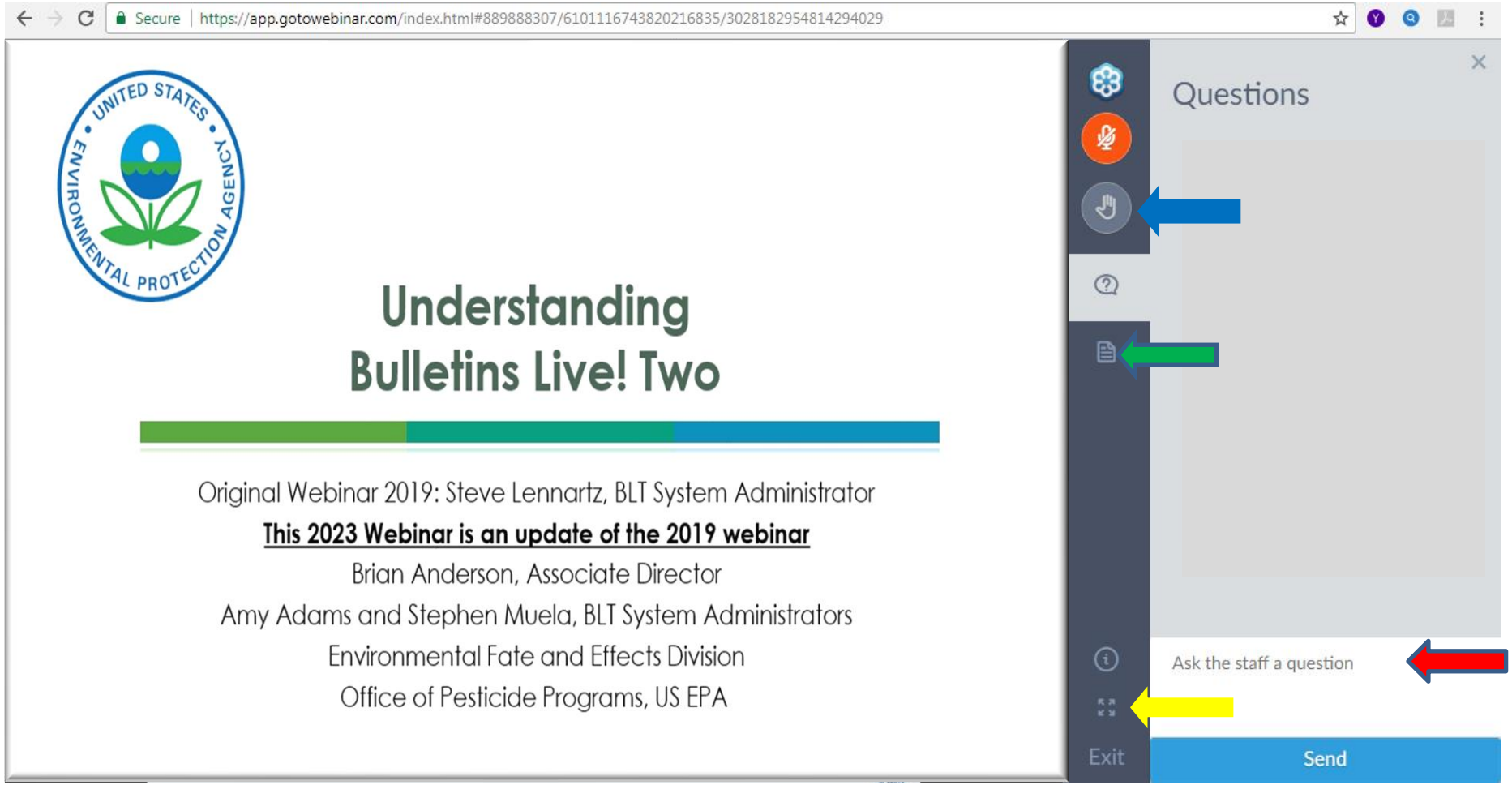
Brian Anderson, Associate Director

Amy Adams and Stephen Muela, BLT System Administrators

Environmental Fate and Effects Division

Office of Pesticide Programs, US EPA

# Tips for Participants



# 2023 update focused on how Bulletins Live! Two (BLT) works

https://www.epa.gov/endangered-species/bulletins-live-two-view-bulletins 67%

An official website of the United States government Here's how you know

EPA United States Environmental Protection Agency

Search EPA.gov

Environmental Topics | Laws & Regulations | Report a Violation | About EPA

Endangered Species

CONTACT US

## Bulletins Live! Two -- View the Bulletins

For assistance in using Bulletins Live! Two, view the tutorial. Also see background, notes and a quick start guide for BLT.

**Directions**

This tool displays Pesticide Use Limitation Areas (PULAs) for products with active Endangered Species Protection Bulletins. To generate a printable bulletin, please follow these steps:

1. Navigate to your intended pesticide application area by using the "Location Search" tool or panning and zooming on the map itself.
2. Select your Application Month from the Application Date dropdown.
3. Search for a specific pesticide product using the EPA registration number and selecting from the search results. If you need assistance finding this registration number, consult the

Unpin

**Location Search:**

Find Place

**Application Month:**

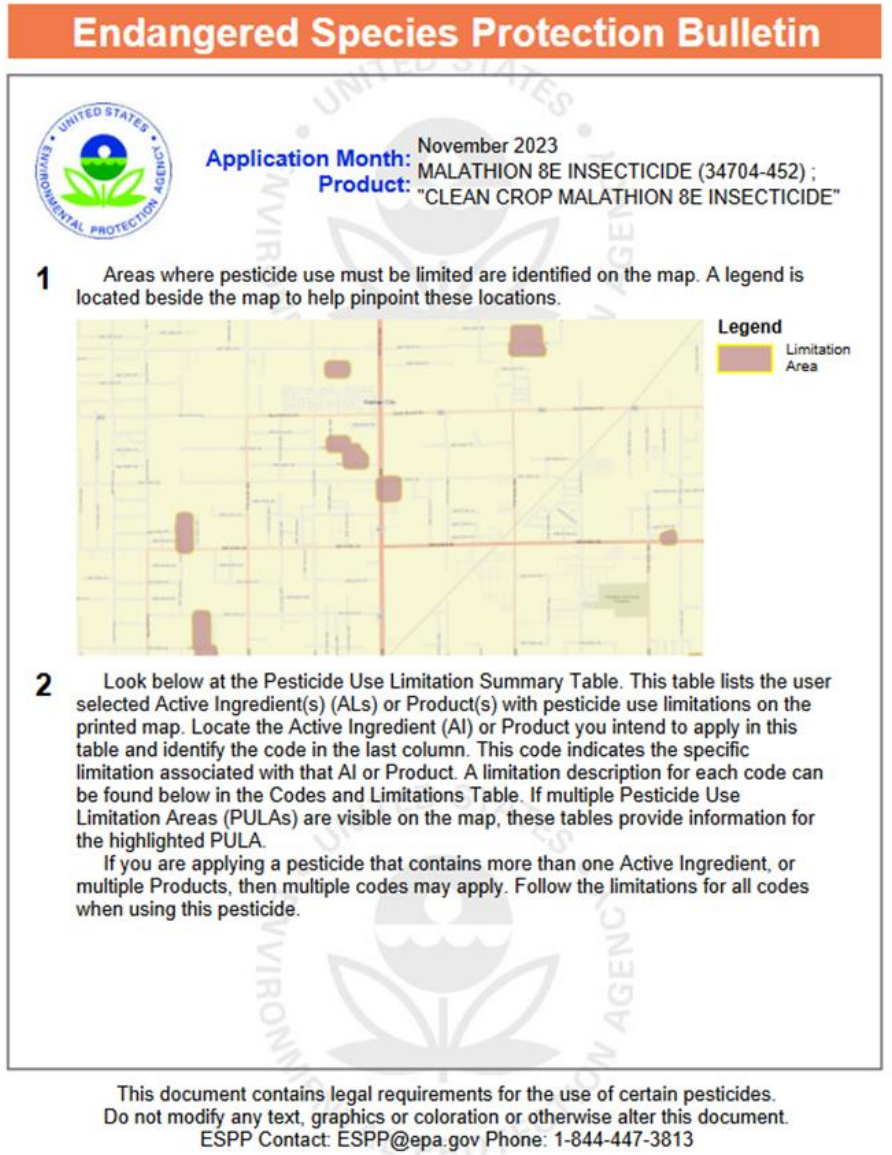
November 2023

**EPA Registration Number:**

# EPA Today's Topics

- **Webinar Purpose**: to provide an overview of the Bulletins Live! Two system, what pesticide applicators need to know about complying with Bulletins, and how and when to access the system and locate applicable bulletins.

- Introduction
  - Overview of Bulletins Live! Two
  - Connection of Bulletins with pesticide labeling
- Demonstration of Bulletins Live! Two
- Frequently Asked Questions
- Contacts



**Endangered Species Protection Bulletin**

**Application Month:** November 2023
**Product:** MALATHION 8E INSECTICIDE (34704-452) ; "CLEAN CROP MALATHION 8E INSECTICIDE"

1 Areas where pesticide use must be limited are identified on the map. A legend is located beside the map to help pinpoint these locations.

Legend
Limitation Area

2 Look below at the Pesticide Use Limitation Summary Table. This table lists the user selected Active Ingredient(s) (ALs) or Product(s) with pesticide use limitations on the printed map. Locate the Active Ingredient (AI) or Product you intend to apply in this table and identify the code in the last column. This code indicates the specific limitation associated with that AI or Product. A limitation description for each code can be found below in the Codes and Limitations Table. If multiple Pesticide Use Limitation Areas (PULAs) are visible on the map, these tables provide information for the highlighted PULA.

If you are applying a pesticide that contains more than one Active Ingredient, or multiple Products, then multiple codes may apply. Follow the limitations for all codes when using this pesticide.

This document contains legal requirements for the use of certain pesticides.
Do not modify any text, graphics or coloration or otherwise alter this document.
ESPP Contact: ESPP@epa.gov Phone: 1-844-447-3813

- **Endangered Species Act (ESA)**
  - Intended to protect and promote the recovery of plants and animals in danger of becoming extinct.
  - Section 7(a)(2) of the ESA requires federal ("action") agencies to insure that any action they authorize, fund or carry out is not likely to jeopardize the continued existence of a federally-listed species or result in destruction or adverse modification of designated critical habitat.
  - FIFRA "actions" subject to the consultation provisions of the ESA may include registering pesticides.

# Introduction (cont.)

- **Endangered Species Protection Program (ESPP)**
  - Helps promote the recovery of listed species
  - Designed to help meet ESA obligations
  - If limitations on pesticide use are necessary to protect listed species in that area, the information is relayed through Endangered Species Protection Bulletins
  - Goal of the pesticide use limitations: to carry out responsibilities under FIFRA in compliance with ESA, without placing undue burden on agriculture and other pesticide users





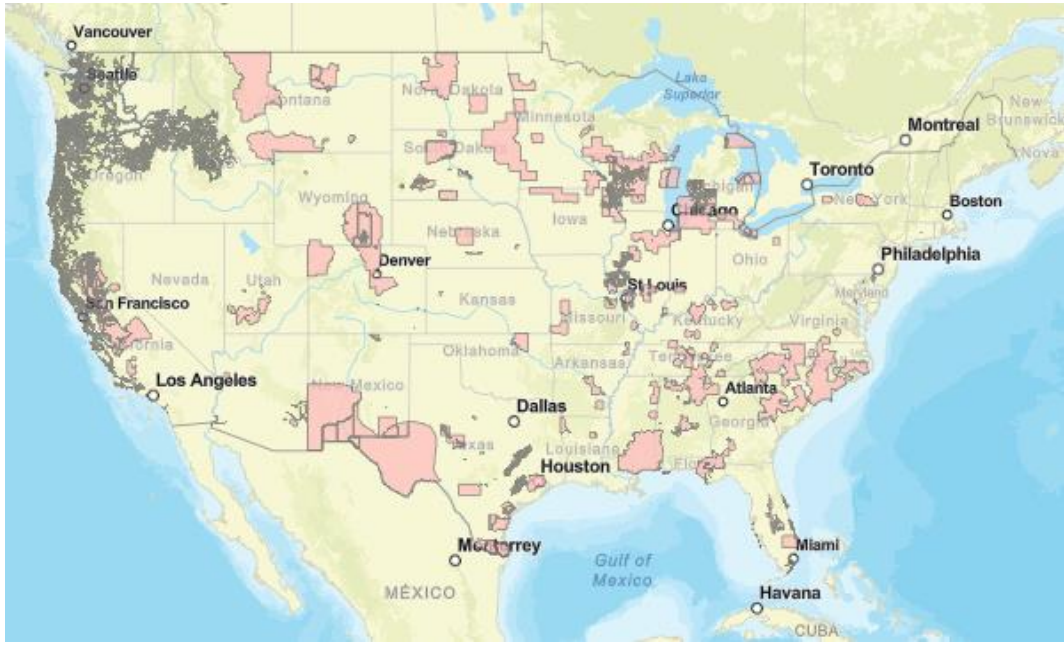
# Why Web-based Mapping for Endangered Species Protections is Used

- Accessibility to a variety of Bulletins Live! Two Users
  - State Lead Agencies
  - Pesticide Applicators
  - Others

- When directed by a product label, pesticide applicators are required to visit the BLT website and follow any mitigations specified for the intended application area and product.

- Allows for location-specific protections

- Information provided by Bulletins includes
  - Location of use limitations
  - Products with limitations
  - Terms of the limitation
  - Does not include identification of species

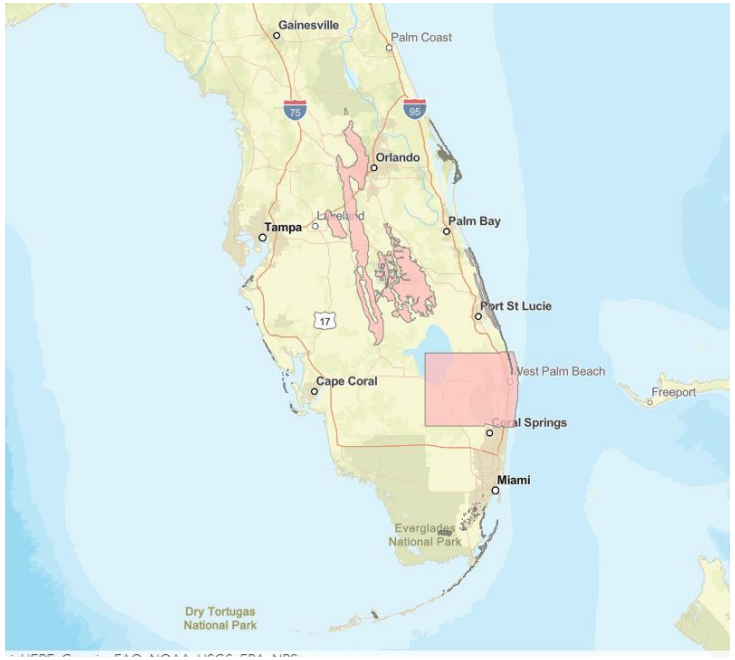


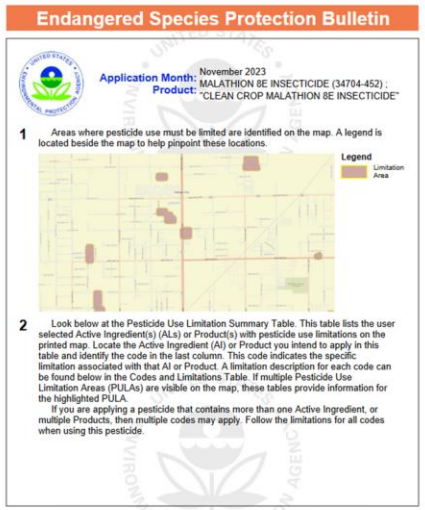
# When Does EPA Create Bulletins?

- If geographically explicit label instructions are needed, then EPA may create Bulletins as part of its regulatory actions
- Goal of Bulletins is to protect listed species and/or their critical habitat in specific locations and, in some cases, during certain times of the year
- EPA plans to create additional Bulletins as it completes registration actions and ESA consultations

# Pesticide Use Limitation Area (PULA) Versus a Bulletin

- Pesticide Use Limitation Area (PULA)- Geographic area where a pesticide limitation(s) specific to listed species applies

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If you are applying a pesticide that contains more than one Active Ingredient, or multiple Products, then multiple codes may apply. Follow the limitations for all codes when using this pesticide.

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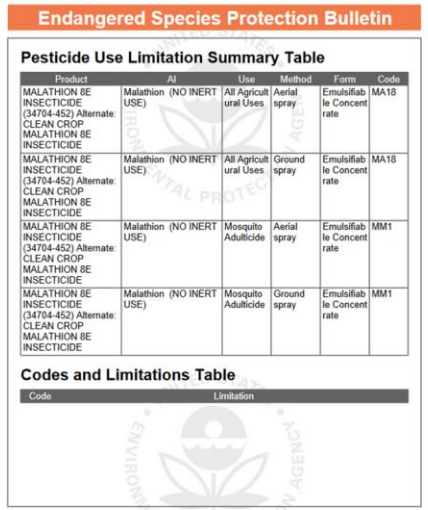
Endangered Species Protection Bulletin

Pesticide Use Limitation Summary Table

| Product | AI | Use | Method | Form | Code |
|---|---|---|---|---|---|
| MALATHION 8E INSECTICIDE (34704-452) Alternate: CLEAN CROP MALATHION 8E INSECTICIDE | Malathion (NO INERT USE) | All Agricultural Uses | Aerial spray | Emulsifiable Concentrate | MA18 |
| MALATHION 8E INSECTICIDE (34704-452) Alternate: CLEAN CROP MALATHION 8E INSECTICIDE | Malathion (NO INERT USE) | All Agricultural Uses | Ground spray | Emulsifiable Concentrate | MA18 |
| MALATHION 8E INSECTICIDE (34704-452) Alternate: CLEAN CROP MALATHION 8E INSECTICIDE | Malathion (NO INERT USE) | Mosquito Adulticide | Aerial spray | Emulsifiable Concentrate | MM1 |
| MALATHION 8E INSECTICIDE (34704-452) Alternate: CLEAN CROP MALATHION 8E INSECTICIDE | Malathion (NO INERT USE) | Mosquito Adulticide | Ground spray | Emulsifiable Concentrate | MM1 |

Codes and Limitations Table

| Code | Limitation |
|---|---|

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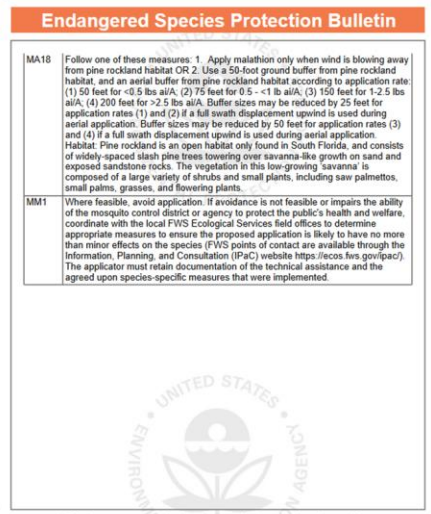
Endangered Species Protection Bulletin

| | |
|---|---|
| MA18 | Follow one of these measures: 1. Apply malathion only when wind is blowing away from pine rockland habitat OR 2. Use a 50-foot ground buffer from pine rockland habitat, and an aerial buffer from pine rockland habitat according to application rate: (1) 50 feet for <0.5 lbs ai/A; (2) 75 feet for 0.5 - <1 lb ai/A; (3) 150 feet for 1-2.5 lbs ai/A; (4) 200 feet for >2.5 lbs ai/A. Buffer sizes may be reduced by 25 feet for application rates (1) and (2) if a full swath displacement upwind is used during aerial application. Buffer sizes may be reduced by 50 feet for application rates (3) and (4) if a full swath displacement upwind is used during aerial application. Habitat: Pine rockland is an open habitat only found in South Florida, and consists of widely-spaced slash pine trees towering over savanna-like growth on sand and exposed sandstone rocks. The vegetation in this low-growing 'savanna' is composed of a large variety of shrubs and small plants, including saw palmettos, small palms, grasses, and flowering plants. |
| MM1 | Where feasible, avoid application. If avoidance is not feasible or impairs the ability of the mosquito control district or agency to protect the public's health and welfare, coordinate with the local FWS Ecological Services field offices to determine appropriate measures to ensure the proposed application is likely to have no more than minor effects on the species (FWS points of contact are available through the Information, Planning, and Consultation (IPaC) website https://ecos.fws.gov/ipac/). The applicator must retain documentation of the technical assistance and the agreed upon species-specific measures that were implemented. |

This document contains legal requirements for the use of certain pesticides. Do not modify any text, graphics or coloration or otherwise alter this document. ESPP Contact: ESPP@epa.gov Phone: 1-844-447-3813

- Bulletin – The PDF from the Bulletins Live! Two application that provides the limitation information for your application site and month
  - If you would like to save the Bulletin for your own records, you can

# Pesticide Use Limitation Area (PULA) Versus Species Range

- PULAs should not be confused with species ranges
- Species range maps show where listed species live, are suspected to live, and areas that impact the species' survival in some way
- PULAs are intended to apply only to areas where pesticide use limitations are needed and may be any of the following:
  - a small area within a species range;
  - applicable only to certain habitats within a species' range; or
  - applicable anywhere a use site is located within a species' range

# Using and Understanding Bulletins Live! Two

- Topics Covered During the Demonstration
  - How to get started by reading the label
  - Using the map application tools
  - Identifying the intended pesticide application area
  - Selecting the application month
  - Refining your search
  - Selecting a PULA
  - Saving/Printing a PDF of a Bulletin, if you would like to save one for your own records.
  - Understanding the components of the Bulletin

**DISCLAIMER:**
**This example is only for demonstrating where to find an EPA Reg. No. on a label, it is not intended as a product endorsement**

Fyfanon ULV Mosquito
EPA Reg No 279-3539

| MALATHION | GROUP | 1B | INSECTICIDE |
|---|---|---|---|

# Fyfanon® ULV Mosquito

ULTRA LOW VOLUME CONCENTRATE INSECTICIDE

**FOR USE ONLY BY FEDERAL, STATE, TRIBAL, OR LOCAL GOVERNMENT OFFICIALS RESPONSIBLE FOR PUBLIC HEALTH OR VECTOR CONTROL, OR BY PERSONS CERTIFIED IN THE APPROPRIATE CATEGORY OR OTHERWISE AUTHORIZED BY THE STATE OR TRIBAL LEAD PESTICIDE REGULATORY AGENCY TO PERFORM ADULT MOSQUITO CONTROL APPLICATIONS, OR BY PERSONS UNDER THEIR DIRECT SUPERVISION.**

| **ACTIVE INGREDIENT:** | |
|---|---|
| Malathion* | 96.5% |
| **OTHER INGREDIENTS:** | 3.5% |
| **TOTAL:** | 100.0% |

* O,O-dimethyl phosphorodithioate of diethyl mercaptosuccinate.
Contains 9.9 lbs. malathion per gallon

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

**SEE [OTHER PANELS] [INSIDE] [BOOKLET] [BACK PANEL] FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND USE DIRECTIONS**

EPA Reg. No.279-3539
NET Contents: _____

EPA Est. No: XXXX-XXX-XXX

FMC Corporation
2929 Walnut Street
Philadelphia, PA 19104

Product of Denmark
® Fyfanon is a registered trademark of FMC Corporation or an affiliate

**ACCEPTED**
08/23/2023
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 279-3539

**DISCLAIMER:**
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Fyfanon ULV Mosquito
EPA Reg No 279-3539

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Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 279-3539

# Using and Understanding Bulletins Live! Two (cont.): *Old* label instructions

**Endangered Species Requirements** – Use of this product in a manner inconsistent with its labeling may pose a hazard to endangered or threatened species. When using this product, you must follow the measures contained in the Endangered Species Bulletin for the area in which you are applying the product. To obtain Bulletins, no more than six months before using this product, consult:

https://www.epa.gov/endangered-species/endangered-species-protection-bulletins or call 1-844- 447-3813. You must use the Bulletin valid for the month in which you will apply the product.

# Using and Understanding Bulletins Live! Two (cont.): *New* label instructions

**Endangered Species Requirements** – Before using this product, you must obtain any applicable Endangered Species Protection Bulletins (Bulletins) within six months prior to or on the day of application. To obtain Bulletins, go to Bulletins Live! Two (BLT) at **https://www.epa.gov/pesticides/bulletins**. When using this product, you must follow all directions and restrictions contained in any applicable Bulletin(s) for the area where you are applying the product, including any restrictions on application timing if applicable. It is a violation of Federal law to use this product in a manner inconsistent with its labeling, including this labeling instruction to follow all directions and restrictions contained in any applicable Bulletin(s). For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov

# Using and Understanding Bulletins Live! Two (cont.)

**Note there are two links, both direct to the same place:**

https://www.epa.gov/pesticides/bulletins

**OR**

https://www.epa.gov/endangered-species/endangered-species-protection-bulletins

## Endangered Species

CONTACT US

- Endangered Species Home
- About the Endangered Species Protection Program
- Assessing Pesticides Under the Endangered Species Act
- Endangered Species: Information For Pesticides Users
- Litigation on Endangered Species and Pesticides
- **Bulletins Live!**
- For Kids

# Endangered Species Protection Bulletins

Endangered Species Protection Bulletins are a part of EPA's Endangered Species Protection Program. Bulletins set forth geographically specific pesticide use limitations for the protection of threatened and endangered (listed) species and their designated critical habitat.

- Obtain Bulletins using EPA's Bulletins Live! Two application.
- Read the tutorial Bulletins Live! Two.
- Go to the quick start guide.
- View the April 2019 webinar for Bulletins Live! Two.
- Learn How to locate the EPA Registration number to search for product in Bulletins Live! Two.

If your pesticide label directs you to this website, you are required to follow the pesticide use limitation(s) found on your label and in the Bulletins Live! Two system for your intended application area, pesticide product, and application month. You may not see any geographically specific use limitations for the product you are applying even if your label directed you to this website because either:

1. EPA has not yet completed the process of identifying whether additional geographically specific use limitations are needed; or
2. there are no additional geographically specific use limitations required for the time period and location you plan to apply the pesticide product.

EPA continues to complete Endangered Species Act consultations and update the Bulletins Live! Two system with additional geographically specific use limitations that may be applicable to your pesticide product in the future. Therefore, before you apply a pesticide, check to see if new or additional directions for the product have been added to Bulletins Live! Two. It's important to note, you have a six-month window to obtain a bulletin before you apply a pesticide (e.g., you

# Summary

- Follow the labeling instructions
- If directed by the product label, visit the Bulletins Live! Two website to check for any Bulletins for your application site and month
- If you would like to save a copy of the Bulletin for your own records, you can
- If your application location changes or the application timing is to occur later than the intended application month that you originally checked, check BLT again
- Contact the ESPP help desk to resolve any questions you may have

# Frequently Asked Questions- General

- The ESPP help desk inbox (espp@epa.gov) and hotline (1-844-447-3813) receives inquiries a few times per month on average.
  - If a human doesn't answer when you call by phone, please leave a message and a human will get back to you.
  - Sometimes we can respond to email more quickly. If your inquiry is especially urgent, write URGENT in the email subject line.
- More inquiries are received when a new Bulletin is released
- Some local pesticide regulators or trade groups will bundle questions and send them directly to the point of contact for a specific chemical.
- Following are some common questions that have been submitted

# Frequently Asked Questions (cont.)

- *Are Bulletins enforceable?*
  - Yes. When directed by a product label, pesticide applicators are required to visit the BLT website and follow any additional mitigations in the intended application area. When users are directed to check Bulletins Live! Two on a pesticide label, Bulletins are enforceable mitigations under FIFRA.
  - Not following the limitation on your Bulletin is a misuse of the pesticide and enforceable under FIFRA
  - If this misuse results in "take" of listed species, the action is also enforceable under the Endangered Species Act by the US Fish and Wildlife Service and National Marines Fisheries Service

# Frequently Asked Questions (cont.)

- *Why can't we see what species the mitigations are for?*
  - At the request of the USFWS and NMFS, species identifications were removed to discourage possible collection or disturbance of listed species by the public.





# Frequently Asked Questions (cont.)

- *My state has several listed species, but the limitations on Bulletins don't seem to match, why?*
  - Bulletins may rely on range data from USFWS and NMFS or are identified through the consultation process with these federal services, which may differ from state agencies by comparison
  - Bulletins are for federally-listed (not state-listed) species.
  - Not all species may be at risk and need Bulletins

# Frequently Asked Questions (cont.)

*What browsers are compatible with Bulletins?*

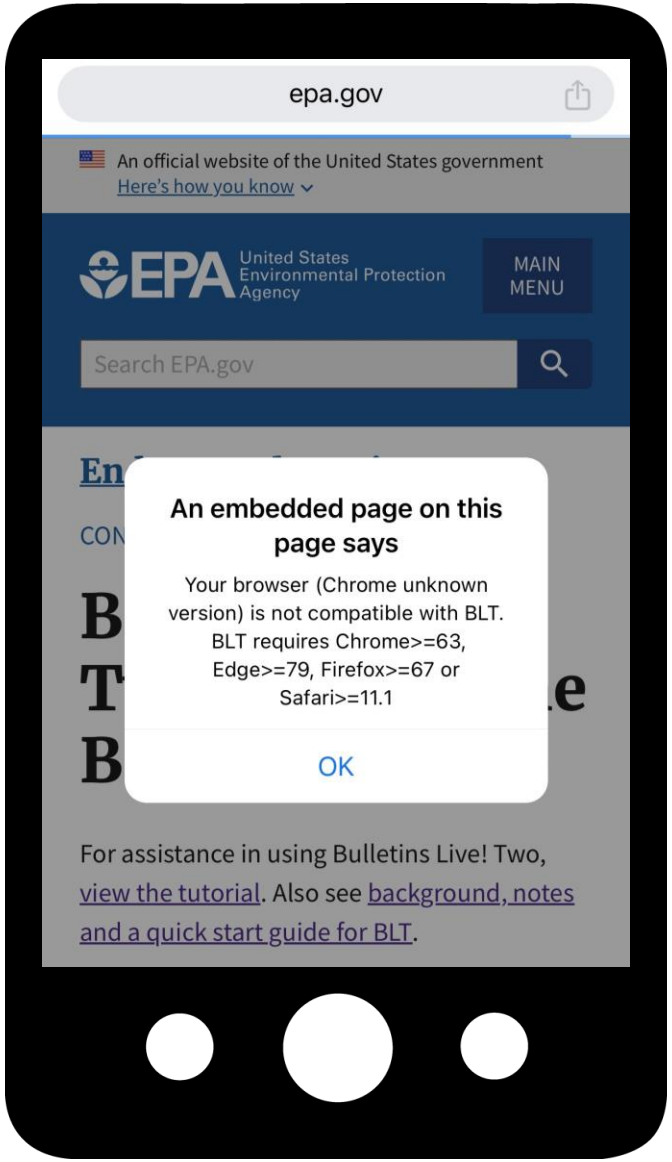
- Google Chrome;
- Microsoft Edge;
- Mozilla Firefox; or
- Safari.
- Looking into improving BLT compatibility with mobile devices (Tablets, Phones, etc.) - see following slides about phone use
- BLT works on most web formats. Not all have been tested. Please share feedback specific to your device and version to the ESPP help desk.

# Notes about using BLT on the phone

- *Does the BLT website work on my cell phone web browser?*
  - Yes, it should be functional on the phone.
    - There was a period of time earlier in 2023 where it was not working on phones, this has been addressed.
    - Contact us and provide the cell phone make/model and web browser if you discover BLT is not working.
    - BLT does not currently exist as an app, you must use your cell phone's web browser to access it.

# Notes about using BLT on the phone

- It is possible you may get a warning message when accessing BLT on the phone.
  - Select "OK" and you should be able to continue using BLT.
  - If you have difficulty reading table text in the website, try holding the phone horizontally.
  - If you *still* have difficulty reading text in any website tables, download the pdf to your phone & read from that.
    - Text may sometimes wrap oddly in the phone browser, depending on the phone screen size.



# Frequently Asked Questions (cont.)

- *Why doesn't the search engine on the Bulletins web application include names for products?*
  - Search using EPA registration numbers. Registration numbers remain consistent.
  - EPA relies on the trade names as supplied by the registrant at the time the Bulletin is created. This name will fill in as you enter the EPA registration number in the search bar.

# Frequently Asked Questions (cont.)

- *What is the difference between an EPA registration number and other numbers found on the product label?*

- **EPA registration number:** An EPA registration number can be found on the product label. Look for "EPA Reg. No." followed by two or three sets of numbers.
  - If your product's registration number has two parts (ex. 1234-12), it has a primary registration number. This is the number that should be entered into the product search in Bulletins Live! Two.

- **Supplemental Distributor Product Number:** If your product's registration number has three parts (ex. 1234-12-123), you have a supplemental distributor product. These products have the same chemical composition and efficacy as primary products, but often have different brand or product names. Enter the first two parts of this registration number (ex. 1234-12-123) into the EPA registration search in Bulletins Live! Two.
- Continues on next slide

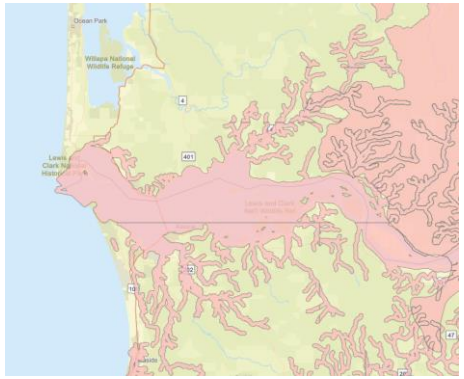
# Frequently Asked Questions (cont.)

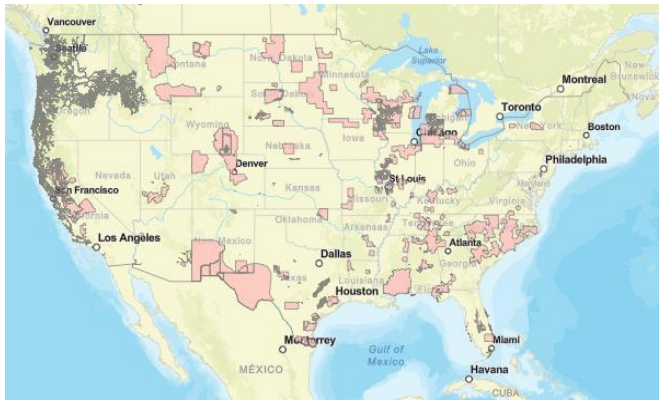
- **Special Local Needs Number:** If your label has "EPA SLN No." followed by the two-letter state designation, then a 6-digit number (ex. EPA SLN No. NC950034). This is a Special Local Need registration number (SLN number) also known as a FIFRA Section 24(c) Registration Number. These Registrations are issued by the states to meet special local needs.
  - Searching with an SLN number will yield no results within the Bulletins Live! Two EPA registration number search. A label that has an SLN should also have a primary registration number that can be entered in BLT.
  - You need to be aware of and follow pesticide use limitations in your area according to both the state AND federal requirements.

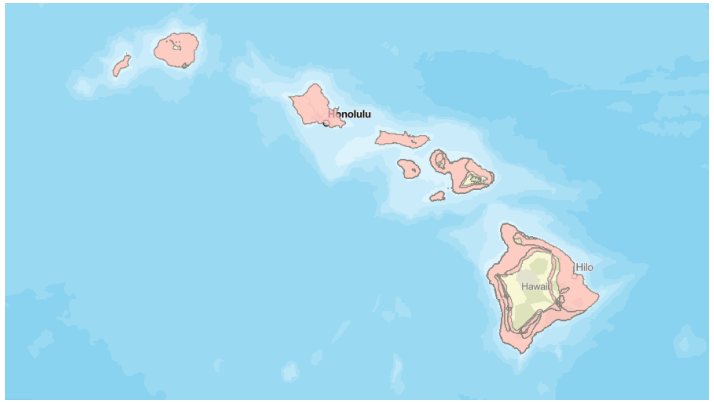
- **Establishment Number:** The EPA Establishment Number "EPA Est. No." should be printed near the EPA Reg. No. Letters normally appear in the middle of the EPA Est. No., setting it apart from the EPA Reg. No. (ex. EPA Est. No. 12345-XY-123). The EPA Est. No. is also typically longer than the EPA Reg. No. It identifies the facility that produced the pesticide and is not used in BLT.

# Frequently Asked Questions (cont.)

- *How often are bulletins updated? For example, what if the spatial area was built using particular information about a species or its habitat that then changes?*
  - Generally, PULA boundaries and/or Bulletins mitigations will not change until the next registration action occurs.
  - However, EPA is exploring options for the broader ESA strategies to allow for changes to PULAs and mitigation options as data evolves





# Frequently Asked Questions (cont.)

- *Understanding the 6-month window between obtaining a Bulletin and application of the pesticide, and if there are changes/additions to a PULA after the Bulletin is printed and before the pesticide is applied.*

- EPA continues to complete Endangered Species Act consultations and update the Bulletins Live! Two system with additional geographically specific use limitations that may be applicable to your pesticide product in the future. Therefore, before you apply a pesticide, check to see if new or additional directions for the product have been added to Bulletins Live! Two. It's important to note, you have a six-month window to obtain a bulletin before you apply a pesticide (e.g., you can obtain a bulletin January 1-July 1 if you plan to apply the pesticide on July 1). If the application month needs to be later, then you need to check the system again during the six month window before the new date (e.g. You can obtain a bulletin February 1-August 1 if you intend to apply August 1 instead of July 1).

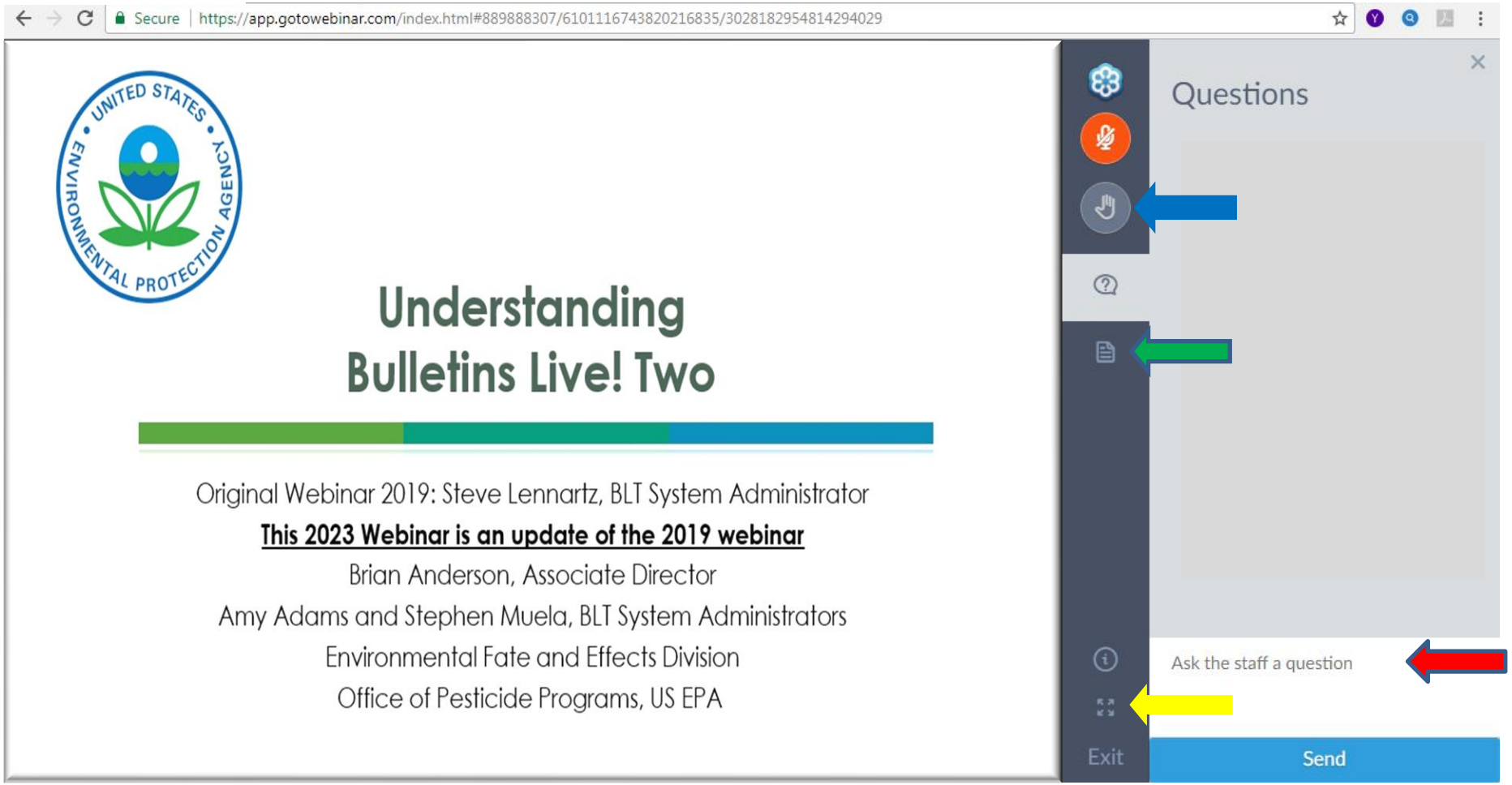
# Where to direct questions?

- Endangered Species Protection Program
  - Help desk inbox
    - espp@epa.gov
  - Hotline
    - 1-844-447-3813
    - Your label may have several phone numbers on it. Review it carefully to ensure you are calling the BLT number.

# Resources

- Bulletins Live! Two
  - https://www.epa.gov/endangered-species/bulletins-live-two- view-bulletins
- Tutorial
  - https://www.epa.gov/endangered-species/bulletins-live-two-blt- tutorial
- Quick Start Guide
  - https://www.epa.gov/endangered-species/endangered- species-protection-bulletins#quick
- How to locate the EPA registration number to search BLT
  - https://www.epa.gov/endangered-species/endangered-species-protection-bulletins#how-to

# Submit Your Related Questions



# Questions?

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# EPA – Endangered Species Workplan Development and Implementation

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PRESENTED BY:
Steven Dwinell
Director, PHARM

# EPA and the Endangered Species Act (ESA)

*Federal Endangered Species Act - 16 U.S.C. §1531 et seq. (enacted in 1973)*

- As a Federal Agency - EPA must:
  Ensure that actions it authorizes, funds, or carries out –
  - do not jeopardize the continued existence of any listed species
  - result in the destruction or adverse modification of designated critical habitat of such species.
- ESA prohibits any action that causes a "taking" of any listed species of endangered fish or wildlife.
- EPA must consult with the U.S. Fish and Wildlife Service (FWS) and/or the NOAA Fisheries Service (NMFS) on actions that could affect listed species

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- Registration of a pesticide is an “agency action”
- Subject to the provisions of ESA
- Therefore – registration cannot result in “jeopardy” or “adverse habitat modification” - JAM

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- Practice was to consult with USFWS and NMFS on each pesticide active ingredient and each listed species
- Resulted in a Biological Opinion from the Services
- Resulted in geographically specific restrictions for certain practices for certain species
- Implemented through County Bulletins – now Bulletins Live Two (BLT)

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- Process was time consuming – 4 to 15 years to complete
- Impacts on pesticide users limited to specific areas for specific species
- EPA has completed <5% of consultations needed
- Over 20 lawsuits for failure to complete process
- EPA was ordered by courts to implement ESA provisions
- Courts could order restrictions on pesticide use
- Resulted in uncertainty for pesticide users and crop producers

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- New strategy adopted in 2022:
  - Meet ESA obligations when registering new conventional pesticides
  - Incorporate mitigation measures before consultations have been completed or even begun
  - Evaluate types of pesticides as a group (e.g. herbicides, insecticides, rodenticides) relative to JAM considerations
  - Apply protections over broader areas and crop types as a preventive measure
  - Apply mitigation measures to types of pesticides, not just specific active ingredients

**EPA is committed to this approach and making rapid progress**

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# Selected Milestones

- **April 2022** – Balancing Wildlife Protection and Responsible Pesticide Use – How EPA's Pesticide Program will meet its ESA Obligations (Workplan)
- **November 2022** – ESA Workplan Update
- **June 2023** – Draft Technical Document for support of Interim Ecological Measures
- **June 2023** – Vulnerable Species Pilot Project
- **July 2023** – Herbicide Strategy

Still to come:

Insecticide Strategy -Rodenticide Strategy

# Comment Opportunities

- Public comment periods of 45-60 days
- Only one comment period extensions so far
- These proposal are detailed and extensively documented
- EPA is meeting with industry and SLA groups outside of public comment period to get input
- Still open to suggestions and ideas

https://www.epa.gov/endangered-species/epas-workplan-and-progress-toward-better-protections-endangered-species

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# Selected Milestones

- **April 2022 – Balancing Wildlife Protection and Responsible Pesticide Use – How EPA's Pesticide Program will meet its ESA Obligations**
- Describes EPA's approach – the "Workplan"

- **November 2022 – ESA Workplan Update**
- Describes efforts to reduce pesticide exposure to non-target organisms as part of FIFRA registration actions
- Includes menu of "Interim Ecological Mitigations" that can be included as directions for use on pesticide labels

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## November 2022 – ESA Workplan Update

- Includes FIFRA Interim Ecological Mitigation (IEM) measures intended to reduce risk to non-target organism
- Will be included in registration decisions, even before re-registration is completed (Interim Decisions)
- Intended for Agricultural crops uses
- Implemented on labels (not in Bulletins)

**Represents a major change in the way ecological risks are managed**

**Will require certain land use practices in order to use a labeled pesticide**

***Soil and water conservation practices that were voluntary will be required to meet conditions of use on label.***

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# Example IEMs:

In order to mitigate exposure from surface water run-off or soil erosion:

- Pesticide use directions will require one or more of the following in order to comply with label directions for use:
    - Vegetative filter strip (minimum width 30 ft for surface water runoff, 20 ft for soil erosion)
    - Field border
    - Field terracing/ contour buffer strips
    - Contour farming
    - Cover cropping
    - No/reduce tillage
    - Grassed waterways
    - Riparian buffer zone/ riparian herbaceous zone
    - Vegetative/grassed ditch banks
    - Runoff retention pond/ water and sediment control basin/ sediment catchment basin/ constructed wetland
    - Strip cropping
    - Vegetative barriers
    - Mulching with natural materials
    - Alley cropping

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Including these conditions raises many questions:

- Definition of the terms (example:  grassed waterways)
- Education and training of applicators
- Enforcement of directions for use
- Documentation of compliance with label instructions
- Applicability of data showing reduced risk from certain products or certain use rates
- Involvement of CCAs, NRCS, SCDs – some agreements are currently confidential

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Labels will also reference Bulletins Live Two (BLT)

https://www.epa.gov/endangered-species/bulletins-live-two-view-bulletins

**Example Label Language:**

*When using this product, you must follow the measures, including any timing restrictions, contained in the Endangered Species Protection Bulletin for the area where you are applying the product. Before using this product, you must obtain a Bulletin at any time within six months of the day of application. To obtain Bulletins, consulthttp://www.epa.gov/espp. For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov.*

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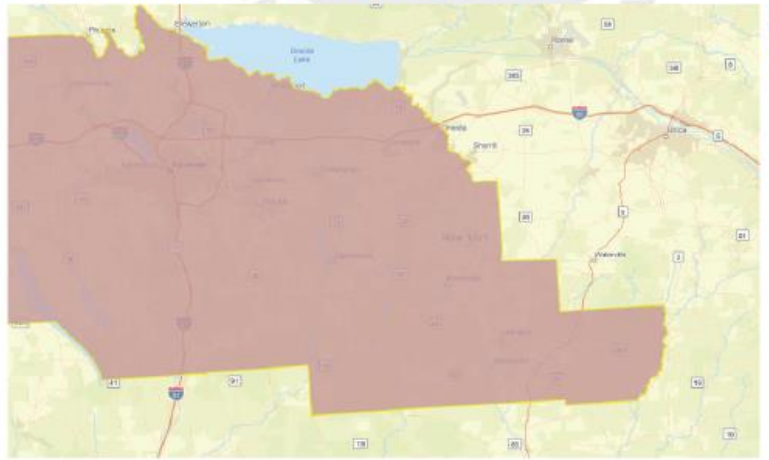
## Endangered Species Protection Bulletin

**Application Month:** October 2023
**Product:** All products with limitations in selected area

1 Areas where pesticide use must be limited are identified on the map. A legend is located beside the map to help pinpoint these locations.




2 Look below at the Pesticide Use Limitation Summary Table. This table lists the user selected Active Ingredient(s) (ALs) or Product(s) with pesticide use limitations on the printed map. Locate the Active Ingredient (AI) or Product you intend to apply in this table and identify the code in the last column. This code indicates the specific limitation associated with that AI or Product. A limitation description for each code can be found below in the Codes and Limitations Table. If multiple Pesticide Use Limitation Areas (PULAs) are visible on the map, these tables provide information for the highlighted PULA.

If you are applying a pesticide that contains more than one Active Ingredient, or multiple Products, then multiple codes may apply. Follow the limitations for all codes when using this pesticide.

This document contains legal requirements for the use of certain pesticides.
Do not modify any text, graphics or coloration or otherwise alter this document.
ESPP Contact: ESPP@epa.gov Phone: 1-844-447-3813

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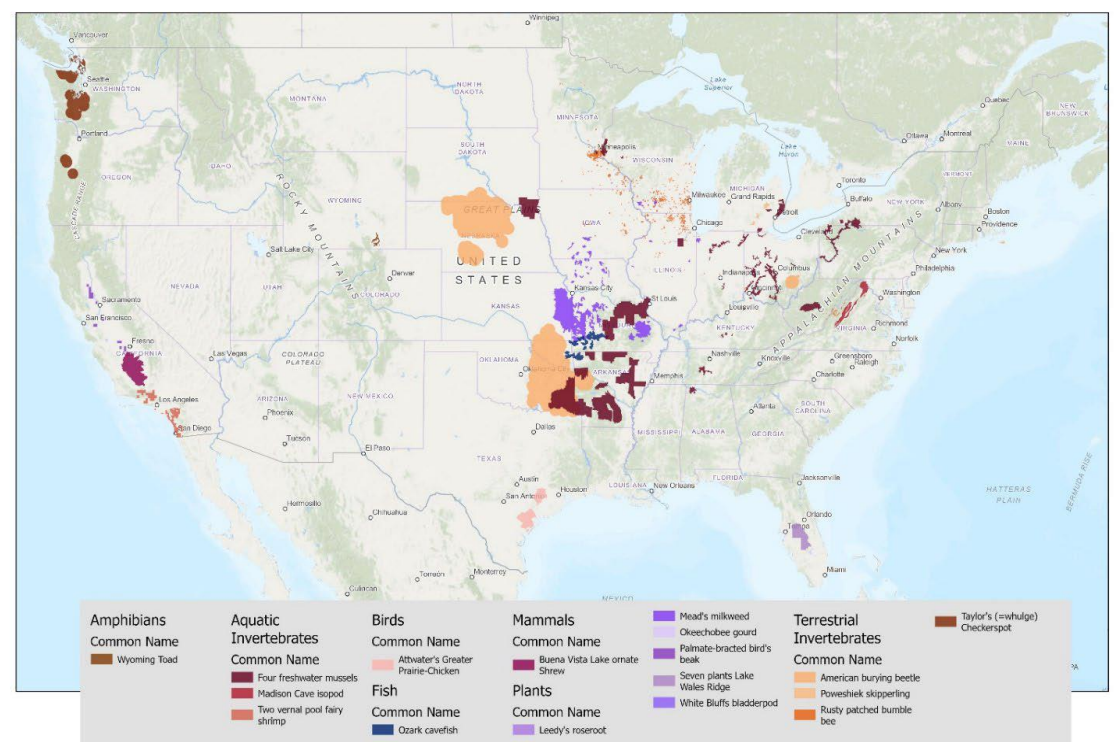
# June 2023 – Vulnerable Species Pilot Project

- Applies to 27 listed species that EPA has determined are particularly vulnerable to potential pesticide effects
- May be expanded at a later date




## Pilot Species

EPA identified the pilot species listed below using documentation from the Services (e.g., 5-year reviews, biological opinions) and spatial data for ranges. These data are on the FWS webpages accessible by clicking the species links. For the species that EPA identified for this pilot, FWS concluded that they have high or medium vulnerability to all relevant stressors and indicated that pesticides may be a potential stressor for the species. FWS also indicated that these pilot species have smaller ranges relative to other listed species, and many of their ranges or critical habitats overlap with those of other listed species. Therefore, protections for these species would benefit other listed species.

The initial set of priority species includes:

- Group of plant species in Lake Wales Ridge area of Florida (including Avon park harebells (*Crotalaria avonensis*), Garrett's mint (*Dicerandra christmanii*), wireweed (*Polygonella basiramea*), scrub blazingstar (*Liatris ohlingerae*), short-leaved rosemary (*Conradina brevifolia*), scrub mint (*Dicerandra frutescens*), Florida ziziphus (*Ziziphus celata*), and several other species that occur in this area)
- Leedy's roseroot (*Rhodiola integrifolia ssp. leedyi*)
- Mead's milkweed (*Asclepias meadii*)
- Okeechobee gourd (*Cucurbita okeechobeensis ssp. okeechobeensis*)
- Palmate-bracted bird's beak (*Cordylanthus palmatus*)
- White bluffs bladderpod (*Physaria douglasii ssp. tuplashensis*)
- Madison cave isopod (*Antrolana lira*)
- Ouachita rock pocketbook (*Arkansia wheeleri*)
- Rayed bean (*Villosa fabalis; freshwater mussel*)
- Scaleshell mussel (*Leptodea leptodon*)
- Winged mapleleaf (*Quadrula fragosa*)
- Riverside fairy shrimp (*Streptocephalus woottoni*) and San diego fairy shrimp (*Branchinecta sandiegonensis*)
- American burying beetle (*Nicrophorus americanus*)
- Poweshiek skipperling (*Oarisma poweshiek*)
- Rusty patched bumble bee (*Bombus affinis*)
- Taylor's checkerspot (*Euphydryas editha taylori*)
- Ozark cavefish (*Amblyopsis rosae*)
- Attwater's prairie chicken (*Tympanuchus cupido attwateri*)
- Buena vista lake ornate shrew (*Sorex ornatus relictus*)
- Wyoming toad (*Bufo hemiophrys baxteri*)

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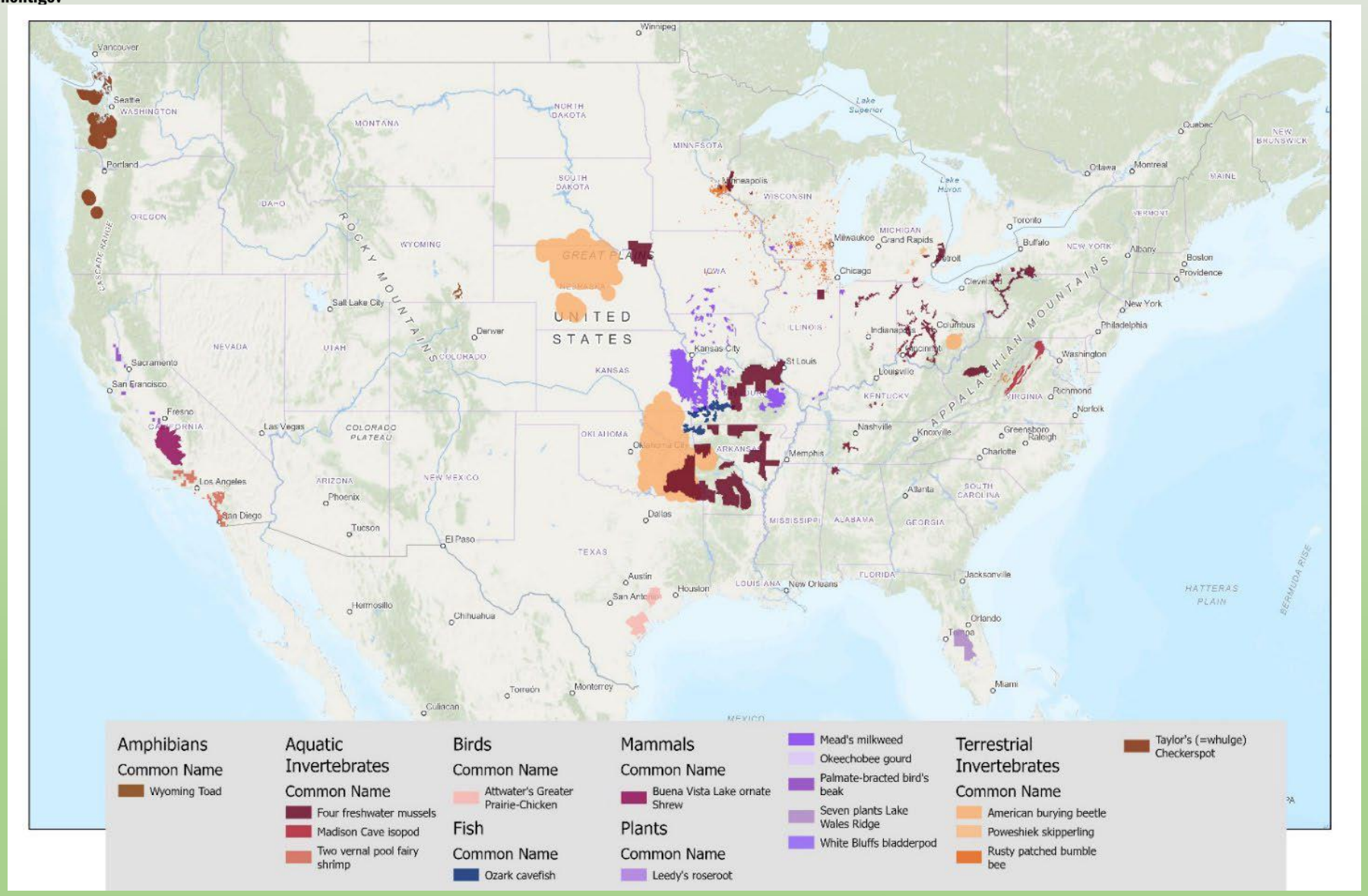
# Geographic Range of Species in VSPP

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## June 2023 – Vulnerable Species Pilot Project

- Proposes pesticide mitigation measures designed to reduce the pilot species' exposures to conventional pesticides from non-residential outdoor uses of those pesticides which includes
  - agricultural
  - non-agricultural use sites
    - rights of way,
    - nursery/ornamentals,
    - forestry,
    - industrial,
    - pasture/rangeland,
    - golf courses,
    - athletic fields,
    - aquatic applications,
    - mosquito adulticide and larvicide applications.

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**Pesticide Use Limitation Areas (PULAs) will be established on a geographic basis.**

**Pesticide mitigation measures are required in a PULA.**

**Mitigations focused on <u>avoidance</u> and <u>minimization</u>**

- **<u>Avoidance</u>**
  - No application in geographic area identified as critical habitat.
  - Exception allowed if approved by FWS at least three months prior to application
- **<u>Minimization</u>**
- intended to reduce the likelihood of future jeopardy/adverse modification determinations and to minimize potential take
  - Application using one or more mitigation measures identified by EPA
  - Mitigation applies in a protective zone around avoidance area

**Restrictions on applications are identified in Bulletins Live Two (BLT)**

**Label language will require that applicators consult BLT <u>before</u> application and comply with directions on that site.**

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## Example of Avoidance and Minimization Areas

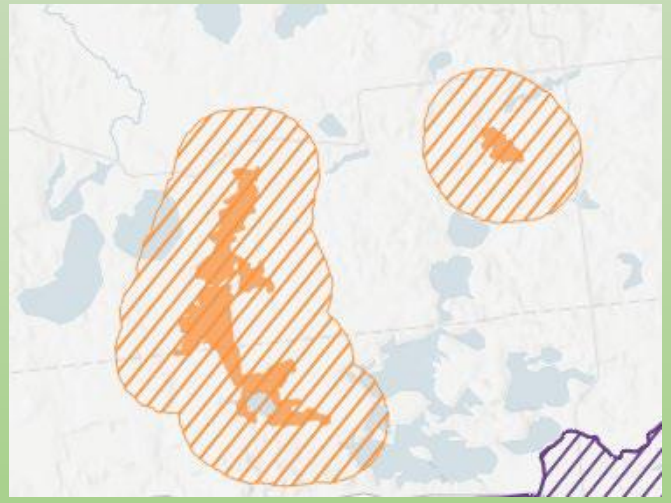

Table 2. Descriptions of Pesticide Use Limitation Areas (PULAs) for Pilot Species.

| Species (Common Name) | State(s) Where PULAs are Located | Avoidance PULA Extent | Minimization PULA Extent | Minimization Mitigations | Max PULA Extent (Acres) |
|---|---|---|---|---|---|
| **Mitigation Area: Delineated location, geographically explicit** | | | | | |
| Leedy's roseroot | MN, NY | Part of range (excluding area in South Dakota) | 2600 ft extension area around avoidance PULA | Drift, Run-off, Species specific[1] | Less than 50,000 |
| Okeechobee gourd | FL | Range | 2600 ft extension area around avoidance PULA | Drift, Run-off, Species specific[1] | Less than 200,000 |
| Poweshiek skipperling | MI, WI, MN | Designated critical habitat | 2600 ft extension area around the avoidance PULA | Drift, Run-off | Less than 50,000 |
| Rusty patched bumble bee | IL, IN, IA, ME, MA, MN, OH, VI, WV, WI | Range | 2600 ft extension area around the avoidance PULA | Drift, Run-off, Species specific[1] | Greater than 1,000,000 |
| Taylor's checkerspot | OR, WI | Range, which includes designated critical habitat | 2600 ft extension area around the avoidance PULA | Drift, Run-off | Greater than 1,000,000 |
| White Bluffs bladderpod | WA | Range, which includes designated critical habitat | 2600 ft extension area around the avoidance PULA | Drift, Species specific[1] | Less than 10,000 |
| **Mitigation Area: Known habitat, not delineated (see Table 3 for habitat description)** | | | | | |
| American burying beetle | AR, KS, MA, NE, OH, OK, RI, SD, TX | Range | Same as avoidance PULA | Drift, Species specific[1] | Greater than 1,000,000 |
| Attwater's prairie chicken | TX | PULA from Malathion BiOp | Same as avoidance PULA | Drift, Run-off | Greater than 1,000,000 |
| Buena Vista Lake ornate shrew | CA | Range, which is inclusive of designated critical habitat | Same as avoidance PULA | Drift, Run-off | Greater than 1,000,000 |

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# Minimization measures to be included in PULAs

Table 4. Draft options for runoff/erosion measures for selected pesticide use site[1].

| Runoff/Erosion Mitigation Practice | Use Site | | | | |
|---|---|---|---|---|---|
| | 1: Field Crops[2] | 2: Orchards | 3: Specialty Crops[3] | 4: Non-Ag[4] | 5: Rice[5] |
| Applications | | | | | |
| Avoid Using Pesticide of a Highly Toxic Hazard Class to invertebrates | ✓ | ✓ | ✓ | ✓ | ✓ |
| 40% rate reduction[6] | ✓ | ✓ | ✓ | ✓ | ✓ |
| In Field | | | | | |
| Contour Farming | ✓ | ✓ | ✓ | -- | -- |
| Cover Crop | ✓ | ✓ | ✓ | ✓ | -- |
| In-field Vegetative Filter Strip[7] | ✓ | ✓ | ✓ | ✓ | -- |
| Mulching | ✓ | ✓ | ✓ | ✓ | |
| Residue and Tillage management | ✓ | -- | ✓ | -- | -- |
| Terrace Farming | ✓ | ✓ | ✓ | -- | -- |
| Grassed Waterways | ✓ | ✓ | ✓ | ✓ | -- |
| Field Characteristics | | | | | |
| Field with <2% slope | ✓ | ✓ | ✓ | -- | ✓ |
| Adjacent to the Field or In-between field and Protection Area | | | | | |
| Vegetative Filter Strips[7] | ✓ | ✓ | ✓ | ✓ | -- |
| Riparian Area (>10m width from average high-water mark to use site) | ✓ | ✓ | ✓ | ✓ | -- |
| Controlled Drainage | | | | | |
| Constructed wetlands or Water and Sediment Control Basins | ✓ | ✓ | ✓ | ✓ | ✓ |

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## Label Language for Avoidance Areas:

*Pesticide applications are prohibited within this area unless the applicator coordinates with the local FWS Ecological Services field offices to determine appropriate measures to ensure the proposed application is likely to have no more than minor effects on the species. The applicator must coordinate with FWS at least 3 months prior to the application. FWS points of contact are available through the Information, Planning, and Consultation (IPaC) website (https://ecos.fws.gov/ipac/). If a permit has been granted by FWS13, no additional coordination with FWS is needed if a pesticide application is made in accordance with an existing FWS permit.*

## Label Language for Minimization Areas

*1. Do not apply when soil in the area to be treated is saturated (if there is standing water on the field or if water can be squeezed from soil).*

*2. Do not irrigate to the point of runoff. Follow label directions if pesticide needs to be watered into the soil for efficacy.*

*3. Do not apply if NOAA/National Weather Service predicts 50% chance or greater of 1 or more inches of rainfall to occur within 48 hours following application.*

*4. Four of the measures in* ***Table 4*** *are required to reduce potential transport of pesticides off treated fields from runoff water and soil erosion into the pilot species' habitats. Formal participation in a State or Federal soil and runoff conservation plan satisfies this requirement.*

*5. The following exemptions to #1-4 apply: a. If the field has subsurface drainage installed, the mitigation measures are not applicable. The subsurface tile drains must release the effluent (water) into water-controlled drainage structures or saturation buffer zones.*

b. *If the lands are managed with a site-specific runoff and/or erosion plan implemented according to the recommendations of a recognized conservation* program, *then no additional runoff/erosion mitigations are needed. Recognized conservation programs include but are not limited to those run by federal and state agencies, a state university extension programs, National Alliance of Independent Crop Consultants, or certified agricultural conservation specialists.*

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## Implementation – Vulnerable Species Pilot Project

- Will be implemented over the next 18 months
- BLT reference language added pesticide product labeling as part of normal registration and registration review actions
- Registrants can add through non-notification
- EPA will develop Bulletins for the initial set of 27 pilot species

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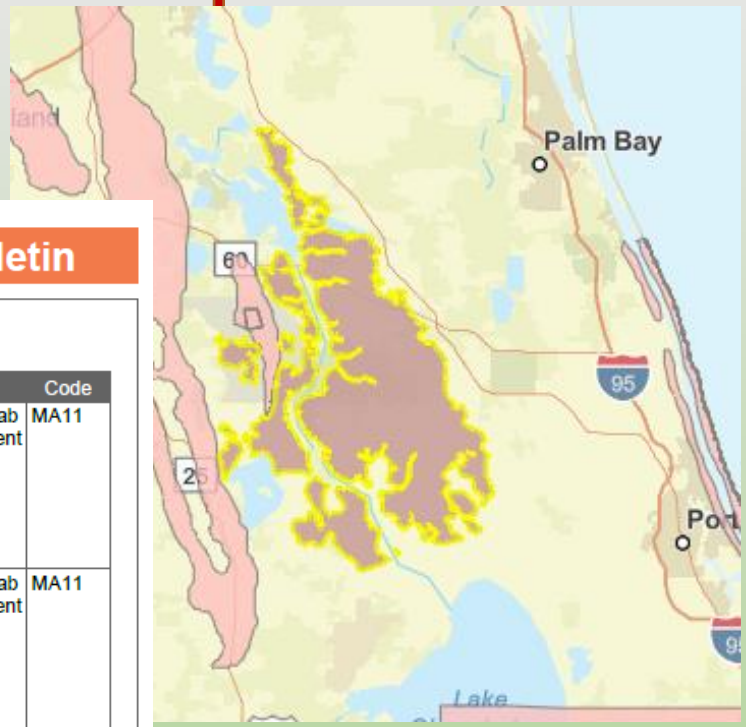
# Pesticide Use Limitation Areas (PULAs):

**<u>PULAS are being published without notice to SLAs!</u>**

Example – Malathion for Mosquito Control in Florida

Florida Department of Agriculture and Consumer Services (FDACS) became aware of this new PULA after it was implemented through a Pesticide Interim Decision (PID) in August 2023




## Endangered Species Protection Bulletin

### Pesticide Use Limitation Summary Table

| Product | AI | Use | Method | Form | Code |
|---|---|---|---|---|---|
| FYAFANON MALATHION INSECTICIDE (5905-196) Inactive: FYAFANON THE PREMIUM GRADE MALATHION | Malathion (NO INERT USE) | All Agricultural Uses | Aerial spray | Emulsifiable Concentrate | MA11 |
| FYAFANON MALATHION INSECTICIDE (5905-196) Inactive: FYAFANON THE PREMIUM GRADE MALATHION | Malathion (NO INERT USE) | All Agricultural Uses | Ground spray | Emulsifiable Concentrate | MA11 |

### Codes and Limitations Table

| Code | Limitation |
|---|---|
| MA11 | Follow one of these measures: 1. Apply malathion only before dawn or after dusk OR 2. Apply malathion only when wind is blowing away from Florida scrub and sandhill habitats OR 3. Use a 50-foot ground buffer from Florida scrub and sandhill habitats, and an aerial buffer from Florida scrub and sandhill habitats according to application rate: (1) 50 feet for <0.5 lbs ai/A; (2) 75 feet for 0.5 - <1 lb ai/A; (3) 150 feet for 1-2.5 lbs ai/A; (4) 200 feet for >2.5 lbs ai/A. Buffer sizes may be reduced by 25 feet for application rates (1) and (2) if a full swath displacement upwind is used during aerial application. Buffer sizes may be reduced by 50 feet for application rates (3) and (4) if a full swath displacement upwind is used during aerial application. Habitat: Scrub and sandhill habitats are generally open habitats with sandy soil seen in patches between the trees, shrubs, and other plants that live in the habitat. Scrub may or may not have trees. If there are trees, they tend to be widely spaced in the case of pine trees, or clustered together in clumps in the case of the shrub-like oak trees found in these habitats. Between the trees (if present) you will see a variety of shrubs, flowering plants, grasses, and lichens. |

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# July 2023 – Herbicide Strategy

EPA approach to:

- determine the need for
- the level of
- and geographic extent of

early mitigations for listed species from agricultural uses of conventional herbicides

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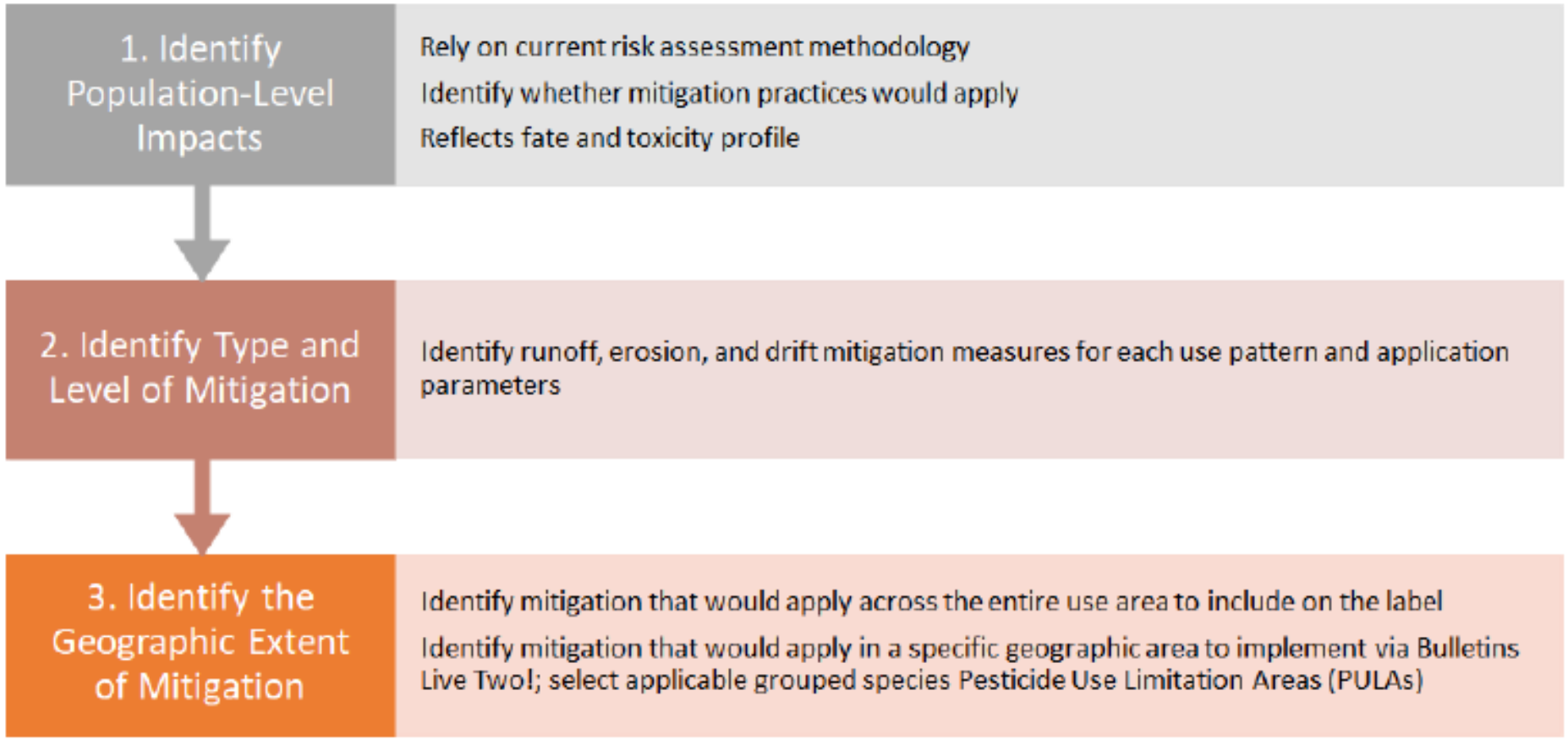


**Figure 4-1. Overview of the Draft Herbicide Strategy Process**

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# Impact of Herbicide Strategy

- change in Directions for Use
- required drift buffers depending on product and use area
- required mitigation measures depending on product and use area
- options chosen must equal required “points”
- additional restrictions in PULAs

**Adds significant new decision-making steps to pest control product selection**

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# Geographic coverage for mitigations Herbicide Strategy

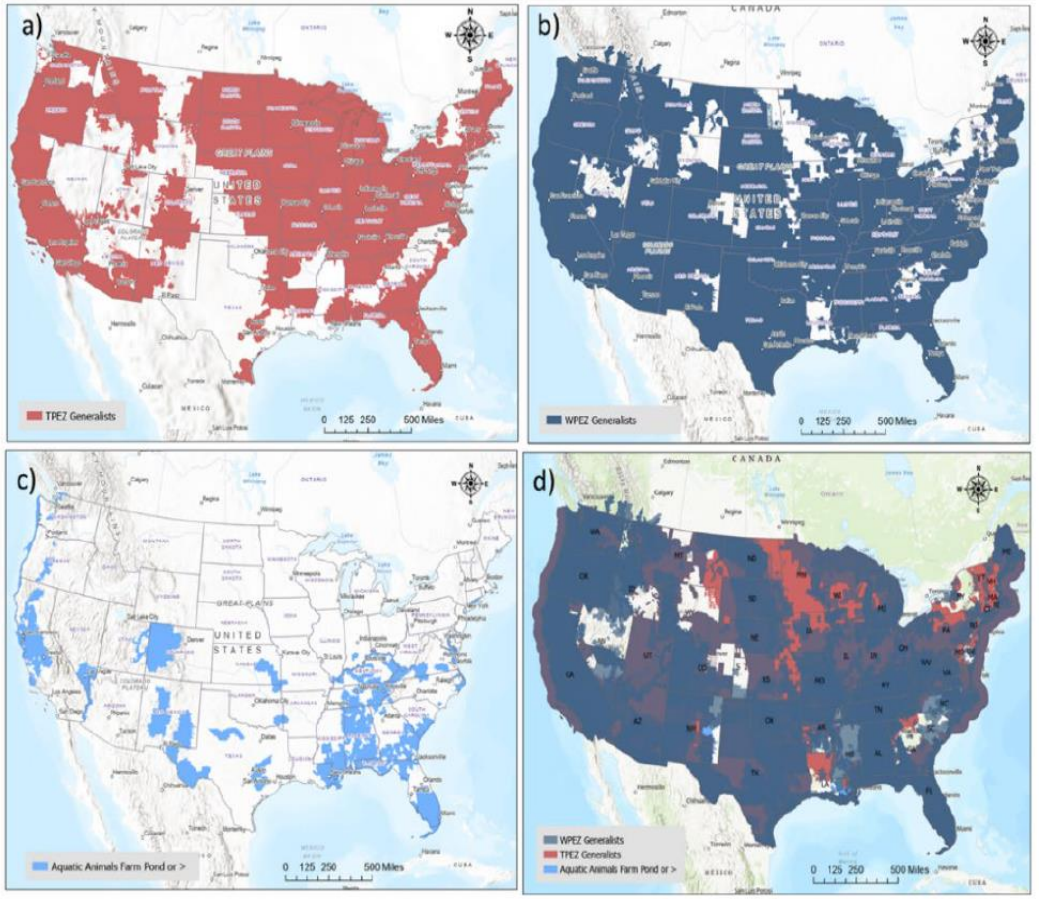
***For the Strategy, mitigation would likely apply throughout the conterminous US when there are concerns for population-level impacts for plants that could impact the diet and/or habitat of listed animal generalists in all of these environments. EPA proposes that implementation would include mitigations for animals on the general labels because they are distributed throughout the majority of the conterminous US. Spatially limited mitigations would not apply.***

Figure 7-1. a) Terrestrial Generalists: Listed animals that generally rely on terrestrial plants (plus their CHs) and have ≥5% overlap with the Cultivated Use Data Layer (UDL) plus 300 m. This list does not include fully aquatic species that are captured in the wetland generalists and/or aquatic animals lists.

b) Wetland Generalists: Listed animals that generally rely on wetland plants (plus their CHs) and have ≥5% overlap with the Cultivated UDL plus 300 m. This list includes aquatic animals found in waterbodies smaller than the EPA farm pond.

c) Aquatic Generalists: Listed animals that rely on aquatic plants (plus their CHs), are found in waterbodies that are equivalent in size to the EPA farm pond or larger, and have ≥5% overlap with the Cultivated UDL plus 300 m.

d) All Listed Animal Generalists

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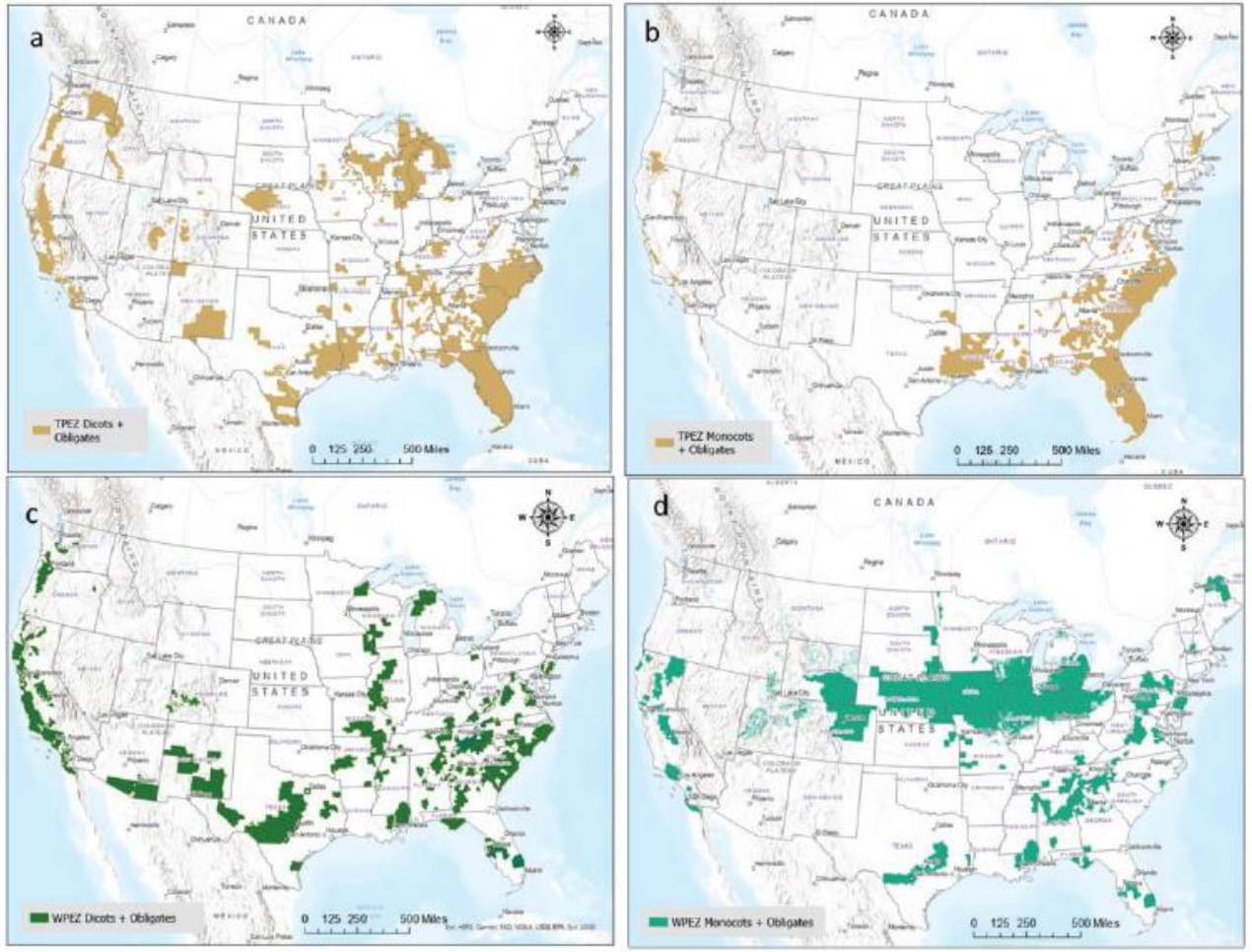
# PULAS for Herbicide Strategy

Figure 7-2. a) PULA 1: Listed dicots, non-flowering plants, and animals with an obligate relationship to these plants located in terrestrial habitats. All species and CHs have ≥5% overlap at 300 m using the Cultivated Use Data Layer (UDL);

b) PULA 2: Listed monocots, non-flowering plants, and animals with an obligate relationship to these plants located in terrestrial habitats. All species and CHs have ≥5% overlap at 300 m using the Cultivated UDL;

c) PULA 3: Listed dicots, non-flowering plants, lichens, and animals with an obligate relationship to these plants located in wetland and aquatic habitats. All species and CHs have with ≥5% overlap at 300 m using the Cultivated UDL; and

d) PULA 4: Listed monocots, non-flowering plants, lichens, and animals with an obligate relationship to these plants located in wetland and aquatic habitats. All species and CHs have with ≥5% overlap at 300 m using the Cultivated UDL.

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# Example: oxyfluorfen

## Drift buffers required on label

**Table 12-14. Spray Drift Mitigation Measures Identified for Listed Animal Generalists as Related to Single Maximum Application Rate, Application Method and Droplet Size.[1]**

| Single Maximum Application Rate (lb ai/A)[2] | Identified Downwind Spray Drift Buffer Distances (ft) | | | | | | |
|---|---|---|---|---|---|---|---|
| | Aerial Application | | | Ground Application | | | |
| | Fine-Medium | Medium-Coarse | Coarse-Very Coarse | Very Fine-Fine, High Boom | Very Fine-Fine, Low Boom | Fine-Medium/Coarse, High Boom | Fine-Medium/Coarse, Low Boom |
| 2.0 | Not permitted on labels | | | 200[e,g,h] | 100[e,g,h] | 100[e,g,h] | 75[f,g,h] |
| 1.5 | | | | 200[e,g,h] | 100[e,g,h] | 100[e,g,h] | 50[g,h] |
| 0.75 | | | | 150[e,g,h] | 75[g,h] | 50[g,h] | 20[i] |
| 0.50 | 300[a,b,c] | 225[a,b] | 150[b,d] | 125[e,g,h] | 50[g,h] | 25[i] | 20[i] |
| 0.25 | 200[a,b] | 125[b,d] | 75[b,d] | 50[g,h] | 20[i] | 10[i] | None[3] |
| Mitigation Measures the Pesticide Applicator can Elect to Reduce Buffer Distances[4] | [a] Buffers ≥175 ft can be reduced by 25 ft if crop height at application is ≥1 ft. [b] Windbreak (release height below top of windbreak) reduces buffer distance by half [c] Buffers ≥250 ft could be reduced by 25 ft if relative humidity at application is >70% [d] Buffers 75-175 ft could be reduced by 25 ft if windspeed at application is 3-7 miles per hour | | | [e] Buffers ≥100 ft could be reduced by 25 ft if relative humidity at application is >60% [f] Fine-Medium/Coarse-Low Boom buffers ≥75 ft could be reduced by 25 ft with coarse or coarser droplets [g] Windbreak/Hedgerow (release height below top of windbreak) reduces buffer distance by half [h] Hooded Sprayers reduce buffer distance by half [i] The applicator would achieve sufficient mitigation with a windbreak or hedgerow (release height below the top of the windbreak/hedgerow) or hooded sprayers alone without a buffer. | | | |

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# Example: oxyfluorfen

## Mitigation points needed for soil application

**Table 12-22. Summary of Use-Based Runoff/Erosion Mitigation Points Identified for the General Label Based on Different Types of Habitats and 4 Pesticide Use Limitation Areas (PULAs).**

| Use | Mitigations Points on the General Label | | Geographically Specific Mitigation Points | |
|---|---|---|---|---|
| | Terrestrial Habitats | Aquatic and Wetland Habitats | PULAs 1,2, 3 and 4 (Terrestrial Habitats)[1] | PULAs 3 and 4 (Aquatic and Wetland Habitats)[1] |
| Artichoke | 7 | 7 | 7 | 7 |
| Beans | 5 | 7 | 7 | 7 |
| Berry | 7 | 7 | 7 | 7 |
| Broccoli | 5 | 5 | 5 | 5 |
| Cabbage | 5 | 5 | 5 | 5 |
| Citrus | 5 | 7 | 7 | 7 |
| Corn | 7 | 7 | 7 | 7 |
| Cotton | 5 | 7 | 7 | 7 |
| Fruiting Vegetables | 5 | 5 | 5 | 5 |
| Garlic | 5 | 5 | 5 | 5 |
| Grape | 7 | 7 | 7 | 7 |
| Onion | 5 | 5 | 5 | 7 |
| Pome Fruit | 5 | 7 | 7 | 7 |
| Soybean | 5 | 5 | 5 | 7 |
| Stone Fruit | 5 | 7 | 7 | 7 |

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# Example: Washington Apples

Mitigation points available for normal practices

| Practice | Points |
|---|---|
| Sandy loam soil | 1 |
| Western agriculture | 1 |
| Irrigation management | 1 |
| Adjacent to field vegetative filter strip | 2 |
| Contour farming with strips | 3 |
| Multiple categories | 1 |
| Total points | 9 |

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# Conclusions:

- The effect of the strategies being proposed is the addition of a significant level of complexity to the decision-making process for agricultural producers when designing their weed management program.

- Absent sufficient understanding by the end user and an effective compliance assurance process, this level of complexity will result in a general failure to achieve the intended protections designed into the HS.

- Existing certification and training programs will not be adequate to incorporate the level of training and information needed to understand and implement these measures.

- Information on what the measures mean in practice, how to implement them, and how to determine if a pesticide application complies will have to be developed and shared among all stakeholders.

- Success of the mitigation measures in preventing jeopardy and adverse modification will be determined by the level of compliance with the requirements.

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**Vulnerable Species Pilot**

- Mitigation measures (applied broadly across different types of pesticides) for species with limited ranges & where pesticides have already been identified as a stressor for the species. ~27 species identified

Public Outreach (Draft White paper & Story Maps) conducted by 6/30/2023

45-day Comment Period for white paper

After outreach, determine if mitigations should be revised or more added by 12/30/2023

Determine how to expand the approach to other vulnerable species by 9/30/2024

**Rodenticide Strategy**

- Address effects to mammals & birds that consume rodenticide bait (1° consumers), & to birds, mammals & reptiles that consume 1° consumers

Mitigation measures developed for 3 representative species (1 mammal 1° consumer; 1 bird 1° consumer & a 2 ° consumer), 1 designated habitat & plan to consider expanding mitigations to apply to ~90 other ESA-listed species.

Mitigation measures for the representative species incorporated into Rodenticide PID's. Issued in 11/2022

Draft Rodenticide BE in 11/2023. Will consider the mitigations identified in Rodenticide PID's

Final Rodenticide BE no later than 11/12/2024

**Rodenticide Biological Evaluation**
Brodifacoum, Bromadiolone, Warfarin & Zinc Phosphide

Draft BE By 11/12/2023

60-day comment period (*With option to extend BE's up to 60 days for good cause*)

Final BE By 11/12/2024 (*or adjusted accordingly due to possible comment extension*)

**Herbicide Strategy**

- Focus on ESA-listed plants & those species that rely on plants
- Address spray drift & runoff transport from treated fields to minimize exposure

Draft Strategy 7/24/2023

60-day comment period

Final Strategy + Response to Comments Document By 5/30/2024

After 3/30/24 - Strategy mitigation measures incorporated into PID's issued under EPA registration review program.

Group PID's, instead of chemical-specific, will be issued as appropriate.

60-day comment period for PID's

**Insecticide Strategy**

Draft Strategy By 7/30/2024

60-day comment period

Final Strategy + Response to Comments Document By 1/17/25 – 3/31/25

After 3/31/25, Strategy mitigation measures incorporated into PID's issued under EPA registration review program.

Group PID's, instead of chemical-specific, will be issued as appropriate.

60-day comment period for PID's

**Fungicide Strategy**

- Strategy to address vulnerable species that may be affected by fungicides

Attempt to agree on Completion date no later than 8/31/2024

**Organophosphate Biological Evaluation**

- BE's: Acephate, Bensulide, Dimethoate, Ethoprop, Naled, Phorate, Phosmet & S,S,S-tributyl phosphorotrithioate
- Nationwide Scale Effects Determination: Dichlorvos (DDVP)
- Other AI's may be added if practicable

Track 1 - all 8 AI's

Draft BE By 3/31/2027

Final BE By 9/30/2027

Track 2
Group 1 - 4 of 8 AI's
Group 2 – 4 of 8 AI's

Draft BE
Group 1 By 3/31/2026
Group 2 By 3/31/2027

60-day comment period

Final BE
Group 1 By 9/30/2026
Group 2 By 9/30/2027

**Compensatory Mitigation**

Intervenors to organize & fund workshop to explore how offsets may be used to address effects of pesticide registrations. Anticipated to occur within 12 months of agreement date; but no more than 24 months of effective agreement date

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Improving communication on this issue:

- EPA Region/SLA committee
- New SFIREG standing Committee
- NRCS/USDA OPMP Involvement
- Regional FWS contacts

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# Bulletins Live! Two (BLT) Tutorial

Bulletins Live! Two (BLT) is the Web-based application to access Endangered Species Protection Bulletins (Bulletins). These Bulletins contain enforceable pesticide use limitations that are necessary to ensure a pesticide's use will not harm a species listed as threatened or endangered (listed) under the Endangered Species Act or their designated critical habitat.

## This application runs most successfully using the following Internet browsers:

- Google Chrome
- Mozilla Firefox
- Safari
- Microsoft Edge

Please ensure that you are accessing BLT using one of the indicated browsers.

## This tutorial explains the steps to use the BLT application, including a section with additional information.

The tutorial includes the following eight sections:

1. Using the map application tools
2. Navigating to the intended pesticide application location (Step 1 on ***Instructions Tab***)
3. Selecting the application month (Step 2 on ***Instructions Tab***)
4. Selecting the EPA Registration Number (Step 3 on ***Instructions Tab***)
5. Selecting a Pesticide Use Limitation Area (PULA) (Step 4 on ***Instructions Tab***)
6. Printing a Bulletin (Step 5 on ***Instructions Tab***)
7. Understanding the components of the PDF Bulletin
8. Additional information

# 1. Using the map application tools

## Match the following letters for the tools with the letters on the image.

**A. Zoom Tool:** Zoom in using the "+" button and zoom out using the "-" button.

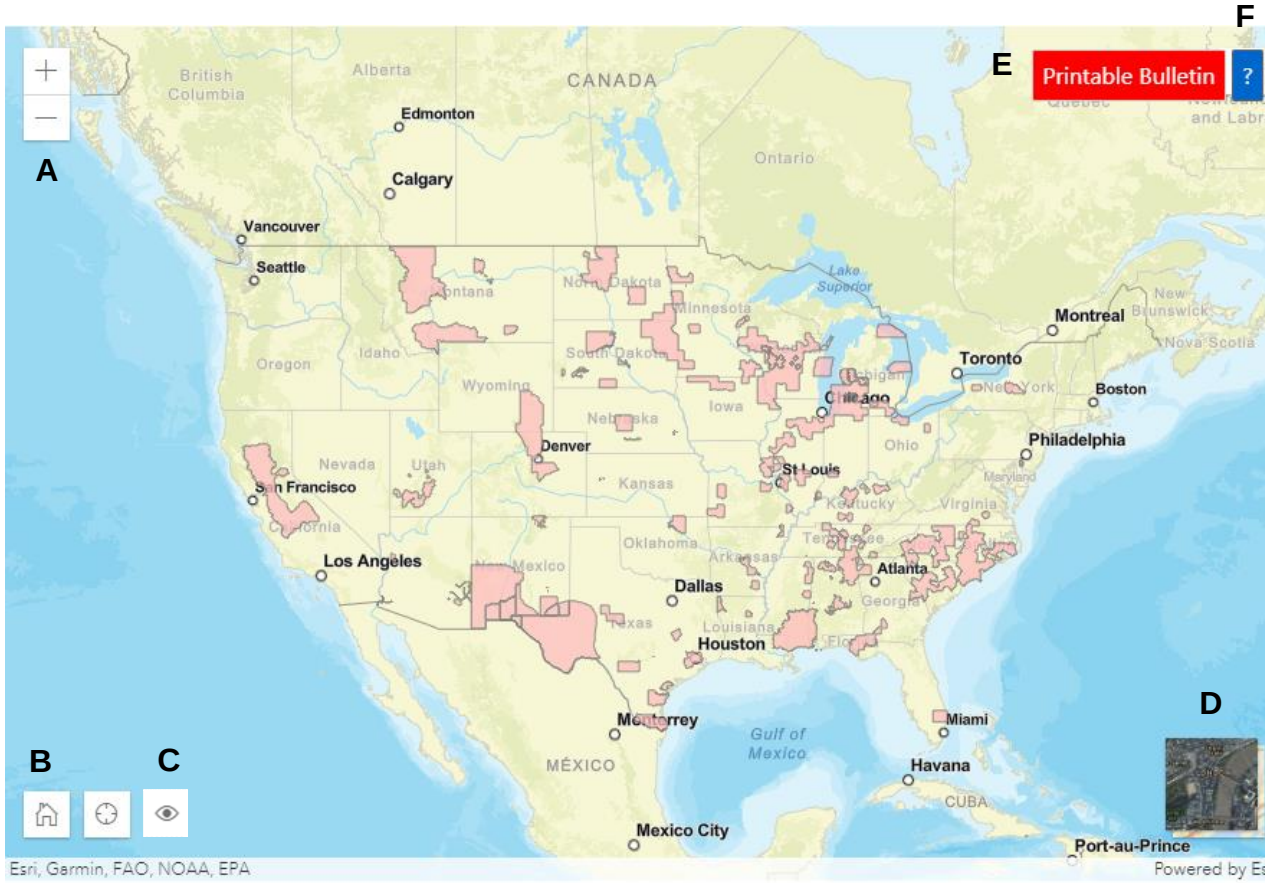
**B. Default Map View Tool**: Click the house in the lower left-hand corner to zoom to the full extent of the Pesticide Use Limitation Areas (PULAs) on the map. The geographic areas on the map where pesticide use limitations are present are referred to as PULAs. A PULA is indicated on the map by a pink shape. These are the geographic areas where pesticide use limitations exist to protect listed species and their designated critical habitat.

**C. Opacity Slider:** Use the opacity slider to increase or decrease the shading intensity of the PULA(s).

**D. Basemap Tool:** Click the box in the lower right-hand corner to change the background. It will say "Toggle Basemap" when your cursor hovers over it.

**E. Printable Bulletin**: This red button in the upper right-hand corner will generate a pdf of the PULA.

**F. Help Button**: This blue button marked with a "?" displays directions for using the application.



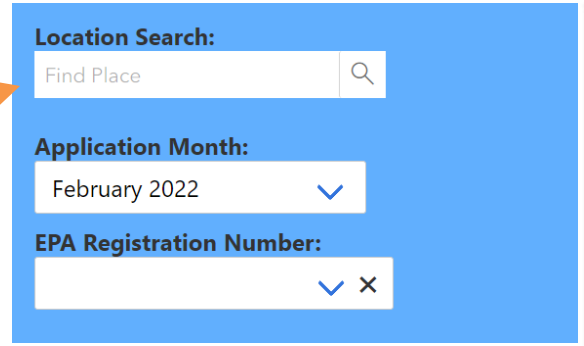
# 2. Navigating to the intended pesticide application location (Step 1 on *Instructions Tab*)

There are three ways to zoom to your intended pesticide application area:

A. Use the “Location Search” tool at the top of the blue search window left of the map. Search options include but are not limited to:

- city (e.g., New York, NY)
- county (e.g., New York County, NY)
- landmark (e.g., Statue of Liberty, NY)
- zip code (e.g., 10004)
- full address (e.g., Statue of Liberty National Monument, Liberty Island, New York, NY 10004) or
- coordinates (latitude and longitude: type longitude first, then latitude) in decimal degrees (e.g., -74.0444, 40.6892).

Names of cities, counties or other landmarks may occur in more than one location across the country; therefore, adding unique identifiers such as the state will help the application find the correct location.

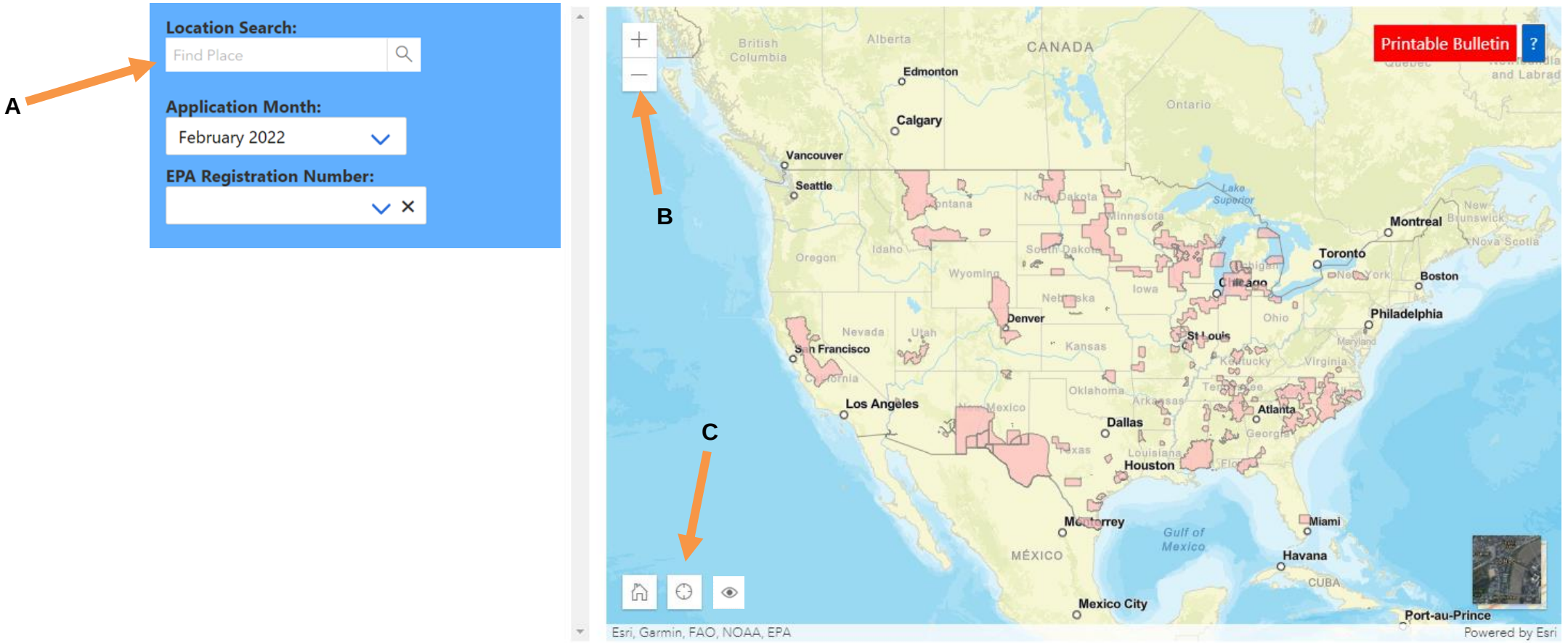



# 2. Navigating to the intended pesticide applicationlocation (Step 1 on *Instructions Tab*)

There are three ways to zoom to your intended pesticide application area:

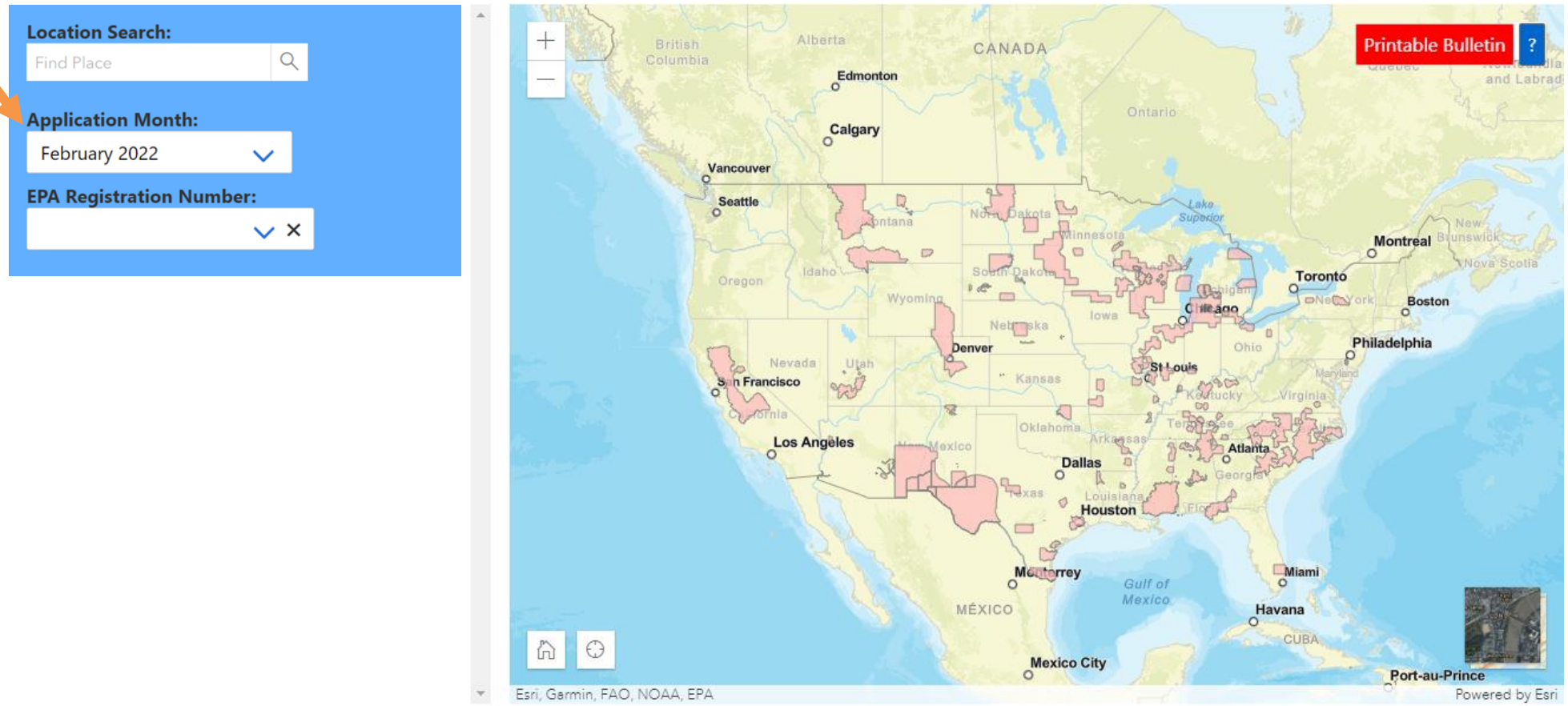
B. Manually zoom to a location by dragging the map to your location and using the “+” and “-” buttons in the upper left-hand corner to zoom in and out.

C. Use the lower left hand “Find my location” button if you are within the pesticide application area and your device’s privacy settings allow your location to be broadcasted.



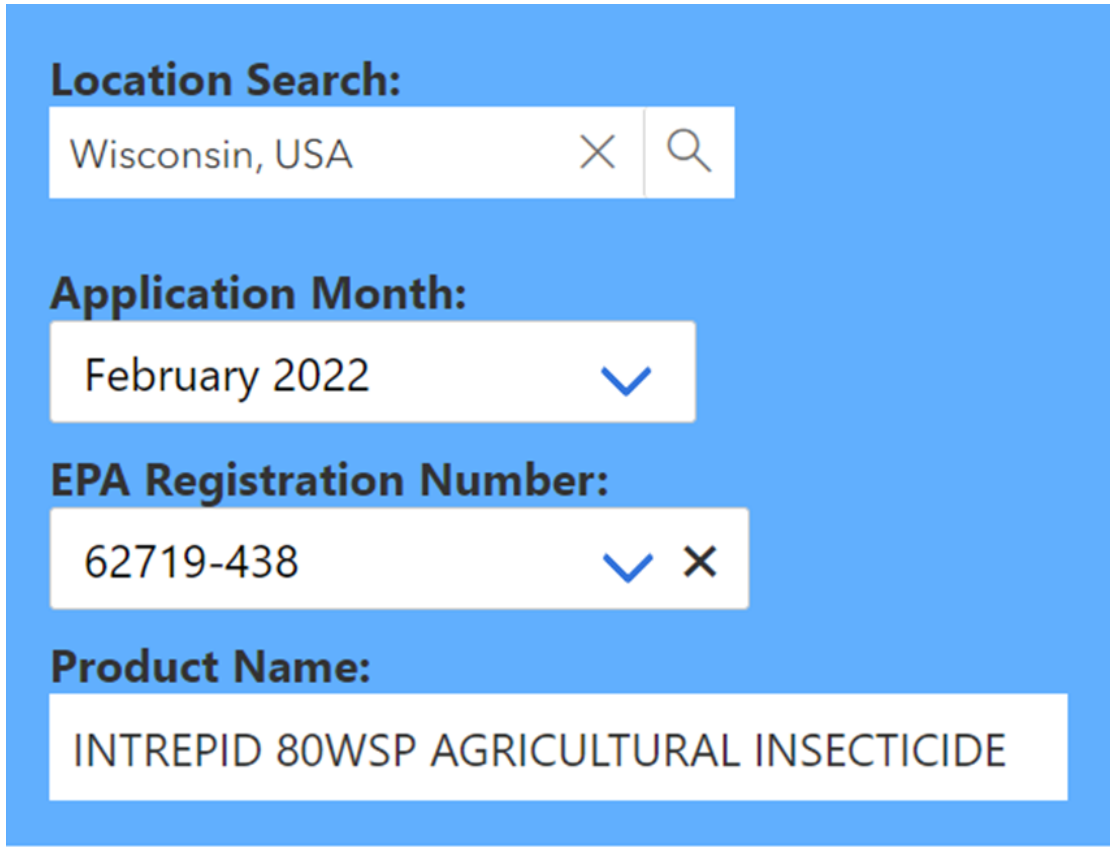
# 3. Selecting the application month (Step 2 on *Instructions Tab*)

After zooming to your intended application area, you must select the month when you intend to make your pesticide application. Bulletins are available for the current month (default option) as well as the next six months. Select a month from the second box in the blue search window left of the map. The “Application Month” box is located below the “Location Search” box. An application month of February 2022 is used in the featured example.



# 4. Selecting the EPA Registration Number (Step 3 on *InstructionsTab*)

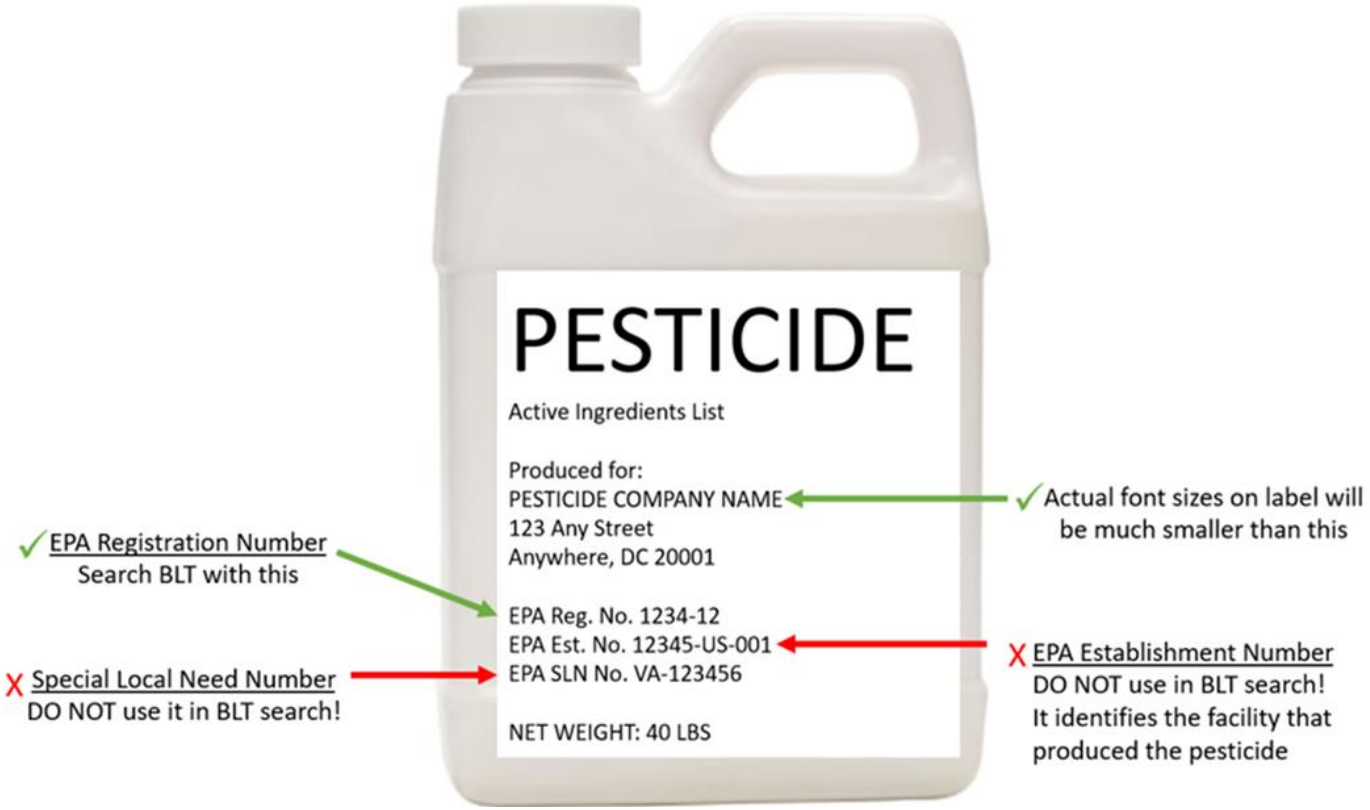
**EPA registration number searches**: See next page for instructions about how to locate the EPA registration number on a pesticide label. A search box for entering the EPA registration number is located below the "Application Month" box. After typing the EPA registration number, only the PULAs for that specific pesticide will appear on the map, and the product name(s) will appear in a box directly beneath the EPA registration number search box. It is not possible to search solely using the product name(s); the EPA registration number MUST be typed first to ensure the correct product is searched. The purpose of the product name(s) box is for a user to verify that the search using the EPA registration number was executed properly. If this does not appear, then the search was not successful.



# 4. Selecting the EPA Registration Number (Step 3 on *InstructionsTab*)

**Locating the EPA registration number on a product label**:

- Look for “EPA Reg. No.” followed by two or three sets of numbers.
- If your product's registration number has **two** parts (ex. 1234-12), it has a **primary registration number**. This is the number that should be entered into the product search in BLT.
- If your product's registration number has **three** parts (ex. 1234-12-123), you have a **supplemental distributor product**. These products have the same chemical composition and efficacy as primary products, but often have different brand or product names. Enter the **first two parts** of this registration number (ex. **1234-12-**~~123~~) into the EPA registration search in Bulletins Live! Two.



# 4. Selecting the EPA Registration Number (Step 3 on *InstructionsTab*)

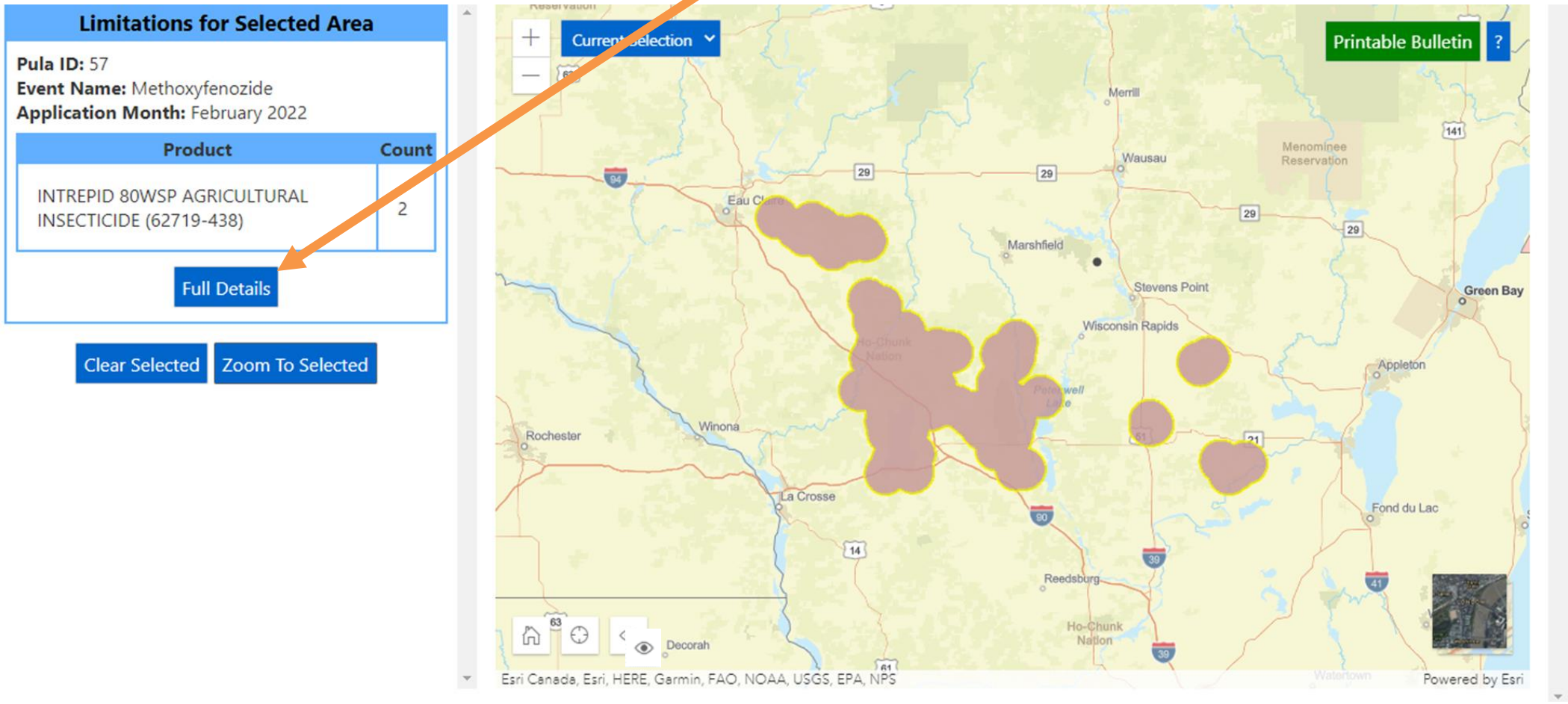
- The EPA Establishment Number (EPA Est. No.) should be printed near the EPA Reg. No. It identifies the facility that produced the pesticide and is not used in BLT. Searching will yield no results.
- If your label has “EPA SLN No.” followed by the two-letter state designation, then a 6-digit number (ex. EPA SLN No. NC950034). This is a Special Local Need registration number (SLN number) also known as a FIFRA Section 24(c) Registration Number. These Registrations are issued by the states to meet special local needs.
- These SLN numbers will not work within the Bulletins Live! Two EPA registration number search.  A label that has an SLN should also have a primary registration number that can be entered in BLT. Please note that bulletins are not intended to replace or override any restrictions that your state may impose. You need to be aware of and follow pesticide use limitations in your area according to both the state AND federal requirements.

# 5. Selecting a PULA (Step 4 on Instructions Tab)

## If a PULA occurs within your intended pesticide application area:

If a PULA occurs within your intended pesticide application area, select the PULA by clicking on it. This will outline the selected PULA in yellow and activate the ***"Limitations for Selected Area"*** results window***.***

Clicking on the blue button at the bottom of the results window that says "Full Details" will display a product summary table of codes, active ingredients, uses, methods, forms, and limitations for the selected PULA.

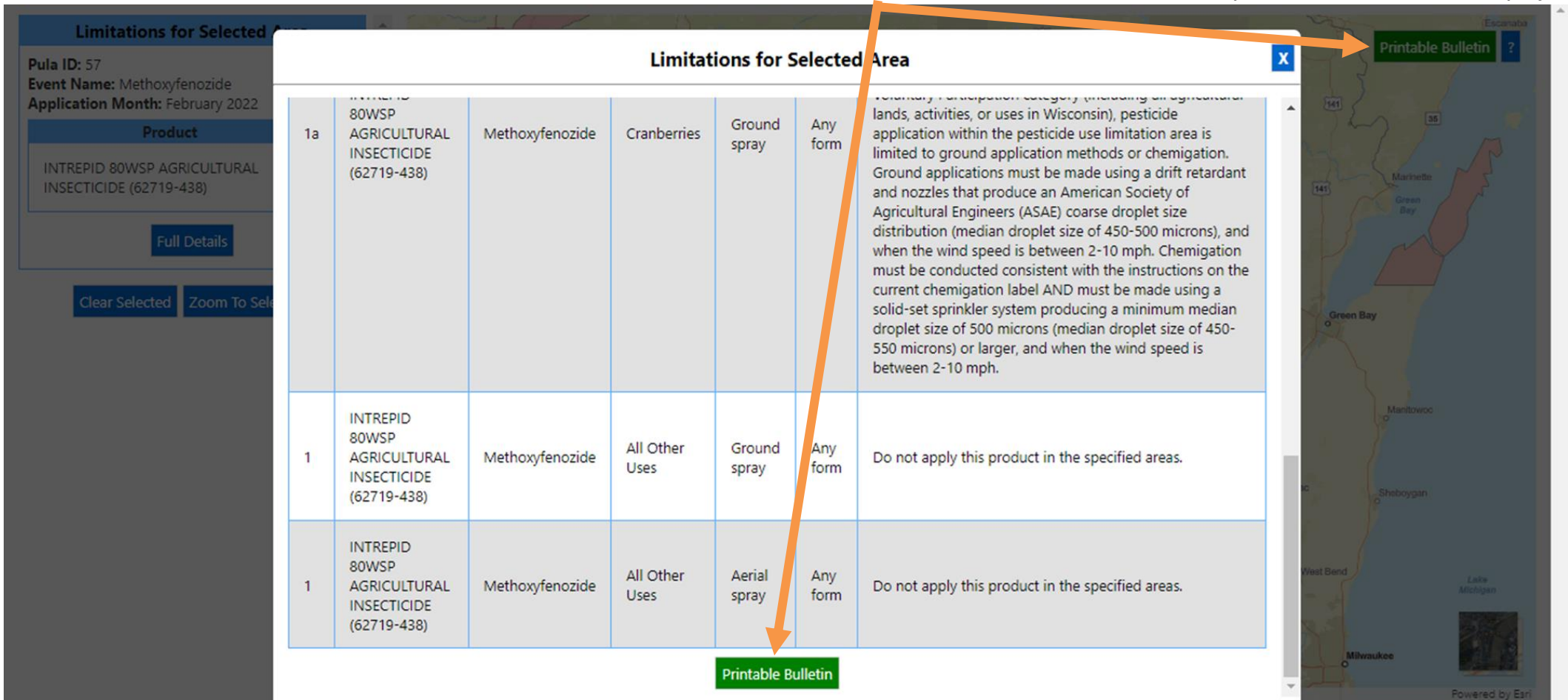


# 6. Printing a Bulletin (Step 5 on *Instructions Tab*)

Print or save a pdf version of the Bulletin for your records, even if no PULAs appear in your intended pesticide application area.

If you see no PULA(s) in your intended application area after entering the location and EPA Reg. No., click on the map's green "Printable Bulletin" button. This creates a pdf that declares no limitations are present.

To print or save a PDF version of the bulletin when there is a PULA present, click the green "Printable Bulletin" button below the product summary table. The button can also be selected in the map when the table is not displayed.

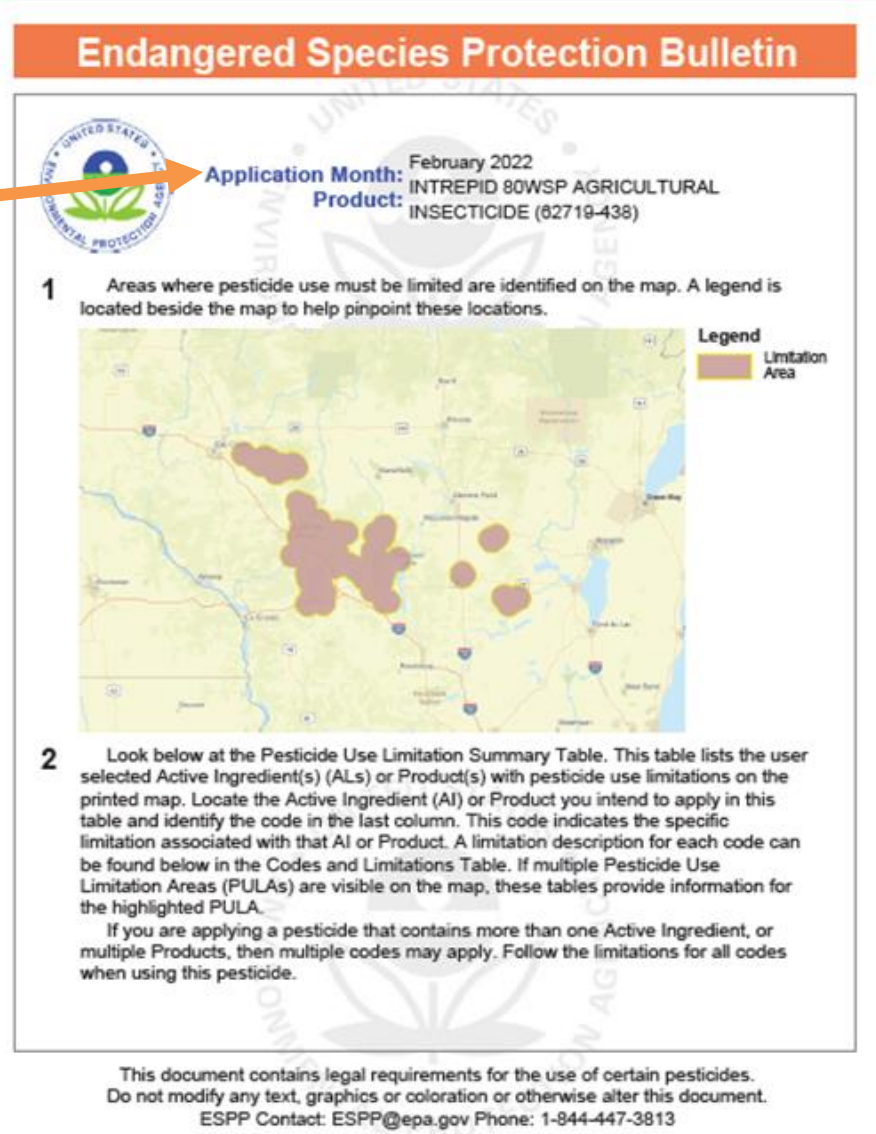


# 7. Understanding the components of the PDF Bulletin

If a PULA occurs within your intended pesticide application area:

The month for which the Bulletin is valid is located at the top of the page. Note: Bulletins are valid for the current month (default option) as well as the next six months.

If you intend to apply a pesticide within the PULA, outlined in yellow, follow the steps found in the Bulletin and the limitations in the Pesticide Use Limitation Summary Table and the Codes and Limitations Table

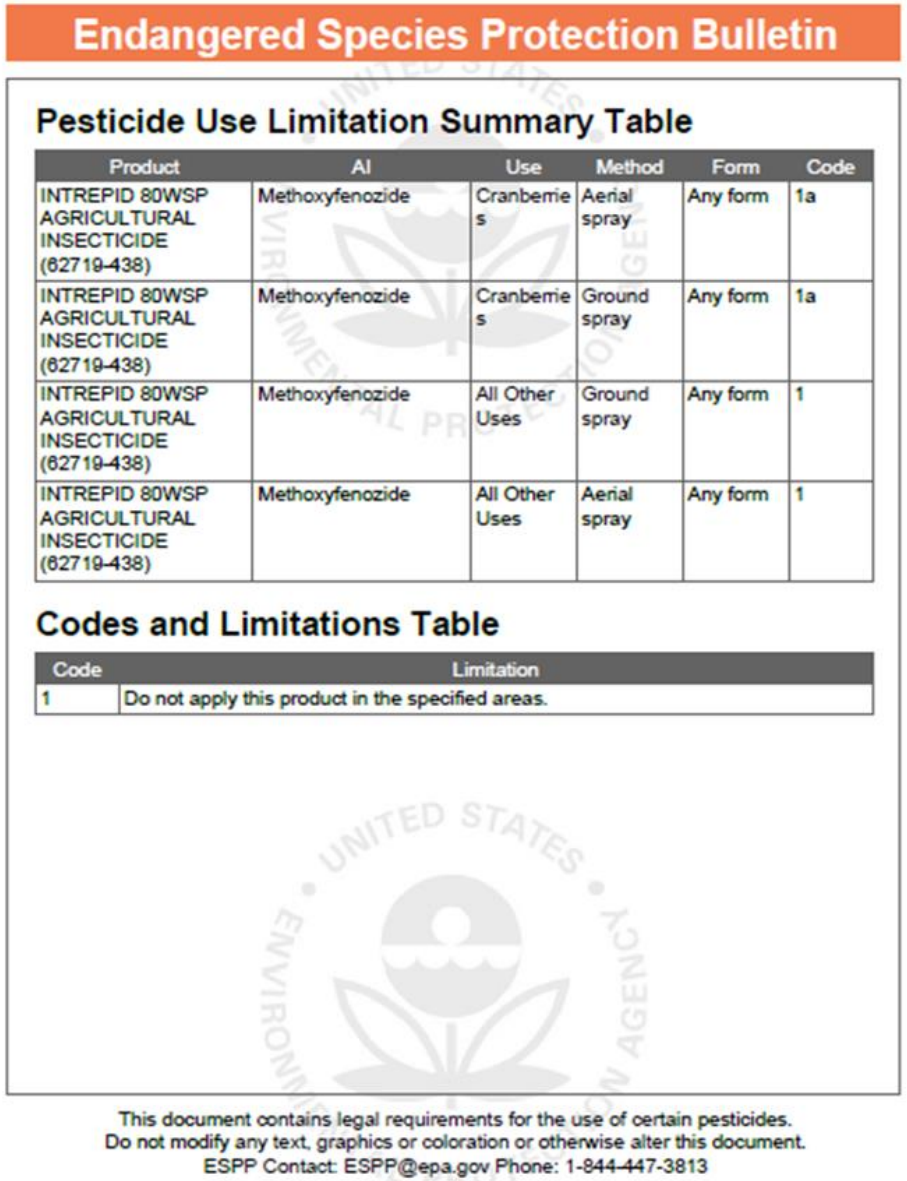


# 7. Understanding the components of the PDF Bulletin

The Pesticide Use Limitation Summary Table identifies the Code(s) associated with the highlighted PULA. It also provides the:

**Product and AI**: These columns include the name of the active ingredient(s) and/or product(s) with pesticide use limitations.

-When using the default search settings, both the active ingredient(s) and product name(s) will be visible in the Pesticide Use Limitation Summary Table, as seen in the example above.



**Endangered Species Protection Bulletin**

**Pesticide Use Limitation Summary Table**

| Product | AI | Use | Method | Form | Code |
|---|---|---|---|---|---|
| INTREPID 80WSP AGRICULTURAL INSECTICIDE (62719-438) | Methoxyfenozide | Cranberries | Aerial spray | Any form | 1a |
| INTREPID 80WSP AGRICULTURAL INSECTICIDE (62719-438) | Methoxyfenozide | Cranberries | Ground spray | Any form | 1a |
| INTREPID 80WSP AGRICULTURAL INSECTICIDE (62719-438) | Methoxyfenozide | All Other Uses | Ground spray | Any form | 1 |
| INTREPID 80WSP AGRICULTURAL INSECTICIDE (62719-438) | Methoxyfenozide | All Other Uses | Aerial spray | Any form | 1 |

**Codes and Limitations Table**

| Code | Limitation |
|---|---|
| 1 | Do not apply this product in the specified areas. |

This document contains legal requirements for the use of certain pesticides.
Do not modify any text, graphics or coloration or otherwise alter this document.
ESPP Contact: ESPP@epa.gov Phone: 1-844-447-3813

# 7. Understanding the components of the PDF Bulletin

The Pesticide Use Limitation Summary Table identifies the Code(s) associated with the highlighted PULA. It also provides the:

**Use:** This column specifies the labeled use pattern or use(s) to which the limitation applies. The use may be specific (*e.g.,* 'cranberries') or general, if referring to all use patterns registered for a particular product (*e.g.,* 'Any Use').

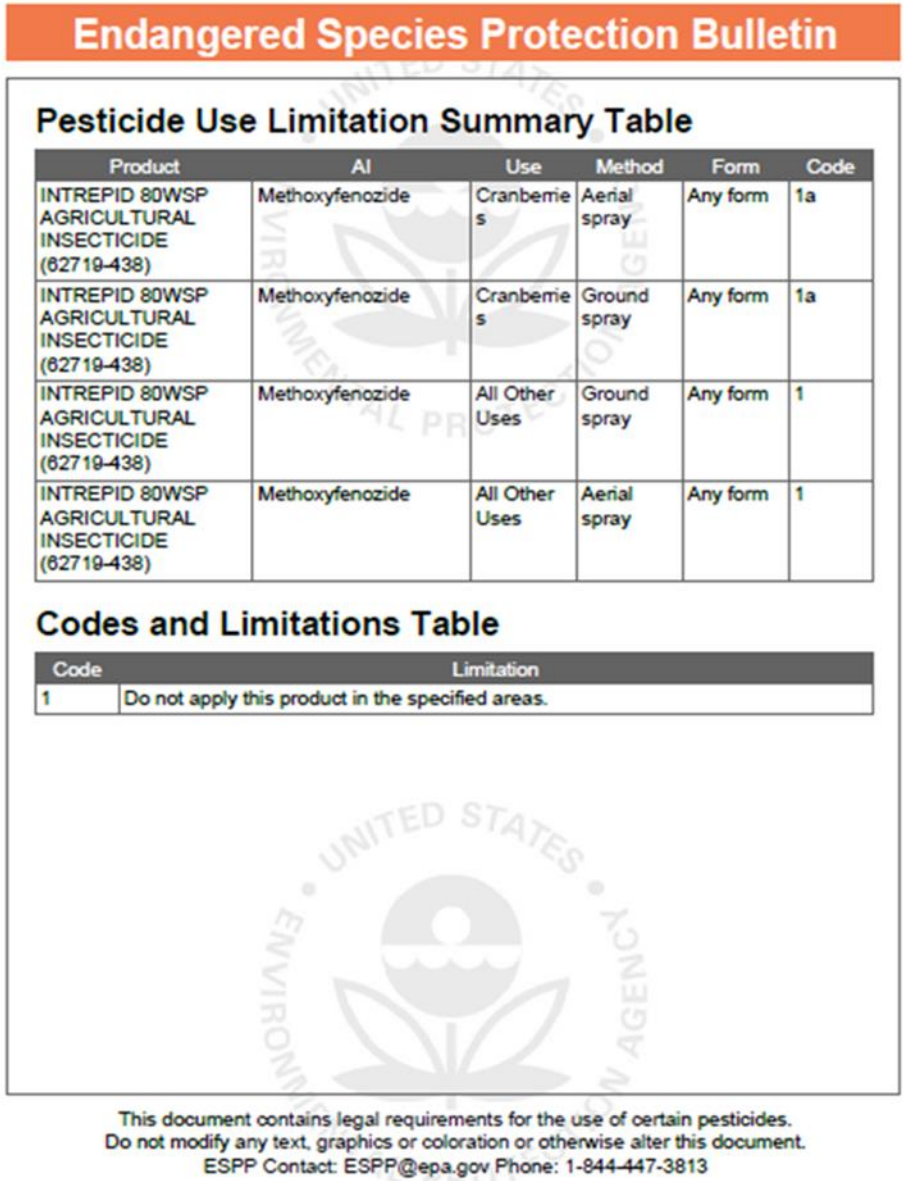
**Method:** This column specifies the application method (*e.g.,* aerial spray, ground spray, seed treatment, bait, broadcast, etc.) associated with the limitation.

**Form:** This column specifies the chemical formulation (*e.g.,* bait, dust, ear tag, liquid, granular, etc.) associated with the limitation.

**Code:** This column specifies the code associated with the limitation. This code can be used to identify the active ingredient(s) and/or product(s) associated with limitation in the Pesticide Use and Limitation Summary Table.

**Limitation:** This column matches the code with a full description of the pesticide use limitation.

When applying a pesticide product with multiple active ingredients, follow all of the codes and corresponding limitations.



**Endangered Species Protection Bulletin**

**Pesticide Use Limitation Summary Table**

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|---|---|---|---|---|---|
| INTREPID 80WSP AGRICULTURAL INSECTICIDE (62719-438) | Methoxyfenozide | Cranberries | Aerial spray | Any form | 1a |
| INTREPID 80WSP AGRICULTURAL INSECTICIDE (62719-438) | Methoxyfenozide | Cranberries | Ground spray | Any form | 1a |
| INTREPID 80WSP AGRICULTURAL INSECTICIDE (62719-438) | Methoxyfenozide | All Other Uses | Ground spray | Any form | 1 |
| INTREPID 80WSP AGRICULTURAL INSECTICIDE (62719-438) | Methoxyfenozide | All Other Uses | Aerial spray | Any form | 1 |

**Codes and Limitations Table**

| Code | Limitation |
|---|---|
| 1 | Do not apply this product in the specified areas. |

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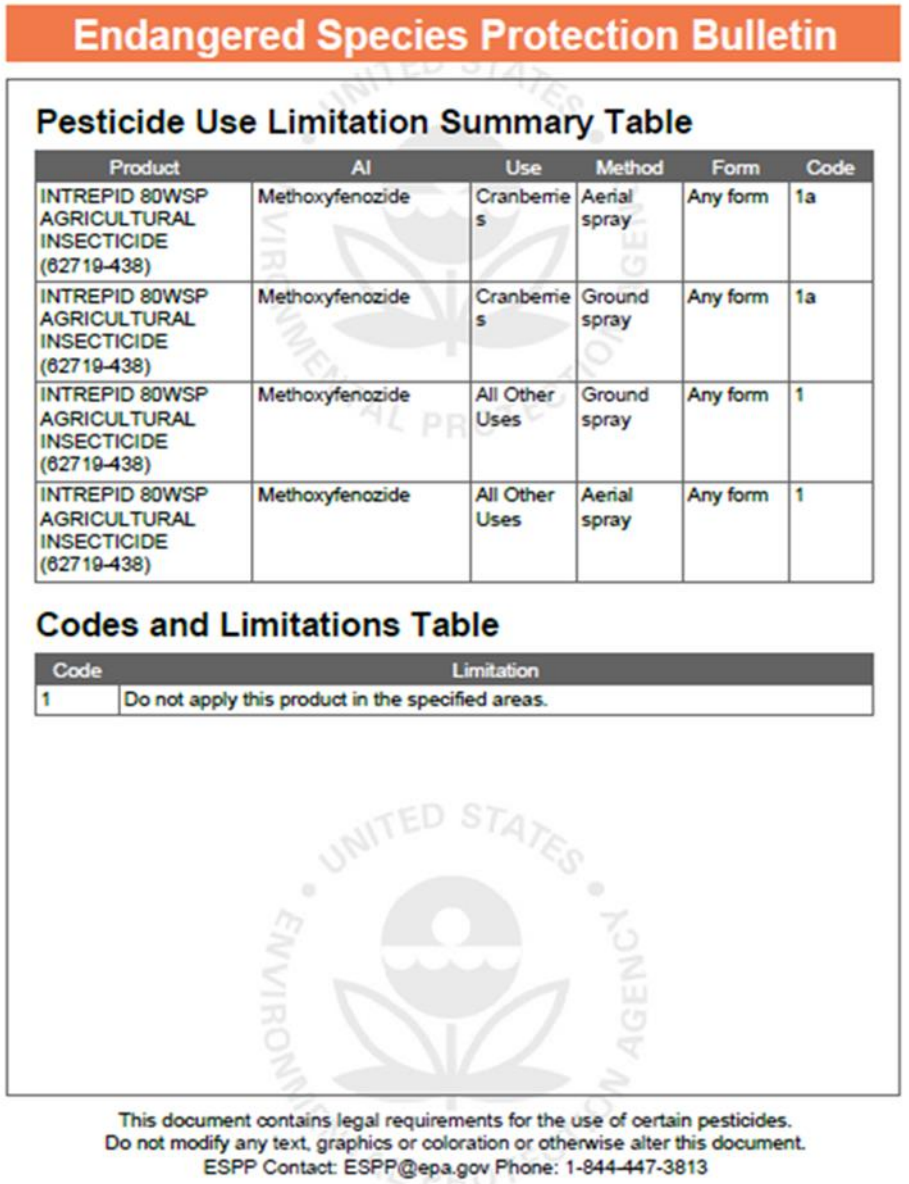
# 7. Understanding the components of the PDF Bulletin

The Pesticide Use Limitation Summary Table identifies the Code(s) associated with the highlighted PULA. It also provides the:

**Code:** This column specifies the code associated with the limitation. This code can be used to identify the active ingredient(s) and/or product(s) associated with limitation in the Pesticide Use and Limitation Summary Table.

**Limitation:** This column matches the code with a full description of the pesticide use limitation.

When applying a pesticide product with multiple active ingredients, follow all of the codes and corresponding limitations.



**Endangered Species Protection Bulletin**

**Pesticide Use Limitation Summary Table**

| Product | AI | Use | Method | Form | Code |
|---|---|---|---|---|---|
| INTREPID 80WSP AGRICULTURAL INSECTICIDE (62719-438) | Methoxyfenozide | Cranberries | Aerial spray | Any form | 1a |
| INTREPID 80WSP AGRICULTURAL INSECTICIDE (62719-438) | Methoxyfenozide | Cranberries | Ground spray | Any form | 1a |
| INTREPID 80WSP AGRICULTURAL INSECTICIDE (62719-438) | Methoxyfenozide | All Other Uses | Ground spray | Any form | 1 |
| INTREPID 80WSP AGRICULTURAL INSECTICIDE (62719-438) | Methoxyfenozide | All Other Uses | Aerial spray | Any form | 1 |

**Codes and Limitations Table**

| Code | Limitation |
|---|---|
| 1 | Do not apply this product in the specified areas. |

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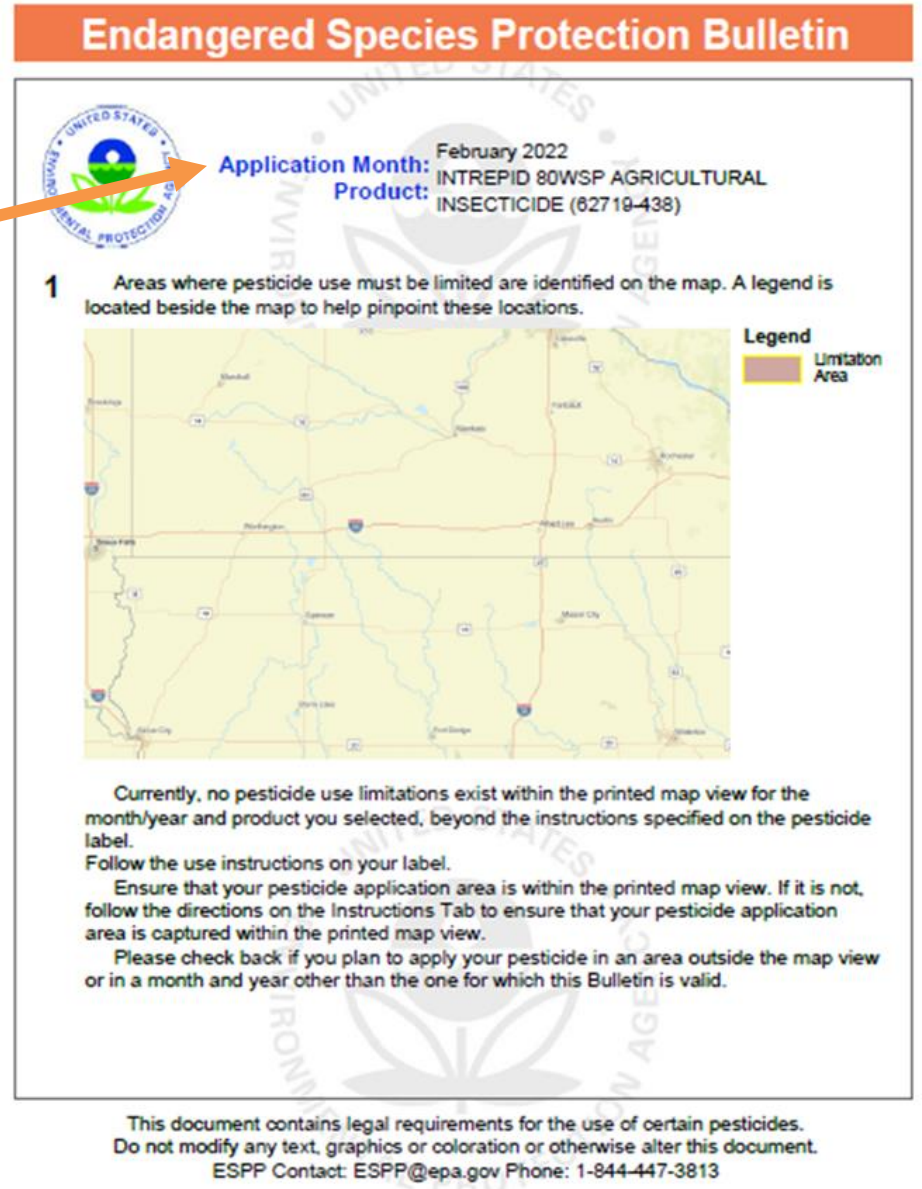
# 7. Understanding the components of the PDF Bulletin

## If no PULAs occur within your intended pesticide application area:

The month for which the Bulletin is valid is located at the top of the page.

If there are no PULAs within the intended application area, no pink-shaded use limitation areas will appear on the map.

If this occurs, there are currently no pesticide use limitations in place to protect listed species at this location for the month indicated at the top of the Bulletin.



**Endangered Species Protection Bulletin**

**Application Month:** February 2022
**Product:** INTREPID 80WSP AGRICULTURAL INSECTICIDE (62719-438)

1 Areas where pesticide use must be limited are identified on the map. A legend is located beside the map to help pinpoint these locations.

**Legend**
Limitation Area

Currently, no pesticide use limitations exist within the printed map view for the month/year and product you selected, beyond the instructions specified on the pesticide label.
Follow the use instructions on your label.
Ensure that your pesticide application area is within the printed map view. If it is not, follow the directions on the Instructions Tab to ensure that your pesticide application area is captured within the printed map view.
Please check back if you plan to apply your pesticide in an area outside the map view or in a month and year other than the one for which this Bulletin is valid.

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# 8. Additional Information:

The geographic area where a pesticide use limitation is present to protect listed species and their designated critical habitat is referred to as a Pesticide Use Limitation Area (PULA).

Each PULA is relevant for the pesticide active ingredient(s) and product(s) specified for that area. The search tools in the BLT application can be used to view specific active ingredients and/or products associated with a given PULA for the intended application area specified in the user-defined search.

Limitation information can be found in the ***Limitations for Selected Area Table*** within the application, and in the PDF version of the Bulletin.

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# EPA Approves New Labels for Cyantraniliprole to Better Protect Endangered Species

## Released on September 28, 2023

The U.S. Environmental Protection Agency (EPA) has approved new labels for the insecticide cyantraniliprole that include new mitigations to protect federally threatened or endangered (listed) species. This action reflects EPA's efforts to meet its obligations under the Endangered Species Act (ESA) by identifying potential effects to listed species, implementing necessary mitigations, and initiating the ESA consultation process with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (referred to as "the Services").

### Background

EPA first registered products containing cyantraniliprole in 2014. Cyantraniliprole is an insecticide that can be used on a variety of fruit, vegetable, and nut crops and as a seed treatment on some crops to control the Asian citrus psyllid as well as lepidopteran insects, dipteran leafminers, fruit flies, beetles, whiteflies, thrips, aphids, leafhoppers, psyllids, and weevils. It is also registered for non-agricultural uses on turf and ornamental plants.

In some instances, cyantraniliprole is the only non-neonicotinoid active ingredient available for growers. Growers and applicators can use cyantraniliprole in rotation with neonicotinoids (or other insecticides) to reduce the potential spread of insecticide resistance. Cyantraniliprole is also a useful addition to Integrated Pest Management (IPM) programs because it is less disruptive to some non-target insects than some insecticide alternatives. These non-target insects are beneficial because they can eat target pests—providing a natural control mechanism.

Following registration, the Center for Biological Diversity and the Center for Food Safety filed a petition for review in the D.C. Circuit, alleging that EPA had not met its ESA consultation obligations before registering products containing cyantraniliprole. In 2017, the D.C. Circuit agreed and remanded the registrations without vacating them for EPA to complete its ESA effects determinations and any necessary consultation with the Services. In November 2022, the court ordered, among other things, that EPA complete cyantraniliprole's ESA effects determination by September 2023.

## EPA's Biological Evaluation

EPA published cyantraniliprole's draft biological evaluation (BE) and supporting documents for public comment in January 2023. The draft BE included a draft effects determination that evaluated the effects of the registration on listed species and designated critical habitats. The draft BE also predicted whether the registered uses of cyantraniliprole presented a potential likelihood of jeopardy to listed species or adverse modification to critical habitats.

Now, EPA is publishing its final BE. Accounting for new mitigation measures registrants agreed to, EPA revised some of its effects determinations and predictions of the likelihood of jeopardy and adverse modification for cyantraniliprole's final BE. EPA evaluated the effects of cyantraniliprole on over 1,700 listed species and over 800 critical habitats in the United States and its territories and determined that cyantraniliprole, with the revised mitigation measures:

- Will have no effect on 33 percent of species and 47 percent of critical habitats (as compared to 25 percent and 33 percent, respectively, from the draft BE);
- May affect but is not likely to adversely affect 31 percent of species and 38 percent of critical habitats (as compared to 34 percent and 54 percent, respectively, from the draft BE); and

- Is likely to adversely affect (LAA) 36 percent of listed species and 16 percent of critical habitats (as compared to 41 percent and 13 percent, respectively, from the draft BE).

An LAA determination means that EPA reasonably expects that at least one individual animal or plant, among a variety of listed species, may be exposed to cyantraniliprole at a sufficient level to have an adverse effect. This is the case even if a listed species is almost recovered to a point where it may no longer need to be listed. Adverse effects to even one individual of a listed species is enough to trigger such a determination. As a result, there are often a high number of LAA determinations. An LAA determination, however, does not necessarily mean that a pesticide is putting a species in jeopardy.

EPA further refined its analysis for the species and critical habitats where it made LAA determinations to predict the potential likelihood that cyantraniliprole use could result in jeopardy or adverse modification. These predictions examine effects of cyantraniliprole at the species scale (as opposed to one individual of a species). Of those species and habitats with an LAA determination, EPA's final BE predicted the uses of cyantraniliprole will not present a potential likelihood of jeopardy to any listed species or adverse modification for their critical habitats with the additional mitigation measures, as compared to 4 percent and 1 percent, respectively, from the draft BE.

For more information, see the final biological evaluation <https://www.regulations.gov/document/epa-hq-opp-2011-0668-0118>.

## Additional Label Requirements to Protect Listed Species

To mitigate effects to listed species and critical habitats, the cyantraniliprole registrants agreed to amend their registrations to add additional mitigation measures. Among other requirements, the revised labels require pesticide applicators to take several measures when using cyantraniliprole, including:

- requiring the use of spray nozzles that result in medium to coarser droplets (these droplets have more mass and are less likely to drift with the wind);
- requiring that applicators maintain a 25- to 50-foot distance from waterbodies during ground and aerial applications, respectively, to protect aquatic species and habitats;

- requiring that applicators maintain a 25-foot buffer around a crop when using an "airblast" sprayer (a sprayer that uses high-speed air to deliver pesticides) to dormant and non-bearing vegetation, or to bearing vegetation that are not at full canopy (such as a pear tree that is not fully leafed);
- requiring the use of swath displacement (a method that accounts for the wind and proactively applies less pesticide to certain areas of a field where spray drift is likely to occur) to reduce off-target spray drift caused by wind during aerial applications; and
- requiring the implementation of additional aerial buffers to protect 18 listed species and two critical habitats listed on EPA's Bulletins Live Two! Website <https://epa.gov/endangered-species/bulletins-live-two-view-bulletins>.

For a complete list of the required mitigations, see the revised product labels.

## Next Steps

Since EPA determined that cyantraniliprole is likely to adversely affect listed species and critical habitats, the Agency has initiated formal consultation with the Services.

During formal consultation, the Services use EPA's final BE to inform their biological opinions, which will include their final determinations of whether the use of cyantraniliprole jeopardizes any listed species or adversely modifies any critical habitat. EPA will continue to work with the Services during the consultation process.

The final BE, revised labels, and other supporting documents are available in docket EPA-HQ-OPP-2011-0668 <https://www.regulations.gov/docket/epa-hq-opp-2011-0668> on www.regulations.gov <https://www.regulations.gov>.

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LAST UPDATED ON SEPTEMBER 28, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

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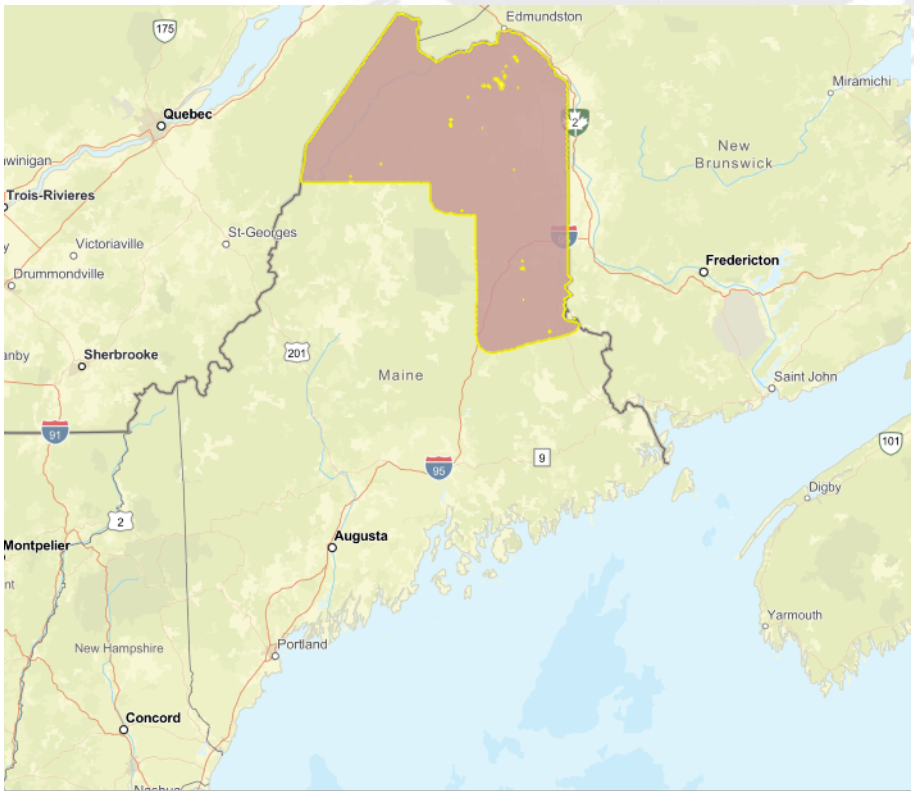
# Follow.

# Endangered Species Protection Bulletin

**Application Month:** November 2023
**Product:** All products with limitations in selected area

**1** Areas where pesticide use must be limited are identified on the map. A legend is located beside the map to help pinpoint these locations.




**2** Look below at the Pesticide Use Limitation Summary Table. This table lists the user selected Active Ingredient(s) (ALs) or Product(s) with pesticide use limitations on the printed map. Locate the Active Ingredient (AI) or Product you intend to apply in this table and identify the code in the last column. This code indicates the specific limitation associated with that AI or Product. A limitation description for each code can be found below in the Codes and Limitations Table. If multiple Pesticide Use Limitation Areas (PULAs) are visible on the map, these tables provide information for the highlighted PULA.

If you are applying a pesticide that contains more than one Active Ingredient, or multiple Products, then multiple codes may apply. Follow the limitations for all codes when using this pesticide.

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# Endangered Species Protection Bulletin

## Pesticide Use Limitation Summary Table

| Product | AI | Use | Method | Form | Code |
|---|---|---|---|---|---|
| BENEVIA insect control (279-9614) Inactive: DUPONT BENEVIA insect control | Cyantraniliprole | All Agricultural Uses | Aerial spray | Emulsifiable Concentrate | CYN23 |
| EXIREL INSECT CONTROL (279-9615) Inactive: DUPONT EXIREL insect control | Cyantraniliprole | All Agricultural Uses | Aerial spray | Emulsifiable Concentrate | CYN23 |
| Mainspring Flora (100-1585) | Cyantraniliprole | All Agricultural Uses | Aerial spray | Granular | CYN23 |
| MAINSPRING GNL (100-1543) Alternate: MAINSPRING GH & N Inactive: HGW86 GH & N INSECT CONTROL | Cyantraniliprole | All Agricultural Uses | Aerial spray | Emulsifiable Concentrate | CYN23 |
| MAINSPRING GNL (100-1543) Alternate: MAINSPRING GH & N Inactive: HGW86 GH & N INSECT CONTROL | Cyantraniliprole | All non-agricultural uses | Aerial spray | Emulsifiable Concentrate | CYN23 |
| MAINSPRING GNL (100-1543) Alternate: MAINSPRING GH & N Inactive: HGW86 GH & N INSECT CONTROL | Cyantraniliprole | Christmas Tree Plantations | Aerial spray | Emulsifiable Concentrate | CYN23 |
| MINECTO DUO INSECTICIDE (100-1421) Inactive: MINECTO DUO INSECTICIDE, A16901B CP | Cyantraniliprole | All Agricultural Uses | Aerial spray | Granular | CYN23 |
| Minecto Pro (100-1592) | Cyantraniliprole | All Agricultural Uses | Aerial spray | Emulsifiable Concentrate | CYN23 |

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# Endangered Species Protection Bulletin

## Codes and Limitations Table

| Code | Limitation |
|---|---|
| CYN23 | For aerial applications using medium to coarse droplet sizes, a 75 foot in-field, wind-directional buffer for windspeeds =<10 mph or a 100 foot in-field, wind-directional buffer for windspeeds 11-15 mph are required. For aerial applications using coarse to very coarse droplet sizes, a 40 foot in-field, wind-directional buffer for windspeeds =<10 mph or a 50 foot in-field, wind-directional buffer for windspeeds 11-15 mph are required. The applicator must maintain the appropriate in-field, wind-directional buffer as described above from treatment sites to any area except the following: 1) Roads, paved or gravel surfaces, 2) planted agricultural fields, 3) agricultural fields that that have been prepared for planting, or 4) areas covered by the footprint of a building, shade house, silo, feed crib, or other man-made structure with walls and/or a roof. In-field, wind directional buffers can be maintained at half the distance required above when windbreaks (e.g., trees or riparian hedgerows) between the application site and all areas except those listed above are present. The windbreak would need to have a row of broad-leaved trees the full length of the treated crop with leaves visible over the entire length, with no significant gaps. The height of the trees or windbreak would need to be at a height greater than the crop to be sprayed. |

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# BENEVIA®

INSECT CONTROL

WITH THE ACTIVE INGREDIENT CYAZYPYR®

ACCEPTED
09/27/2023
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 279-9614

GROUP 28 INSECTICIDE

**For foliar applications to bulb, legume and tuberous and corm vegetables; cotton; oil seed crops; peanuts; soybeans; tobacco and tree nuts for pest management of sucking and chewing insects that can vector certain plant diseases, aiding in optimization of the crop's potential.**

| *Active Ingredient* | *By Weight* |
|---|---|
| **Cyantraniliprole** | |
| 3-bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide | 10.26% |
| *Other Ingredients* | 89.74% |
| TOTAL | 100.00% |

BENEVIA® is an oil dispersion. SHAKE WELL BEFORE USING.

Contains 0.83 lb. active ingredient per gallon.

EPA Reg. No. 279-9614 EPA Est. No. _____

**Nonrefillable Container** Net: _____

OR

**Refillable Container** Net: _____

Not for sale, sale into, distribution and/or use in Nassau and Suffolk counties of New York State.

## KEEP OUT OF REACH OF CHILDREN

# CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

## FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

For questions regarding emergency medical treatment, you may contact 1-800-331-3148 for information.

## PRECAUTIONARY STATEMENTS
## HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION:** Causes moderate eye irritation. Avoid contact with eyes. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

## PERSONAL PROTECTIVE EQUIPMENT

**Applicators and other handlers must wear:**

Long-sleeved shirt and long pants.

Shoes plus socks.

After the product has been diluted in accordance with label directions for use, shirt, pants, socks, and shoes are sufficient Personal Protective Equipment. Follow manufacturer's instructions for cleaning/maintaining personal protective equipment (PPE). If no such instructions for washables are available, use detergent and hot water. Keep and wash PPE separately from other laundry.

**Sold By**

FMC

**FMC Corporation**
**2929 Walnut Street**
**Philadelphia, PA 19104**

## USER SAFETY RECOMMENDATIONS

**USERS SHOULD:** Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

## PHYSICAL OR CHEMICAL HAZARDS

Do not place product near or allow product to come into contact with strong oxidizing substances (such as potassium permanganate) since a hazardous chemical reaction may occur.

## ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic invertebrates and oysters. Do not apply directly to water. Drift and runoff may be hazardous to aquatic organisms in water adjacent to use sites. This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are foraging the treatment area.

**Surface Water Advisory-**

This product may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having high potential for reaching surface water via runoff for several weeks after application. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of cyantraniliprole from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

**Ground Water Advisory-**

This chemical has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow.

## PROTECTION OF POLLINATORS

APPLICATION RESTRICTIONS EXIST FOR THIS PRODUCT BECAUSE OF RISK TO BEES AND OTHER INSECT POLLINATORS. FOLLOW APPLICATION RESTRICTIONS FOUND IN THE DIRECTIONS FOR USE TO PROTECT POLLINATORS.

Look for the bee hazard icon  in the Directions for Use for each application site for specific use restrictions and instructions to protect bees and other insect pollinators.

**This product can kill bees and other insect pollinators.**

Bees and other insect pollinators will forage on plants when they flower, shed pollen, or produce nectar.

Bees and other insect pollinators can be exposed to this pesticide from:

- Direct contact during foliar applications, or contact with residues on plant surfaces after foliar applications
- Ingestion of residues in nectar and pollen resulting from foliar applications.

When Using This Product Take Steps To:

- Minimize exposure of this product to bees and other insect pollinators when they are foraging on pollinator attractive plants in and around the application site.
- Minimize drift of this product onto beehives or to off-site pollinator attractive habitat. Drift of this product onto beehives or off-site to pollinator attractive habitat can result in bee kills.

Information on protecting bees and other insect pollinators may be found at the Pesticide Environmental Stewardship website at: http://pesticidestewardship.org/PollinatorProtection/Pages/default.aspx.

Pesticide incidents (for example, bee kills) should immediately be reported to the state/tribal lead agency. For contact information for your state, go to: www.aapco.org/officials.html. Pesticide incidents should also be reported to the National Pesticide Information Center at: www.npic.orst.edu or directly to EPA at: beekill@epa.gov

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

**ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS**: Before using this product, you must obtain any applicable Endangered Species Protection Bulletins ('Bulletins') within six months prior to or on the day of application. To obtain Bulletins, go to Bulletins Live! Two (BLT) at **https://www.epa.gov/pesticides/bulletins**. When using this product, you must follow all directions and restrictions contained in any applicable Bulletin(s) for the area where you are applying the product, including any restrictions on application timing if applicable. It is a violation of Federal law to use this product in a manner inconsistent with its labeling, including this labeling instruction to follow all directions and restrictions contained in any applicable Bulletin(s). For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov.

1. **FOR CROPS UNDER CONTRACTED POLLINATION SERVICES**

Do not apply this product while bees are foraging. Do not apply this product until flowering is complete and all petals have fallen unless the following conditions is met.

- If an application must be made when managed bees are at the treatment site, the beekeeper providing the pollination services must be notified no less than 48-hours prior to the time of the planned application so that the bees can be removed, covered or otherwise protected prior to spraying.

2. **FOR FOOD CROPS AND COMMERCIALLY GROWN ORNAMENTALS NOT UNDER CONTRACT FOR POLLINATION SERVICES BUT ARE ATTRACTIVE TO POLLINATORS**

Do not apply this product while bees are foraging. Do not apply this product until flowering is complete and all petals have fallen unless one of the following conditions is met:

- The application is made to the target site after sunset
- The application is made to the target site when temperatures are below 55˚F
- The application is made in accordance with a government-initiated public health response
- The application is made in accordance with an active state-administered apiary registry program where beekeepers are notified no less than 48-hours prior to the time of the planned application so that the bees can be removed, covered or otherwise protected prior to spraying
- The application is made due to an imminent threat of significant crop loss, and a documented determination consistent with an IPM plan or predetermined economic threshold is met. Every effort should be made to notify beekeepers no less than 48- hours prior to the time of the planned application so that the bees can be removed, covered or otherwise protected prior to spraying.

## RESTRICTIONS

- Do not make ground applications within 25' or aerial applications within 50' of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, permanent streams, wetlands or natural ponds, estuaries, and commercial fish farm ponds). Do not cultivate within 30' of these aquatic areas to allow growth of a vegetative filter strip.
- For foliar uses, do not apply during rain.
- When making air blast applications to orchard crops with sparse canopies a 25 foot buffer is required between the application site and all adjacent areas except for roads (and other paved or gravel surfaces), agricultural areas (fields that have been planted into or prepared for planting), and structural areas (buildings or other man-made structures with walls and/or a roof). A sparse canopy occurs during the period of dormancy starting from first leaf drop at the end of the season until vegetation is fully leafed out in the spring, and on young orchard crops that are not yet bearing.
- Do not treat plants grown for transplanting. Not for use in nurseries, plant propagation houses, or greenhouses by commercial transplant producers on plants being grown for transplanting.
- Do not apply BENEVIA® to the soil or through drip irrigation systems. May be used on crops on this label grown for seed production.
- Do not use in residential areas.
- Do not apply BENEVIA® insect control through any irrigation system unless specified in the crop section of this label.
- Unless otherwise stated for a specific crop, do not apply a total of more than 0.4 lb ai/A of CYAZYPYR® or cyantraniliprole containing products per calendar year. This is the total from all application methods (eg. seed, soil, foliar).

## AGRICULTURAL USE REQUIREMENTS

BENEVIA® must be used only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label about personal protective equipment, restricted-entry interval, and notification to workers (as applicable).

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

For early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear:

- Coveralls
- Shoes plus socks
- Chemical resistant gloves (made of any waterproof material)

BENEVIA® must be used in accordance with the directions for use on this label, or as otherwise permitted by FIFRA. Always read the entire label, including the Limitation of Warranty and Liability.

BENEVIA® is an oil dispersion that can be applied as a foliar spray on labeled crops or by overhead chemigation in potatoes and bulb vegetables to control listed insects. BENEVIA® is specially formulated for maximum performance by foliar applications in bulb, legume and tuberous and corm vegetables; cotton; oil seed crops; peanuts; soybeans; tobacco and tree nuts. Do not apply directly to the soil or through drip irrigation as doing so may damage the plant root system. BENEVIA® is mixed with water for application.

BENEVIA® is a member of the anthranilic diamide class of insecticides with a novel mode of action acting on insect ryanodine receptors. Although BENEVIA® has contact activity, it is most effective through ingestion of treated plant material. After exposure to BENEVIA®, affected insects will rapidly stop feeding, become paralyzed, and typically die within 1 - 3 days, reducing both direct damage and the transmission of some insect transmitted diseases. Early season applications of BENEVIA® improve crop establishment and growth vigor by controlling a range of pests that attack seedlings. Time applications to the most susceptible insect pest stage, typically at egg hatch and/or newly hatched larvae or nymphs, before populations reach damaging levels. When pest populations are high, use the highest listed application rate for that pest. For best results when targeting control of sucking pests, begin applications when insect populations first appear. BENEVIA® has preventative activity, but low curative activity for sucking pests.

## *INTEGRATED PEST MANAGEMENT*

FMC supports the use of Integrated Pest Management (IPM) programs to control pests. This product may be used as part of an IPM program, which can include biological, cultural, and genetic practices, aimed at preventing economic pest damage. IPM principles and practices include field scouting or other detection methods, correct target pest identification, population monitoring, rotation of insecticides with different modes-of-action, and treating when target pest populations reach locally determined action thresholds. For best results with sucking pests, apply at specified rates when insects first appear. Consult your state cooperative extension service, professional consultants or other qualified authorities to determine appropriate action treatment threshold levels for treating specific pest/crop or site systems in your area.

## *SCOUTING*

Monitor insect populations to determine whether or not there is a need for application of BENEVIA® based on locally determined pest management guidelines. More than one treatment of BENEVIA® may be required to control a population of pests.

## *INSECT RESISTANCE MANAGEMENT*

For resistance management, BENEVIA® is a Group 28 Insecticide. Repeated and exclusive use of BENEVIA® (cyantraniliprole) or other Group 28 insecticide belonging to the anthranilic diamide class of chemistry may lead to the buildup of resistant strains of insects in some crops.

Some insects are known to develop resistance to products used repeatedly for control. Because the development of resistance cannot be predicted, this product may be used as part of a resistance management strategy established for the use area. These strategies may include incorporation of cultural and biological control practices, alternation of mode-of-action classes of insecticides on succeeding generations and the most susceptible life stage. Consult your local or state agricultural authorities for details.

Unless directed otherwise in the specific crop/pest sections of this label, the best practices are to follow these instructions to delay the development of insecticide resistance:

- Avoid using the same mode of action (same IRAC group number) on consecutive generations of insect pests.
- Make no more than 2 applications of BENEVIA® (cyantraniliprole) or other Group 28 products per generation to the same insect species on a crop.
- Application to the next generation of target pest(s) must be with an effective product with a different mode of action (non- Group 28 insecticide).
- Make no more than 2 successive applications within a 30-day period to the same insect species on a crop. The following application to the target pest(s) must be with an effective product with a different mode of action.
- Avoid using less than the labeled rates of BENEVIA® when applied alone or in tank mixtures.
- Target the most susceptible insect life stages, whenever possible.
- Monitor insect populations for product effectiveness. If resistance to BENEVIA® develops in your area, BENEVIA® or other products with a similar mode of action, may not provide adequate control.
- If poor performance cannot be attributed to improper application or extreme weather conditions, a resistant strain of insect may be present. If you experience difficulty with control and resistance is a reasonable cause, immediately consult your local FMC company representative or agricultural advisor for the best alternative method of control.

For additional information on insect resistance monitoring, visit the Insecticide Resistance Action Committee (IRAC) on the web at http://www.irac-online.org.

## APPLICATION

Apply at the specified rates when insect populations reach locally determined action thresholds. For best results with sucking pests, begin applications when insects first appear. Consult the cooperative extension service, professional consultants or other qualified authorities for local pest management guidelines in your area.

Apply follow-up treatments of BENEVIA®, as specified, to keep pest populations under threshold limits. Refer to the Resistance Management section of this label for further guidance on follow-up treatments. See individual crop sections of this label for specific minimum spray intervals.

Use sufficient water to obtain thorough, uniform coverage.

BENEVIA® may be applied by: foliar ground (including overhead chemigation in potatoes and bulb vegetables), or aerial application equipment.

BENEVIA® may be applied via overhead sprinkler chemigation systems on potatoes and bulb vegetables. Use of the highest labeled rate for the specified pest may be necessary when making overhead chemigation applications.

For aerial application use the following directions unless otherwise specified in specific crop/pest sections of this label or other supplemental labeling: use a minimum of 5 gallons per acre (gpa) of water for bulb vegetables, cotton, oil seed crops and tuberous and corm vegetables and use 10 gallons per acre (gpa) for tree nuts. Use of the highest labeled rate for a specified pest may be necessary when making aerial applications.

For foliar ground applications use the following directions, unless otherwise specified in specific crop/pest sections of this label or other supplemental labeling: use a minimum of 10 gal per acre (gpa) of water for bulb vegetables, cotton, oilseed crops and tuberous and corm vegetables and use a minimum of 30 gallons per acre (gpa) for tree nuts.

***Use of Adjuvants*** - In some situations where coverage is difficult to achieve such as closed canopy, dense foliage, plants with waxy leaf surfaces, or less than optimum applications equipment, an adjuvant may improve performance. Use a proven and recommended adjuvant that does not affect foliage and/or fruit finish. Tank mixes of BENEVIA® with spreading and penetrating adjuvants can result in adverse crop response. See specific crop instructions in the following crop tables.

## SPRAY PREPARATION

Spray equipment must be clean and free of previous pesticide deposits before applying BENEVIA®. Fill spray tank 1/4 to 1/2 full of water. Add BENEVIA® directly to spray tank. Mix thoroughly to fully disperse the insecticide, once dispersed continued agitation is required. Use mechanical or hydraulic means; do not use air agitation. Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures.

***Acidification of Spray Tank*** - If the pH of the spray tank after all products have been added and mixed is above pH 8, adjust to pH 8 or less using a registered acidifying agent. If the spray tank pH is 8 or less no adjustment of the spray tank pH is necessary. Spray tanks of pH 8 or less can be held for up to 8 hours before spraying. Do not store the spray mixture overnight in the spray tank.

***Compatibility*** -Since formulations may be changed and new ones introduced, premix a small quantity of a desired tank mix and observe for physical incompatibility (settling out, flocculation, etc.). Spray volumes of less than 3 gallons of water and tank mixtures of more than two products can increase the chances of incompatible spray mixtures. A jar test (as described below) should be conducted when label guidance is not given or prior experience with a specific tank mixture is unknown. The jar test should follow the proper sequence of addition at the spray water volume planned to assure that the tank mix is compatible. Constant agitation may be needed during mixing and spraying of mixtures.

This product can be mixed with pesticide products labeled for use on crops on this label in accordance with the most restrictive of label limitations and precautions. Do not exceed labeled dosage rates. This product cannot be mixed with any product containing a label prohibition against such mixing.

Steps to conduct a jar test to determine physical tank mix compatibility of BENEVIA® with other products:

- Add clean water to jar proportional to the planned water volume that will be used in the spray tank (a jar size of 8-16 oz is acceptable).
- Using the most restrictive PPE of the products to be tested, mix proper proportions of BENEVIA® and desired tank mix partner(s) as will be present in the spray tank, add one product at a time following the sequence of addition according to formulation type provided in this label.
- Seal and shake mixture after each product is added.
- Allow to stand for 1 hour.
- View jar to determine if settling, flocculation, crystallization or any other undesirable changes have happened.
- If none of the above is observed or the solution can be easily remixed after shaking, the mixture is compatible with BENEVIA®.
- If the tank mix is not compatible, a higher water volume, reduced rate of the tank mix partner(s), reduced number of tank mix partners or a compatibility agent may be needed.

***TANK MIXTURES AND CROP SAFETY***- BENEVIA® is an oil in water emulsion. The crop safety of BENEVIA® alone or in tank mix with many common insecticides, fungicides, nutritionals and adjuvants has been found to be acceptable. Tank mixes of BENEVIA® with some products formulated as emulsifiable concentrates (EC), strobilurin fungicides (for example Cabrio and Quadris), copper and sulfur based fungicides, chlorothalonil based fungicide formulations (for example, Bravo Weather Stik), and the fungicides Captan, Tanos, Rally and Manzate may result in adverse crop response. Some materials including oils, surfactants, adjuvants, nutritionals and pesticide formulations when applied individually, sequentially, or in tank mixtures may solubilize the plant cuticle, facilitate penetration into plant tissue, and increase the potential for crop injury.

The application of strobilurin fungicides in a short time sequence (i.e., seven days apart or less between applications) before or after BENEVIA® may also result in adverse crop response. Applying BENEVIA® with any product that produces adverse crop response in a tank mixture, specifically including, but not limited to, those listed above, may also cause adverse crop response when applied in a short time sequence. Such uses should be tested as described below before broad application is made.

Crop varieties can differ in their responsiveness to tank mixtures, and environmental conditions can have an influence on product performance and crop response. It is not possible to test BENEVIA® alone or with all possible tank mix combinations and sequences on all varieties under all environmental conditions. When considering the use of a tank mixture on a labeled crop without prior experience, or which is not specifically described on BENEVIA® product labeling or in other FMC product use instruction, or when applying any of the aforementioned products in close sequence with BENEVIA®, it is important to check crop safety first. To test for crop safety prepare a small volume of the intended tank mixture or sequence, apply it to an area of the target crop as directed by both this and the tank mix partner product labels, and

observe the treated crop to ensure that a phytotoxic response does not occur.

It is the pesticide user's responsibility to ensure that all products are registered for the intended use. Read and follow the applicable restrictions and limitations, and directions for use, on all product labels involved in tank mixing. Users must follow the most restrictive directions for use and precautionary statements on each product in the tank mixture. Use of BENEVIA® in any tank mixture or sequence of applications that is not specifically described on BENEVIA® product labeling or in other FMC product use instructions, could potentially result in crop injury. To the extent allowed by law, FMC will not be responsible for any crop injury arising from the use of a tank mixture or sequence of applications that is not specifically described on BENEVIA® product labeling or in other FMC product use instruction.

***Tank Mixing Sequence*** -Add different formulation types in the sequence indicated below*. Allow time for complete mixing and dispersion after addition of each product.

1. Water soluble bag (WSB)
2. Water soluble granules (SG)
3. Water dispersible granules (WG, XP, DF)
4. Wettable powders (WP)
5. Water based suspension concentrates (SC)
6. Water soluble concentrates (SL)
7. Suspoemulsions (SE)
8. BENEVIA® and other oil based suspension concentrates (OD)
9. Emulsifiable concentrates (EC)
10. Surfactants, oils adjuvants
11. Soluble fertilizers
12. Drift retardants

* Unless otherwise specified by manufacturer directions for use or by local experience.

## CHEMIGATION - Overhead Sprinkler - Potatoes and Bulb Vegetables

The following types of irrigation equipment may be used for chemigation applications to potatoes and bulb vegetables: overhead sprinkler irrigation systems.

Apply BENEVIA® in sufficient water and of sufficient duration to ensure the specified rate is applied evenly to the entire treated area. Inject BENEVIA® downstream from any water filtration system.

Do not connect any irrigation system used for pesticide applications to a public water system unless the pesticide label- prescribed safety devices are in place. Public water system means a system for the provision to the public of piped water for human consumption, if such system has at least 15 service connections or regularly serves an average of at least 25 individuals at least 60 days out of the year.

**See "Required System Safety Devices For All Chemigation Systems" at the end of the Chemigation section.**

***APPLICATION INSTRUCTIONS FOR CHEMIGATION USING OVERHEAD SPRINKLER SYSTEMS - POTATOES AND BULB VEGETABLES***

Types of Chemigation Systems: BENEVIA® may be applied to potatoes and bulb vegetables through overhead sprinkler irrigation systems, including the following; center pivot, end tow, hand move, lateral move, side roll, solid set and wheel line. The irrigation system used must provide uniform water distribution.

***Directions for Chemigation:***

***Preparation***

A pesticide tank is recommended for the application of BENEVIA® in chemigation systems.

Thoroughly clean the injection system and tank of any fertilizer or chemical residues using a standard clean-out procedure. Dispose of any residues in accordance with State and Federal laws. With the mix tank 1/4 to 1/2 full with water and the agitator running, measure the required amount of BENEVIA® and add it to the tank. The highest labeled rate for the specified pest may be necessary when making overhead chemigation applications. Then add additional water to bring your total pesticide mixture up to the desired volume for your application. Note: Always add BENEVIA® to water, never put BENEVIA® into a dry tank or other mixing equipment without first adding water. See "Tank Mixing Sequence" section of the container label for tank mixing sequence. Continue to agitate the mixture throughout the application process. Use mechanical or hydraulic agitation, do not use air agitation.

**Injection Into Chemigation Systems**

Inject the proper amount of BENEVIA® into the irrigation water flow using a positive displacement injection pump or a Venturi injector. Injection should occur at a point in the main irrigation water flow to ensure thorough mixing with the irrigation water. For continuously moving systems, inject the solution containing BENEVIA® into the irrigation water line continually and uniformly throughout the irrigation cycle. Apply in no more than 0.2 inches of water per acre. For overhead sprinkler systems that are stationary, add the solution containing BENEVIA® to the irrigation water line and apply no more than 0.2 inches of water per acre.

**Uniform Water Distribution**

The irrigation system used for application of BENEVIA® must provide for uniform distribution of BENEVIA® treated water. Non-uniform distribution can result in crop injury, lack of effectiveness or illegal pesticide residues in or on the crop being treated. Ensure the irrigation system is calibrated to uniformly distribute the chemigation application to the crop. Contact the equipment manufacturer, the local University Extension agent or other experts if you have questions about achieving uniform distribution of the application.

**Equipment Calibration**

Calibrate the irrigation system and injector before applying BENEVIA®. Calibrate the injection pump while the system is running using the expected irrigation rate. If you have questions about calibration, you should contact your state extension service specialists, equipment manufacturer or other experts.

**Proposed Administrative Consent Agreement**
**Background Summary**

**Subject:** Green Shield Pest Solutions
985 Portland Road, Suite 101
Saco, ME 04072

**Date of Incident(s):** August 9, 2023 & September 14, 2023

**Background Narrative:** On August 9, 2023, a licensed applicator for Green Shield Pest Solutions applied Talstar P Insecticide, EPA Reg. No. 279-3206, to the residential property located at 16 Sea Garden Circle in Kennebunk, Maine for control of mosquitoes and ticks. The property at 16 Garden Circle is within 250 feet of a property listed on the Maine 2023 Pesticide Notification Registry. The 2023 Notification Registry participant informed Board staff that they had not been notified about the application. During the follow-up use inspection, a Company manager acknowledged not checking the 2023 Pesticide Notification Registry for new participants.

On September 14, 2023, a licensed applicator for Green Shield Pest Solutions applied Talstar P Insecticide, EPA Reg. No. 279-3206, to the residential property located at 16 Sea Garden Circle in Kennebunk, Maine for control of mosquitoes and ticks. The property at 16 Garden Circle is within 250 feet of a property listed on the Maine 2023 Pesticide Notification Registry. The 2023 Notification Registry participant informed Board staff that they had not been notified about the application. During the follow-up use inspection, Company office staff acknowledged their failure to contact the registry member prior to this application.

**Summary of Violations:** CMR 01-026, Chapter 28, Section 2 (D) requires commercial applicators to provide advance notification of outdoor pesticide applications made within 250 feet of the property of any participant on the current year Notification Registry.

The violations described above are considered a second and third offense within a four-year period pursuant to 7 M.R.S. § 616-A (2) A (2).

**Rationale for Settlement:** Green Shield Pest Solutions failed to check the 2023 Pesticide Notification Registry for new participants and client application sites that are within 250 feet of the registry members' property resulting in the first violation of failure to notify. That after review of the 2023 Pesticide Notification Registry and acknowledgement of failure to notify in August of 2023, Green Shield Pest Solutions failed to notify the same registrant prior to an outdoor pesticide application to the same property in September of 2023. These violations occurred within a four-year period of a previous violation for a pesticide application made at the incorrect property in 2021.

**Attachments:** Proposed Consent Agreement

NOV 16 2023
CK # 209
CK Amt: $500
CK Date: 209

**STATE OF MAINE**
**DEPARTMENT OF AGRICULTURE, CONSERVATION AND FORESTRY**
**BOARD OF PESTICIDES CONTROL**

| | | |
|---|---|---|
| In the Matter of: | ) | ADMINISTRATIVE CONSENT |
| Green Shield Pest Solutions | ) | AGREEMENT |
| 985 Portland Rd. Ste. 101 | ) | AND |
| Saco, Maine 04072 | ) | FINDINGS OF FACT |

This Agreement by and between Green Shield Pest Solutions (hereinafter referred to as the "Company") and the State of Maine Board of Pesticides Control (hereinafter referred to as the "Board"), as approved by the Office of the Attorney General ("OAG"), is entered into pursuant to 22 M.R.S. § 1471-M(2)(D) and in accordance with the Enforcement Protocol amended by the Board on December 13, 2013.

The parties to this Agreement agree as follows:

1. That on August 9, 2023, Tyler Whitten, a licensed commercial applicator employed by the Company, applied Talstar P, EPA Reg. No. 279-3206, to the residential property located at 16 Sea Garden Circle in Kennebunk, Maine for control of mosquitoes and ticks.

2. That 16 Garden Circle is within 250 feet of a property listed on the Maine 2023 Pesticide Notification Registry.

3. That the 2023 Notification Registry participant residing within 250 feet of the application site contacted the Board and informed the Board that they had not been notified about the application described in Paragraph 1.

4. That a Board representative conducted a follow up inspection with Tyler Whitten on August 14, 2023. Whitten stated that he was unaware that the application described in Paragraph 1 was to a property listed on the 2023 Pesticide Notification Registry.

5. That Company manager Gregory England stated that the Company had applied pesticides to the property described in Paragraph 1 in prior years. He further stated that the participant located within 250 feet of their customer was a new participant in 2023, and that he had failed to observe the new addition.

6. That on September 14, 2023, Shayne McIntyre, a licensed commercial applicator employed by the Company, applied Talstar P, EPA Reg. No. 279-3206, to the residential property located at 16 Sea Garden Circle in Kennebunk, Maine for control of mosquitoes and ticks.

7. That 16 Garden Circle is within 250 feet of a property listed on the Maine 2023 Pesticide Notification Registry.

8. That the 2023 Notification Registry participant residing within 250 feet of the application site contacted the Board and informed the Board that they had not been notified about the application described in Paragraph 6.

9. That a Board representative conducted a follow-up inspection with Shayne McIntyre on September 19, 2023. McIntyre stated that he was unaware that the application described in Paragraph 1 was to a property listed on the 2023 Pesticide Notification Registry.

10. That Company Office Manager, Louise Atkinson, and Company Supervisors, Colby Thayer and Brian Nash, were also present during the inspection on September 19, 2023.

11. That Office Manager, Louise Atkinson, is responsible for conducting notifications for the Company. Ms. Atkinson could not recall making notification nor could she find evidence of notification in the call logs for the application described in Paragraph 6.

12. That CMR 01-026, Chapter 28, Section 2 (D) requires commercial applicators to provide advance notification of outdoor pesticide applications made within 250 feet of the property of any participant on the current year Notification Registry.

13. That the Company failed to provide advance notification to a registry participant when conducting an outdoor commercial pesticide application within 250 feet of a listed participant.

14. That the circumstances described in Paragraphs 1 through 11 constitute two violations of CMR 01-026, Chapter 28, Section 2 (D).

15. That the Company entered into an Administrative Consent Agreement and Findings of Fact on February 25, 2022, to resolve a violation of Maine pesticide law which occurred on June 9, 2021.

16. That the violations described in Paragraph 14 are considered a second and third offense within a four-year period pursuant to 7 M.R.S. § 616-A (2).

17. That the Company expressly waives:

    A. Notice of or opportunity for hearing;

    B. Any and all further procedural steps before the Board; and

    C. The making of any further findings of fact before the Board.

18. That this Agreement shall not become effective unless and until the Board accepts it.

19. That in consideration for the release by the Board of the causes of action which the Board has against the Company resulting from the violations referred to in Paragraph 8, the Company agrees to pay a penalty to the State of Maine in the sum of $5,500.00 by November 21, 2023. (Please make checks payable to Treasurer, State of Maine).

20. The Board and OAG grant a release of their causes of actions against the Company for the specific violations cited in the immediately preceding paragraph (Paragraph 13) on the express condition that all actions listed in Paragraph 13 of this Agreement are completed in accordance with the express terms and conditions of this Agreement and to the satisfaction of the Board and the OAG. The release shall not become effective until the Company has completed its obligations pursuant to Paragraph 13.

21. Any non-compliance with any term or condition of this Agreement, as determined by the Board and OAG in their sole discretion, voids the release set forth in Paragraph 13 of this Agreement and may lead to an enforcement, suspension/revocation, equitable, and/or civil violation action pursuant to Titles 7 and 22 of the Maine Revised Statutes and/or M.R. Civ. P. 80H.

22. Nothing in this Agreement shall be construed to be a relinquishment of the Board's or OAG's powers under Titles 7 and 22 of the Maine Revised Statutes against the Company for any other violations other than those expressly listed in this Agreement.

23. This instrument contains the entire agreement between the parties, and no statements, promises, or inducements made by either party or agent of either party that are not contained in this written contract shall be valid or binding; this contract may not be enlarged, modified, or altered except in writing signed by the parties and indorsed on this Agreement.

24. The provisions of this Agreement shall apply to, and be binding on, the parties and their officers, agents, servants, employees, successors, and assigns, and upon those persons in active concert or participation with them who receive actual notice of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement of three pages.

GREEN SHIELD PEST SOLUTIONS

By: Colby Thayer Date: 11/13/23

Type or Print Name: Colby Thayer

BOARD OF PESTICIDES CONTROL
By: _____ Date: _____
John Pietroski, Acting Director

APPROVED:
By: _____ Date: _____
Carey Gustanski, Assistant Attorney General

**Public Review Document -** EPA is releasing this document solely for the purpose of public review and comment. Please submit comments to **Docket ID # EPA-HQ-OPP-2023-0562** at https://www.regulations.gov.

***** 11/8/2023 *****

# WHITE PAPER: Benefits of the Adoption of Structured Content and Digital Pesticide Labels

U.S. Environmental Protection Agency

Office of Chemical Safety and Pollution Prevention

# Table of Contents

## Executive Summary

The Office of Pesticide Programs (OPP) is seeking input on the creation, submission, review, approval, and distribution of structured content pesticide labels. Structured content is information or content that is organized in a predictable way and is digital content, which is typically organized with metadata. Currently, the pesticide registration process is mostly manual, which leads to time consuming reviews, potentially inconsistent approval of language, and high cost to both registrants and regulators. The increasing complexity of pesticide labels and inconsistency across label language and placement of information on labeling are challenges for pesticide users and the public seeking information about how to use the products. Structured content digital labels would streamline and standardize the submission, review, and access to label content, providing benefits across the spectrum of stakeholders.

OPP is in the developmental stage of creating both a structured label and structured digital label. The structured label would provide the framework for consistent placement and order of the regulated portions of label information, and the structured digital label would use the framework of structured labeling and organize the contents as data. Using a structured digital label would streamline the submission and review process, improve consistency and readability of label language, and make information more accessible to pesticide users and the public. The standardized format would present information clearly and consistently, making it easier for pesticide applicators and handlers to identify necessary information on the label. In turn, the clarity would support adherence to label instructions and the protection of human health and the environment.

In addition to developing a framework for structured labels and structured digital labels, OPP is also planning to identify key fields needed for the structured digital label during the process phases. OPP is requesting public comment on all aspects of the structured label content, including but not limited to the anticipated benefits, risks, challenges, key fields, and proposed phases of adoption.

## What are Structured Labels and Structured Digital Labels?

A structured label is a template for consistent placement and order for all required label information and would be available to use for all registered pesticide types. EPA expects that structured labels would be submitted as PDFs for review and registration processes.

A structured digital label is a digital framework that organizes the contents of labels as data (including metadata) which can be reorganized, searched, and displayed in multiple outputs according to the needs of any user, including regulators, registrants, NGOs, enforcement officials, end users, and the public.

### What do they have in common?

Structured labels and structured digital labels will have the same fields in common and will contain the same required information for registration. Examples of required fields would be active ingredient, product name, company name, and use sites. Both label types would require a change from the narrative structure of pesticide labels to utilizing more direct language and tables, most notably for application rates.

### How are they different?

A structured label will provide a standard framework for key fields specifying the location and placement of information within the pesticide label. The structured digital label will have the same fields as the structured label and further provide the underlying field metadata providing greater context, search capability, and adaptability. A structured label would be a static file, while a structured digital label would be a data file that could be rendered in multiple formats.

## Background

OPP has previously announced four label registration digitization programs: the Central Database Exchange (CDX) for pesticide registration submissions, Web-distributed Labels, the Electronic Confidential Statement of Formula Application (e-CSF), and the Office of Pesticide Programs Electronic Label (OPPEL) pilot.

CDX[1] was first introduced by the Agency in 2002 for secure submission of data to the Agency across programs. Since 2020, essentially all studies and label registrations are submitted to OPP through CDX. The widespread adoption of CDX for pesticide submissions streamlined the process by essentially eliminating the physical paper submissions that required hand delivery, scanning, and processing.

In May 2021, the Agency publicly launched the e-CSF[2] application, an online tool to create and submit confidential statement of formula electronically on CDX. Features of e-CSF include a structured standardized format, drop down menus with pre-approved vocabulary, and self-validation checks to confirm key fields are populated prior to submission. The validation checks provide significant time savings for both the Agency and registrants, preventing lost time between initial review and additional submissions.

Web-distributed labeling for pesticide products[3] was announced in 2014 with guidance to registrants for the voluntary adoption of making pesticide labeling available via the internet. With this approach, registrants could distribute pesticide products with a label that includes a

[1] https://cdx.epa.gov/
[2] https://www.epa.gov/pesticides/epa-launches-new-electronic-confidential-statement-formula-application
[3] https://www.epa.gov/pesticide-labels/web-distributed-labeling-pesticides#:~:text=Labeling%20available%20online%20%2D%20called%20web,than%2030%20pages%20of%20instruction.

website link that refers users to legally valid labeling they could download with the most current version of state- and site-specific labeling. The Agency expects that web-distributed labeling would make it easier for pesticide users to better understand and comply with pesticide labeling. One barrier that has prevented adoption of web-distributed labeling is the lack of standard digital label development and submission systems.

In 2014, OPP piloted a program called the "Office of Pesticide Program Electronic Label" (OPPEL[4]). The pilot was a partnership of nine stakeholders working together to develop a standardized digital label format. Most of the label contents were structured and standardized, but sections such as the application instructions were not. The allowed a large amount of customization within the application instructions. Having to complete the structured sections of the labeling and a separate portion for the application instructions created duplicative work for both registrants, at the label creation stage, and EPA at the label review stage. While this project laid important groundwork for terminology and structure for structured labeling submissions, the Agency does not intend to propose the adoption of the current OPPEL system.

## Other Federal Label Standardization and Digitization and Efforts

Consumers in the U.S. have become accustomed to seeing the nutrition information in a standard format on food products. Prior to the late 1960's, labels rarely included nutrition information or any standard format. Beginning in the 1970's, there was a steady progression of voluntary guidelines and rulemakings on claims, but no standard was developed. Dr. Louis W. Sullivan, then Secretary of the U.S. Department of Health and Human Services stated, "The grocery store has become a Tower of Babel and consumers need to be linguists, scientists and mind readers to understand the many labels they see."[5] The Agency's current pesticide labels contain a similar lack of standardization in the pesticide marketplace.

The Food and Drug Administration (FDA) implemented a standardized labeling for food nutrition content in 1993[6] and for medicine in 2002[7]. The standard required electronic label submissions in 2004[8] with regular updated guidelines and requirements as of 2019[9]. U.S. consumers have continued to benefit from the clarity, consistency, and improved safety achieved through these standardization efforts.[10] The Agency expects to achieve similar gains in understanding with the standardization of pesticide labels.

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[4] https://www.epa.gov/pesticide-registration/office-pesticide-program-electronic-label-oppel-pilot
[5] National Library of Medical History of Nutrient Labeling: https://www.ncbi.nlm.nih.gov/books/NBK209859/
[6] Nutrition Labeling and Education Act (NLEA) of 1990. Final regulations were published on January 6, 1993.
[7] Federal Register of March 1999, the Food and Drug Administration published the OTC Drug Facts Label Regulation. Requiring the new format to be adopted by May 2002.
[8] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-content-labeling
[9]Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications Guidance for Industry (2019).
[10] https://labels.fda.gov/

## Challenges with the Current Approach

The Office of Pesticide Programs' label submission and review processes pose several challenges. Currently, labels are submitted as PDF files using the CDX without any standardized format. Submissions must include all of the necessary elements and follow the minimum placement requirements at 40 CFR part 156[11], but the submitter has discretion to arrange some of the elements. This variability in placement and formatting results in extended review times for the submission since the required elements may be in different locations. Furthermore, there are often multiple iterations of submitted labels with rearranged components, requiring the review of the entire package, lengthening the review process, and creating unnecessary redundancy. Similar situations also occur when reviewing marketing claims on labels and other language that is not required.

The current label submissions present downstream challenges to identifying key information for risk assessments and regulatory review documents. Under federal law, all pesticide active ingredients are required to be re-evaluated every 15 years.[12] As part of this process, the Agency needs to compile risk-associated information, such as application rates, personal protective equipment (PPE), reapplication timing, and efficacy. This information is often presented throughout the label and may be difficult to locate. Currently, the Agency compiles information from each label and enters it into various assessments, models, and regulatory documents. This process is manual and involves creating summary documents requiring significant Agency resources. This is inefficient and increases the likelihood of errors since the documents must be manually updated with each new submission or added use.

The number of new registrations and label updates for existing registrations have increased steadily over the past decade, which when combined with lower staffing levels has amplified the inefficiencies with the current processes. Registration actions may also include non-PRIA label updates, language related to the Endangered Species Act (ESA), or required text associated with the registration review process. Given the large number of registered products, and the long lifecycle of registration review, there is a need to explore ways to make the process more efficient while maintaining protections for human health and the environment.

The pesticide marketplace and user experience are hindered by the lack of label standardization. Technical innovations are currently limited due to the variability of labels. States and NGOs that offer pesticide training and certification programs spend time and resources educating users to navigate labels to find the necessary information rather than focusing the curriculum on terminology or best practices.

[11] Front panel placement requirements: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-156
[12] https://www.epa.gov/pesticide-reevaluation/registration-review-process

## Benefits of Structured Labels

### Increased Registration Accuracy, Quality, and Efficiency

Structured labels and the structured digital labels offer benefits for regulators, users, the regulated community, and the public. A structured label could enhance label accuracy, quality, review efficiency, and consistency. The initial use of standardized labels could improve the review process by utilizing standard structures to eliminate the need for reviewers to hunt through the document to find the required sections and language. Furthermore, structured digital labels could improve label quality with validation checks, vetted terminology, and optional pre-populated fields with consistent label language, potentially even including marketing claims associated with the selected active ingredient. A structured digital label submission could be compared electronically to previous submissions, highlighting changes to allow for a focused and streamlined review. Both structured labels and structured digitals labels would allow OPP and state regulators to focus on comparing substantive changes rather than spending time and resources reviewing labels in their entirety.

The significant effort of mining the label text for information needed for risk assessments would be reduced through the adoption of a structured label with a use rate table incorporated within the label's instructions. The current manual transcription process used to compile information from use rate tables would be eliminated with a structured digital label. Submissions could be validated electronically against approved use rates to indicate whether a new risk assessment is necessary. The structured digital label would have key fields identified for a risk assessment in an exportable, quantifiable format, eliminating the potential for the risk assessment values to differ from the label instructions.

Structured digital labels could offer self-certified fields, such as contact numbers, incident reporting information, links, QR codes, and language translations. If the automated label review only identifies changes in the self-certified fields, the label could be approved without the need for a manual secondary review. Structured digital labels could also offer the option to use suggested language from EPA (e.g., language from the label review manual, pesticide registration notices, new guidelines, or ESA mitigation[13]). Automated review could identify that the label includes mandated language and validation could confirm it is appropriate to the product, reducing the need for manual secondary review. While registrants would have the option to use customized language in their submission, this would be flagged during the automated review for additional manual review. The availability of a tool that contains statements already accepted by EPA for use on labeling would improve consistency across regulatory decisions and product labeling.

[13] Regulations.gov OPP ESA Work Plan: https://www.regulations.gov/docket/EPA-HQ-OPP-2022-0908

## Regulatory Consistency

The digitization of labels would enable OPP to build a comprehensive database of registrations that can be cross-referenced against upcoming decisions to ensure consistency in rates, mitigation measures, and marketing claims. With data and metadata from registrations, OPP staff could identify whether labels are in line with current standards and more easily identify which product labels need to be updated as part of the registration review process. If labels need updates, digital labels could allow for automated notification of all affected registrants. This automated process would also reduce the time between identification of risk mitigation measures during registration review and implementation of labeling updates that result in strengthened protections in the field. Similar notification processes could be used to address human or environmental risk mitigation as necessitated by legislation, rulemaking, or litigation. There is potential under this scenario to automate the entirety of such changes, thereby eliminating the need for additional manual review.

## International Harmonization

A structured label both as a PDF and digital label could improve readability, consistency, and clarity for labels within the United States; international harmonization could further improve consistency and clarity between multiple markets. Label harmonization could also promote trade and further increase regulatory efficiency by allowing regulators to cooperate and utilize shared standards and guidelines, reducing the time and resources required for individual regulators. Standardized vocabulary (e.g., names of pests, diseases, use sites) could also facilitate the translation of labels for international markets, ensuring consistent information dissemination across countries. Registrants could gain cost savings by reducing the time to develop different product labels, reducing transportation burdens, and increasing the possibility of the same physical label being sold in multiple markets.

## Enforcement

The Agency anticipates that standardized structure and vocabulary would reduce likelihood that labels with unclear or unenforceable language are registered. The creation process for structured digital labels should further reduce this likelihood by offering a library of EPA-accepted language for different label sections. While the Agency would continue to allow registrants to submit custom language, the language would be flagged for manual review. Using language already reviewed and accepted by EPA should reduce the number of products with unclear or problematic language, decreasing product misuse and enforcement issues in the marketplace.

Connecting the Active Pesticide Product Registration Informational Listing (APPRIL) with structured label would enhance the accessibility, and availability of information. Digital labels could be validated and searched. This would facilitate faster and improved compliance for various labels required for the commercial production, transportation, and sale of pesticides.

Structured digital labels could be added to application records. A digital environment can maintain a log of usage with more detail than the current paper-based application records. The additional detail would be helpful in both enforcement activities and incident investigations.

## Safety and Stewardship

The adoption of structured digital labels is expected to improve health and ecological stewardship by enhancing user-friendliness and reducing the likelihood of misuse and incidents, which can pose risks to human health and the environment. Embedded links and updated contact information in a digital label would make it easier to report incidents, enabling prompt responses from state and regional offices.

Structured digital labels could enable equipment manufacturers and third parties to develop software that interfaces with their equipment, facilitating planning, loading, spraying, and disposal of the pesticide in specific regions and for the user's equipment. One potential opportunity is the creation of apps that allow downloadable label information databases, accessible without an active internet connection in the field.

The availability of a searchable database would empower users to find products effective against public health diseases such as SARS-CoV-2 and Norovirus, and disease vectors such as rodents and mosquitoes, or to find "Design for the Environment" products, which have been determined to meet certain rigorous criteria for efficacy and effects on human health and the environment, contributing to overall health and environmental well-being.

Digital labels have the capability to embed spatial data, allowing for the programming of buffers around listed species or sensitive habitats. When combined with GPS-enabled spraying equipment, these labels could enable automatic avoidance of sensitive areas, minimizing potential harm to non-target organisms and ecosystems. Moreover, digital labels could be linked with Bulletins Live Two! (BLT) and potentially replace the current system. This integration addresses the limitations of BLT in handling the large number of endangered species and designated critical habitat GIS files expected to be created by the Agency in the coming years.

## End Users and Stakeholders

The Agency hosts the Pesticide Product and Label System (PPLS)[14] and APPRIL[15]. Both are public-facing repositories of all active pesticide registrations. With PPLS, the public can search for the PDF label by a product name, company name, or chemical name and their numeric equivalent codes. While this repository is useful, it is best suited for people to gain access to an electronic version of a label that they are already aware of, not a way to search for products to use. Launched in August 2022, APPRIL allows users to search for pesticide products using a wide

[14] Pesticide Product and Label System: https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:1
[15] Active Pesticide Product Registration Informational Listing (APPRIL): https://ordspub.epa.gov/ords/pesticides/f?p=APPRIL_PUBLIC:2

array of fields, such as pesticide categories, use pattern, and pests. However, these keyword tags are not fully populated for all registrations and are not yet standardized. Lastly, the Agency hosts a website that does allow users to search by need for insect various repellents. The "*Find the repellent that is right for you"*[16] site is a useful demonstration of the utility of allowing the public to search products based on need rather than a product number. With the adoption of structured digital labeling, the Agency could replace or expand PPLS/APPRIL to allow users to search for products by numerous key fields and associated metadata. The Agency anticipates this would be a valuable tool for the public. Individuals facing new pest pressures could search the database for all registered products that meet their needs, including products effective against public health pathogens and their vectors. Similarly, those implementing resistance management strategies through rotating modes of action can search for products based on their modes of action, enabling them to select a rotation that suits their requirements. Additionally, during periods of supply constraint, end-users would be able to search for alternative products.

Just as PPLS/APPRIL is utilized by other stakeholders, the Agency anticipates this publicly available database could be utilized by others to provide additional benefits to the end users. Agricultural extension programs or NGOs could provide additional guidance on product efficacy, resistance management, and localized factors that the end user should be aware of.

In addition to helping users find the right product to meet their needs, a robust, searchable product database would allow improved accessibility in the field. Either through the Agency website, third-party apps or third-party websites, improved access and readability of the label is anticipated. Instead of a static PDF, technologies could allow the option for users to access a version of the labeling with the necessary information relevant to the user's specific crop, site, application method, or pest. This approach would improve label readability, as traditional labels can span hundreds of pages, requiring users to navigate between distant sections. Embedded features could include unit conversions, optimization for mobile devices, hyperlinks to factsheets, label translations, and other helpful tools.

A standardized label structure, whether in digital or non-digital format, would enable third-party companies, states, stakeholder groups, and NGOs to enhance their training programs. Existing labels do not have consistency in terms of placement and language for key information. With a standardized label structure, the training can move from helping applicators and handler figure out where on each label information can be found to understanding the content and meaning of keywords.

[16] Find the Repellent that is Right for You: https://www.epa.gov/insect-repellents/find-repellent-right-you#search%20tool

## Supporting Emerging Agricultural Technology

Emerging agricultural technology has the potential to shift the agricultural market to a safer and more sustainable future. Examples of emerging technology include variable pesticide application determined by spatial data, targeted applications utilizing visible recognition and utilizing autonomous/unmanned systems. These advancements in application technology have the potential to reduce overall pesticide application tonnage, increasing effectiveness while also avoiding application to ecologically sensitive areas. The existing narrative form of application instructions that vary from label to label hinder such possible innovations from being adopted in the marketplace. Adopting a structural digital label could promote the development and adoption of emerging agricultural technology. For additional details on of emerging technology and Pesticide Program Dialogue Committee (PPDC)'s recommendations for actions the Agency should take, please review the PPDC Emerging Agricultural Technologies Working Group 2022 – 2023 Final Report.[17]

## Anticipated Reception and Overcoming Concerns

### Why Now?

Pesticide registration applications have severe backlogs, leading to outdated information on labels and a slowdown in business. The registrant community wants regulatory certainty and clarity, as well as registration decisions informed by data. State agencies and inspectors want clear, enforceable language. Stakeholders including non-governmental organizations, pesticide safety educators, and farmworker advocacy organizations want faster incorporation of additional protections for human health and the environment. These factors, combined with limited Agency resources that necessitate efficiency, making digital labels a critical need for the pesticide marketplace.

The Agency is doing more work with fewer resources. OPP has embarked on a digital transformation and is rapidly building its ability to collect and analyze data. Costs of technology adoption are dropping and potential returns on investment are growing. Adoption of structured labeling and structured digital labeling would dovetail with the Agency's internal focus on digitizing data.

The convergence of these factors, along with the rapid technology development, makes it an ideal time to pursue development of structured labels and structured digital labels to meet the needs of all stakeholders.

[17] Pesticide Program Dialogue Committee (PPDC) Emerging Agricultural Technology Working Group Final Report: https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/ppdc-emerging-technologies-workgroup

### Addressing Technical Challenges

OPP anticipates concerns and acknowledges there are technical challenges that could be faced during the transition to a structured digital label. Some registrants may face challenges adapting their products to the new standardized structure and, later, full digitalization. Some of the challenges might include transitioning many labels from the current format to the structured label format, and developing a mechanism to compile and submit a structured digital label. OPP hopes that in the future, the Agency will have the resources to make available a label builder.

Another challenge is access to structured digital labels. Cellular coverage, while ever-expanding, is not yet universal, particularly in rural areas. So, while most end-users and inspectors can use mobile devices to access labels, OPP plans to ensure that the necessary information is still printed on the product containers.

### Potential Use of Artificial Intelligence (AI) Tools

Recent developments in AI have shown the ability to organize and process unstructured text and data. However, complex narrative documents still present a challenge that is far beyond the capabilities of today's AI tools. Labels are unique and do not follow a standard format for organizing the information. Multiple application rates and instructions are given depending on various field conditions specified in narrative text. Matching the correct application rate with intended conditions and required mitigation is something the Agency is not confident current AI tools can do reliably at this point. Organizing labels in a structured manner where automated tools could verify if required information is present is more likely to succeed and facilitate a searchable database of both structured PDF labels and structured digital labels. However, as AI tools advance, the Agency will reevaluate this position.

## Next Steps

### Partnerships and Harmonization

OPP has been reaching out to various stakeholders and international groups to cooperate while creating a structured digital label. Other regulators worldwide are dealing with the same inefficiencies caused by the submission of static unstructured PDF labels and are at various stages of developing digital labels. OPP has been reaching out to multiple trade partners and is seeking to collaborate efforts and harmonize labels as much as possible.

### Implementation and Adoption

Stakeholders, registrants, and fellow regulators want to know how the structured digital label will be adopted and whether it will ultimately become mandatory. Making structured digital label submission mandatory would require OPP to revise the regulations through rulemaking. While OPP does not anticipate making structured digital label submissions mandatory in the

near future, the Agency will encourage its adoption. Although CDX digital submissions are not required, CDX label submissions are the only way labels have been submitted since 2020. Just like CDX, OPP expects that the inherent benefits of using structured digital labels would drive adoption. As the label review efficiencies and time savings of structured and digital labels become quantified, it is possible that the Agency will set new estimated timelines for structured labels and structured digital labels as compared to traditional unstructured labels.

## Anticipated Phases

OPP is considering the following phases in moving towards adoption of structured labeling and structured digital labeling.

**1: Request Use Rate Table**

The Registration Division of OPP regularly requests a "Use Rate Summary Table" (fields are listed in the Key Fields section in Appendix 1) with "new use" label submissions. This table helps clarify the use site and application rates that are being proposed in the new label. The first step towards an improved label review would be to request a "Use Rate Summary Table" along with the initial submission for all new registration actions.

**2: Test Digital Submission Tools**

The Agency is seeking digital submissions tools to evaluate from various stakeholders and will report on progress as the evaluations take place.

**3: Propose Standardized Label Format for Public Comment**

The Agency is currently collaborating with multiple stakeholders on both structured label designs and structured digital labels. EPA plans to consider the outcome of the various collaborations, along with the comments on this publication, in developing a single structured label proposal that will be issued for public comment.

**4: Allow for the voluntary submission of labels utilizing the standardized structure and request that traditional labels be submitted with a supplementary site-index**

Following adoption of the structured label format, the Agency could allow for the submission of labels utilizing that format. If registrants would prefer to submit labels in the current, unstructured format, the Agency would request that they submit their PDF labels along with a site-index that includes all use sites, rates, applications methods, and mitigation that would impact risk assessments.

**5. Launch a pilot program allowing for submission of structured digital labels**

OPP is working with multiple stakeholders developing structured labels and structured digital label tools. Following the testing outlined in step 2 and using comments on the proposed

standardized label format outlined in step 3, OPP would launch a pilot program for receiving and reviewing digital product labels as part of the registration process.

**6. Launch a public structured digital label builder**

If the pilot program of step 5 is successful, the Agency plans to allow submission of digital labels from all stakeholders. The framework for the structured digital label would be based on the feedback received under step 3. Recognizing that some registrants may not have sufficient resources to transition their products to use structured digital labeling, OPP hopes that in the future, the Agency will have the resources to make available a publicly available label builder that could be used by registrants to ease the burden of transition.

**7. Update the Pesticide Product and Label System (PPLS) and Active Pesticide Product Registration Informational Listing (APPRIL)**

PPLS and APPRIL are the Agency's pesticide label repositories; they store PDF labels for all federally registered pesticides. As digital labels are registered, the Agency plans to expand PPLS and AAPRIL to capitalize on the capabilities of structured digital labels. PPLS currently only has a few searchable terms, like product name and active ingredient. Digital labels will allow more searchable terms, most notably use sites, mode of action, and pests.

## Request for Public Comment

With the publication of this white paper, OPP seeks feedback on all aspects of this document, along with feedback on previous digitalization efforts referenced in this document.

Requested Comment Topics:

1. Are there additional benefits to the adoption of structured labeling or structured digital labeling that have not been captured? If so, please describe.
2. Are there additional challenges associated with the adoption of structured labeling or structured digital labeling that have not been captured? If so, please describe.
3. Please provide feedback on the anticipated phases of OPP's work towards structured labeling and structured digital labeling.
    - Can any of anticipated phases be done concurrently?
    - Is there a different order to the phases? If so, please provide a suggestion and rationale for reordering.
    - Are any activities necessary in the development of structured labels and structured digital labels not accounted for in the anticipated phases? If so, please describe.
4. Are there additional efforts underway around development of structured labels or structured digital labels that EPA should be aware of? If so, please provide information for EPA's consideration.

5. Are there elements of the current “narrative” labels that could not be translated into structured labeling or structured digital labeling? If so, what are the elements and what are the barriers to their adoption?
6. Please comment on the key fields listed in Appendix 1.

## Appendix 1: Key Fields

### Anticipated Fields for a Use Rate Summary Table

- Use Site
    - Use Site
    - Use Location
    - Formulation(s)
    - Max Application Rate
    - Max Applications a Year
- Scenario
    - Application Target
    - Application Type
    - Application Equipment
    - Application Timing
    - Max Finish Spray Concentration
    - Max Single Rate
    - Max number of applications per crop cycle
    - Max number of crop cycles per year
    - Max number of applications per year
    - Mass Rate per year
    - Minimum retreatment interval (MRI)
    - Preharvest Interval (PHI)/ Pre-grazing Interval (PGI) Preslaughter Interval (PSI)
    - Site Specific Personal Protection Equipment (PPE)
    - Geographic Restrictions
    - Other Site/Scenario Specific Restrictions & Limitations
    - Registration Numbers

### Anticipated Fields for the Structured Digital Label Fields

The Organisation for Economic Co-operation and Development published the *Report on OECD Surveys on Pesticide Product Labels Data Elements to Support the Sharing of Pesticide Labels Data* on March of 2023[18]: this report listed out key fields that were mostly shared between Canada, Australia, United Kingdom, European Food Safety Authority, New Zealand and Germany. These are also all fields that OPP has determined to be essential and will incorporate them in any future structured label so that international harmonization is as seamless as possible. Below are the key fields that OPP is proposing to serve as a foundation for future structured digital label.

[18] Organisation for Economic Co-operation and Development. *Report on OECD surveys on pesticide product label data elements to support the sharing of pesticide label data*: https://one.oecd.org/document/ENV/CBC/MONO(2021)44/en/pdf

1. Document Information:
    - File name
    - Company Name/Logo
    - Agency (EPA, PMRA and so on) Company number
    - Product number
    - Document ID
    - Version
2. Restricted Use Pesticide Statement
3. Ingredient Statement
    - *Mode of Action**[19]
    - *Active Ingredients**
    - Ingredient Statement
    - Identified Inert Statement
    - Deterioration/Expiration Statement
    - *Product Density (required for liquids)**
    - *Mass Product per Miscellaneous Application**
4. Child Hazard Warning/Signal Warning
    - Signal Word
    - Child Hazard Warning/Signal Word Statement
    - Signal Word Qualifiers (Optional)
5. Product Profile
    - *Primary Brand Name**
    - *Packaged Form**
    - *Pesticide Classification(s)**
    - Alternative Name(s)
    - Product Profile Statement
    - Product Formulation Information
    - Legal Statements
6. Precautionary Statements
    - Precautionary Statements
    - First Aid Statement
    - Hazards to Human and Domestic Animals Statement
    - Personal Protective Equipment Statement
    - Engineering Controls Statement
    - User Safety Recommendation Statement
    - Environmental Hazards Statement
    - Physical or Chemical Hazards Statement

[19] Fields that would be included in a Site Index are marked with "*" and in *italic*

7. Directions for Use
    - Directions for Use Statement
    - Agricultural Use Requirement Statements
    - Resistance Management Statement
    - Spray Drift Management Statement
    - Rotational Crop Intervals Statement
    - Seed Bag Labeling Requirements Statement
    - Storage and Disposal Statement
8. Use Site Application Instructions
    - Use Site/Commodity
    - Use Site Locations Application Instructions Statement
    - Warranty/Disclaimer Statement
    - Marketing/Advertiser Claims
    - Public Health Claims
    - Marketing/Advertising Claims Statement
    - Certification(s) and Seal(s)
    - Additional Documentation and Label Screen (file upload)
    - Tank Mix/Adjuvant Information
9. *Product Identification**
    - *Restrictions/Limitations (repeated for Product/Site/Scenario if necessary)*
        i. *Geographic Areas*
        ii. *Use Site Food Relationships*
        iii. *Maximum AI Rate Across Products per Time*
        iv. *Rotational Crop restrictions apply to this product.*
        v. *Applicator Class Restriction(s)*
        vi. *Personal Protection Equipment (PPE)/Engineering Control(s)*
        vii. *Re-Entry Interval (REI)*
        viii. *Minimum Retreatment Interval (MRI)*
        ix. *Pre-Harvest Interval Restrictions*
        x. *Pre-Grazing/Pre-Feeding Interval Restrictions*
        xi. *Pre-Slaughter Interval Restrictions*
        xii. *Buffered Areas*
        xiii. *Max Release Height*
        xiv. *Max Wind Speed*
        xv. *Application Temperature Range*
        xvi. *ASABE Droplet Sizes(s)*
        xvii. *Soil Incorporation Depth and Time*
        xviii. *Restricted Soil Type(s)*
        xix. *Minimum Percent Soil Organic Matter*
        xx. *Minimum Age of Animal to Be Treated*

xxi. *Minimum Weight of Animal to Be Treated*
xxii. *Bulletins Live Two Statement on the label*
xxiii. *Endangered Species Mitigation Requirements*
xxiv. *Water Protection Statement(s)*
xxv. *Restrictions which limit Secondary Manufacturing of materials treated using this product.*
xxvi. *Restricted Use Site Location(s)*
xxvii. *Restricted Application Target(s)*
xxviii. *Restricted Application Type(s)*
xxix. *Restricted Application Equipment*
xxx. *Restricted Application Timing (Time of Day)*
xxxi. *Restricted Application Timing (Timing of Pest)*
xxxii. *Restricted Application Timing (Use Site Status)*

- *Use Site Information* (Including ag and non ag application locations)*
  i. *Use Site Attributes*
  ii. *Use Site/Commodity*
  iii. *Use Site Location(s)*
  iv. *Use Site Yearly Rate*
    1. *Use Site Yearly/Crop Cycle Rate*
    2. *Maximum Number of Applications per Site per Time*
    3. *Maximum Site Application Rate per Time*
- *Scenario Information* (Use variations depending various factors including target pest, timing or site conditions)*
  i. *Action(s) Against Pest*
  ii. *Action(s) Against Plant Disease*
  iii. *Plant Regulator(s)*
  iv. *Single Application Minimum Rate*
  v. *Single Application Maximum Rate*
  vi. *Use Rate Explanation*
  vii. *Acre Rate for Non-Standard Target Measures*
  viii. *Minimum Diluent/Carrier or Maximum Finish Spray Volume per Area*
  ix. *Residence/Contact Time*
  x. *Maximum Number of Applications per Scenario per Time*
  xi. *Minimum Application Rate per Scenario per Time*
  xii. *Maximum Application Rate per Scenario per Time*
  xiii. *Maximum Number of Crop Cycles per Year*
- *Scenario Attributes**
  i. *Form As Applied*
  ii. *Application Target(s)*
  iii. *Application Type(s)*

iv. *Application Equipment*
v. *Application Timing (Site Status)*
vi. *Application Timing (Time of Day)*
vii. *Application Timing (Timing of Pest)*
viii. *Application Placement Instructions*
ix. *Application Rate Explanation*
x. *Application Rate Conditions*

streamline the LQSR by conforming and referencing the updated ISO 17025: 2017 (E) and ASTM E1583–17. OPPT has reviewed the updated laboratory standards and identified any gaps or areas where additional clarification or criteria are needed between ISO 17025: 2017 and ASTM E1583–17 and the proposed LQSR 4.0. These additional clarifications or criteria are included throughout the proposed draft.

EPA is also proposing updates in LQSR 4.0 which are needed to support EPA's implementation of EPA's lead-based paint program, specifically the activities under 40 CFR part 745 which are being reconsidered in a separate action titled, "Reconsideration of the Dust-Lead Hazard Standards and Dust-Lead Post-Abatement Clearance Levels" (88 FR 50444, August 1, 2023) (FRL–8524–01–OCSPP). For example, EPA is proposing in this action to clarify that the laboratory must demonstrate that the test and/or sampling methods used can achieve a quantitation limit equal to or less than 50% of the lowest action level for dust wipe samples for the relevant surface area (*e.g.,* windowsills, floors). EPA is requesting comment on the impact of the proposed revision as it relates to laboratory capabilities to meet the proposed lower regulatory limits. Learn more about EPA's efforts to lower the dust-lead hazard standards and post-abatement dust-lead clearance levels under TSCA sections 402 and 403: *https://www.epa.gov/lead/hazard-standards-and-clearance-levels-lead-paint-dust-and-soil-tsca-sections-402-and-403.*

*Authority:* 15 U.S.C. 2601 *et seq.*

Dated: November 8, 2023.

**Denise Keehner,**

*Director, Office of Pollution Prevention and Toxics.*

[FR Doc. 2023–25141 Filed 11–14–23; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[EPA–HQ–OPP–2023–0562; FRL–11546–01–OCSPP]**

## Pesticides; White Paper Describing Benefits of Structured and Digital Content Labels for Pesticide Products; Notice of Availability and Request for Comment

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on a white paper describing the benefits of the creation, submission, review, approval, and distribution of structured content and digital pesticide labels. Structured labels are information or content that is organized in a predictable way, and digital content is those categorized fields with metadata. The current process for submitting, reviewing, and approving labels is time-consuming for both registrants and regulators. The increasing complexity of pesticide labels, inconsistent label language across products, and inconsistent placement of information on the labels often creates significant challenges for pesticide users and the public seeking information about how to use the products. Structured content and digital labels could streamline and standardize the submission, review, and access to label content, providing benefits across the spectrum of stakeholders. In addition to developing a framework for structured content and digital labels, EPA intends to identify the key information needed for the structured digital label.

**DATES:** Submit your comments on or before March 14, 2024.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2023–0562, through *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

**FOR FURTHER INFORMATION CONTACT:** Christian Bongard, Information Technology and Resources Management Division (7602M), Office of Program Support, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (706) 566–2238; email address: *bongard.christian@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Executive Summary

*A. Does this action apply to me?*

You may be potentially affected by this action if you are a producer, registrant, or user of pesticide products. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Chemical Producers (NAICS 32532), *e.g.,* pesticide manufacturers or formulators of pesticide products, pesticide importers or any person or company who seeks to register a pesticide.
- Agricultural Establishments (Crop Production) (NAICS code 111).
- Nursery and Tree Production (NAICS code 111421).
- Agricultural Pest Control and Pesticide Handling on Farms (NAICS code 115112).
- Crop Advisors (NAICS codes 115112, 541690, 541712).
- Agricultural (Animal) Pest Control (Livestock Spraying) (NAICS code 115210).
- Forestry Pest Control (NAICS code 115310).
- Wood Preservation Pest Control (NAICS code 321114).
- Pesticide Registrants (NAICS code 325320).
- Pesticide Dealers (NAICS codes 424690, 424910, 444220).
- Research & Demonstration Pest Control, Crop Advisor (NAICS code 541710).
- Industrial, Institutional, Structural & Health Related Pest Control (NAICS code 561710).
- Ornamental & Turf, Rights-of-Way Pest Control (NAICS code 561730).
- Environmental Protection Program Administrators (NAICS code 924110).
- Governmental Pest Control Programs (NAICS code 926140),

Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

*B. What is the Agency's authority for taking this action?*

This action is being taken under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*).

*C. What action is the Agency taking?*

EPA is announcing the availability of and soliciting public comment on the document entitled "White Paper: Benefits of the Adoption of Structured Content and Digital Pesticide Labels" (also referred to as the White Paper), a copy of which is available in the docket. The White Paper describes a framework for the creation, submission, review, approval, and distribution of structured content and digital pesticide labels.

Structured content is information or content that is organized in a predictable way, and digital labels are typically classified with metadata. Currently, the pesticide labels are reviewed and approved during the registration process, which can involve time consuming manual reviews, approval of labeling language focused on each product, without considering consistency across products, and a non-digital label that can increase the transaction cost to both registrants and regulators. The increasing complexity of pesticide labels, inconsistent label language across products, and inconsistent placement of information on the labels, often creates significant challenges for pesticide users and the public seeking information about how to use the products. Structured content and digital labels could streamline and standardize the submission, review, and access to label content, providing benefits across the spectrum of stakeholders. In addition to developing a framework for structured content and digital labels, EPA intends to also identify the key information needed for the structured digital label during the registration process.

EPA is requesting public comment on all aspects of the Structured Label Content, including but not limited to the anticipated benefits, risks, challenges, key fields, and proposed phases of adoption. In addition, the Agency is seeking specific feedback on several topics discussed in Unit II.

*D. Why is the Agency taking this action?*

Historically, the pesticide registration process often leads to time consuming reviews, potential approval of inconsistent label language, and high cost to both registrants and regulators. The increasing complexity of pesticide labels and inconsistency across label language and placement of information on labeling are challenges for pesticide users and the public seeking information about how to use the products. Structured content digital labels would streamline and standardize the submission, review, and access to label content, providing benefits across the spectrum of stakeholders.

*E. Does this document contain binding requirements?*

This document describes EPA's proposed framework for developing structured labels and structured digital labels. The requirements in the statutes are binding on EPA and registrants, respectively, but this document does not impose any binding requirements on EPA or outside parties. The strategies outlined in this document further the general goals of the program, and EPA may depart from the strategies where circumstances warrant and without prior notice. In general, however, EPA will continue to offer notice and comment on proposed decisions that implement these strategies.

*F. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit CBI to EPA through *https://www.regulations.gov* or email. If you wish to include CBI in your comment, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* hen preparing and submitting your comments, see the commenting tips and instructions at *https://www.epa.gov/dockets/*commenting-epa-dockets.

## II. Request for Comments

EPA is seeking comment on all aspects of the White Paper and is particularly interested in public comment on the following questions related to previous digitalization efforts referenced in the White Paper.

1. Are there additional benefits to the adoption of structured labeling or structured digital labeling that have not been captured? If so, please describe.

2. Are there additional challenges associated with the adoption of structured labeling or structured digital labeling that have not been captured? If so, please describe.

3. Please provide feedback on the anticipated phases the Office of Pesticide Program's work towards structured labeling and structured digital labeling.

- Can any of anticipated phases be done concurrently?
- Is there a different order to the phases?
- Are any activities necessary in the development of structured labels and structured digital labels not accounted for in the anticipated phases? If so, please describe.

4. Are there additional efforts underway around development of structured labels or structured digital labels that EPA should be aware of? If so, please provide information for EPA's consideration.

5. Are there elements of the current "narrative" labels that could not be translated into structured labeling or structured digital labeling? If so, what are the elements and what are the barriers to their adoption?

6. Please comment on the key fields listed in Appendix 1 in this document.

## III. Paperwork Reduction Act (PRA)

The strategies outlined in the White Paper describe information collection activities that do not create any new paperwork burdens that require additional approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.* The information collection activities associated with pesticide registration are already approved by OMB under OMB Control No. 2070–0226, entitled "Consolidated Pesticide Registration Submission Portal" (EPA ICR No. 2624.01).

*Authority:* 7 U.S.C. 136 *et seq.*

Dated: November 8, 2023.

**Michal Freedhoff,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

[FR Doc. 2023–25140 Filed 11–14–23; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

**[EPA–HQ–OA–2013–0320; FRL–11531–01–OA]**

## Public Comment on the Revised Technical Guidance for Assessing Environmental Justice in Regulatory Analysis

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of public comment period.

**SUMMARY:** The Environmental Protection Agency (EPA) is announcing a 60-day public comment period on the draft revision of the *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* (EJ Technical Guidance). The EJ Technical Guidance was first published in 2016. The EPA is updating it to reflect the state of the science; new peer-reviewed agency guidance; and new terminology, priorities, and direction, including Executive Order 14096. The purpose of this guidance is to outline analytic expectations and discuss technical approaches and methods that can be used by agency analysts to evaluate EJ concerns for regulatory actions. This technical guidance builds on the EPA's experience in evaluating environmental

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## EPA Issues Advanced Notice of Proposed Rulemaking for Public Comment to Seek Additional Information on Use of Pesticide Treated Seed and Paint

The U.S. Environmental Protection Agency (EPA) is issuing an advanced notice of proposed rulemaking (ANPRM) for public comment to seek additional information on the use of pesticide-treated seed and paint products. In particular, EPA is looking to better understand whether or to what extent pesticide-treated seed and paint need to be further regulated. Based on the Agency's findings, EPA may pursue a rule or take administrative action to address any issues with the use of pesticide-treated seed and paint. Comments can be submitted to docket EPA-HQ-OPP-2023-0420 at www.regulations.gov for the next 60 days.

**Background**

Pesticide-treated seeds have been treated by pesticides such as fungicides, insecticides and nematicides prior to use to protect them from diseases, insects, or other pests that could harm a crop. Pesticide-treated paints are treated with antimicrobial pesticides to preserve liquid paint and to protect dried paint from mold and/or algae growth.

These products are exempt from registration requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) if they meet the exemption criteria pursuant to a regulation known as the Treated Article Exemption. Rather than registering treated seed or paint under FIFRA, EPA requires registration of the pesticide that is used to treat the seed or paint (known as the "treating pesticide"). During the pesticide registration and registration review process, the agency completes comprehensive human health and ecological risk assessments to ensure that use of

the pesticides—including use of the treated seeds and paints—will not cause unreasonable adverse effects to human health or the environment.

However, states and other stakeholders have raised questions about the clarity and enforceability of instructions specifically relating to use of the treated seed products (i.e., instructions relating to the storage, planting, and management of the treated seed). And, in April 2017, the Center for Food Safety (CFS) filed a petition with EPA that asked the Agency to interpret or amend the Treated Article Exemption so that it does not cover seeds treated with systemic pesticides, and to aggressively enforce registration and labeling requirements for such treated seeds. EPA denied the petition in September 2022, but its response mentioned its intent to issue this ANPRM and to explore the option of a rulemaking to regulate the use of treated seed. EPA is also using this ANPRM to consider requiring labeling instructions on treated paint products. The labeling would address potential risks of concern for professional painters who do not use personal protection equipment when applying treated paint.

**ANPRM Details**

EPA is seeking comment on:

- how growers manage treated seed products, including how they store, plant, and dispose of these products;
- the extent to which treated seed products are used in the United States;
- whether or to what extent treated seed products are being distributed, sold, and used contrary to treating pesticide and seed bag tag labeling instructions;
- whether label language recently proposed for use of paint products treated with diuron—which may be proposed for other treated paint products—should be made enforceable, and if not, whether other regulatory or administrative options should be considered;
- whether those who manufacture treated seed and paint should be subject to some registration and reporting requirements under FIFRA section 7 or other requirements (e.g., filing of a “notice of arrival” for all imported treated products; and
- whether further regulatory or administrative measures are appropriate to ensure the safe use of treated seed and paint.

After reviewing public comments, EPA will consider further actions, which may include regulations to limit the scope of the regulatory Treated Article Exemption, enforcing use violations, and taking administrative action to clarify labeling requirements or reduce the use of a treating pesticide.

To comment on the ANPRM, visit EPA-HQ-OPP-2023-0420 at www.regulations.gov.

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## EPA Releases Draft Biological Evaluations of Dinotefuran and Acetamiprid Effects on Endangered Species

The U.S. Environmental Protection Agency (EPA) is releasing two draft biological evaluations (BEs) that include EPA's draft effects determinations for the neonicotinoid insecticides dinotefuran and acetamiprid on federally listed endangered and threatened (listed) species and designated critical habitats. The draft BEs will be available for public comment for 60 days.

### Background on Dinotefuran and Acetamiprid

Dinotefuran is an insecticide to control aphids, whiteflies, thrips, leafhoppers, scales, leaf miners, and other insects in agricultural crops such as root vegetables, leafy vegetables, berries, cereal grains, and oilseed crops (*e.g.*, cotton). In addition to the agricultural uses, there are a wide variety of non-agricultural uses, including Christmas trees, forestry, turf, and ornamental applications.

Acetamiprid is an insecticide to control piercing sucking pests (such as aphids) on a variety of crops including fruit and fruit trees, tree nuts, vegetables, sweet corn, cotton, soybean, and tobacco, as well as non-agricultural uses such as ornamentals, nurseries, and vegetables grown for transplant.

The timing of the issuance of these draft BEs is tied to a lawsuit filed by the Natural Resources Defense Council (NRDC) against EPA on October 3, 2017, alleging that EPA violated the Endangered Species Act (ESA) by failing to consult with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (the Services) on the effects to listed species of pesticide product registrations containing one of three

pesticide active ingredients—acetamiprid, dinotefuran, and imidacloprid. In January 2021, EPA and NRDC agreed, through a stipulated partial settlement agreement, to resolve the claim concerning imidacloprid by requiring EPA complete a final BE with an effects determination for imidacloprid, which was released in June 2022. EPA also initiated consultation with the Services on imidacloprid. In March 2022, EPA and NRDC agreed to resolve the remaining two claims (acetamiprid and dinotefuran). Specifically, by October 2024, EPA must complete its final effects determinations and request initiation of any necessary ESA consultation from the Services on the potential effects of acetamiprid and dinotefuran on any listed species and critical habitat. EPA's release of the draft effects determinations for these two insecticides is an important step in meeting its October 2024 commitment to complete final effects determinations.

**Draft Biological Evaluations**

EPA's draft effects determinations in the draft BEs finds that dinotefuran and acetamiprid are "likely to adversely affect" (LAA) listed species and designated critical habitats. An LAA determination means that EPA reasonably expects that at least one individual animal or plant, among a variety of listed species, may be exposed to dinotefuran or acetamiprid at a sufficient level to have an adverse effect. This is the case even if a listed species is almost recovered to a point where it may no longer need to be listed.

In these draft BEs, EPA also refined its analysis to predict the potential likelihood that dinotefuran or acetamiprid use could result in "jeopardy" (*i.e.*, potential impacts to the survival of listed species) for any listed species or "adverse modification" of any critical habitats. In contrast to its LAA determinations, EPA's predictions of the potential likelihood of future jeopardy and adverse modification examine the effects of both active ingredients to populations of a species, rather than to an individual. EPA predicts that there is a potential likelihood that approved uses of dinotefuran and acetamiprid could result in future jeopardy or adverse modification findings for some listed species and critical habitats. The Services, however, are responsible for making jeopardy/adverse modification findings in their biological opinions.

As part of its assessment, EPA evaluated the effects of dinotefuran and acetamiprid on over 1,700 listed species and over 800 designated critical habitats in the United States and its territories.

EPA's draft determinations are that dinotefuran:

- Causes no effect on 240 listed species (14%) and 111 designated critical habitats (13%).
- Is not likely to adversely affect 216 listed species (13%) and 91 critical habitats (11%).

- Is likely to adversely affect 1259 listed species (73%) and 624 critical habitats (76%).

Of the species with LAA determinations, EPA predicted a potential likelihood of jeopardy for 151 listed species (9%) and a potential likelihood of adverse modification of 59 (7%) designated critical habitats.

EPA's draft determinations are that acetamiprid:

- Causes no effect on 278 listed species (16%) and 293 designated critical habitats (35%).
- Is not likely to adversely affect 432 listed species (25%) and 224 critical habitats (27%).
- Is likely to adversely affect 1,005 listed species (59%) and 309 critical habitats (37%).

Of the species with LAA determinations, EPA predicted a potential likelihood of jeopardy for 169 listed species (10%) and a potential likelihood of adverse modification of 51 designated critical habitats (6%).

After considering the public comments on the draft BEs, EPA will make appropriate changes, issue a final BE, and initiate consultation, as necessary. If a formal consultation is necessary, the Services would use EPA's effects determinations to inform their biological opinions, which will include the final determinations of whether a pesticide jeopardizes listed species or adversely modifies critical habitats.

The draft BEs will be available for public comment for 60 days in the dinotefuran docket (EPA-HQ-OPP-2023-0506) and the acetamiprid docket (EPA-HQ-OPP-2023-0513) on regulations.gov.

Learn more about EPA's work on ESA and the Agency's plans to meet its ESA obligations on the EPA website, which features interactive, visual StoryMaps about EPA's Vulnerable Species Pilot.

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EPA

# Pesticide Update

EPA's Office of Chemical Safety and Pollution Prevention

## EPA Publishes New Webpage to Answer Frequently Asked Questions on the EPA/FDA Whitepaper on Modernizing Oversight of Products for Animals Regulated as Pesticides or New Animal Drugs

The U.S. Environmental Protection Agency (EPA) and the U.S. Food and Drug Administration (FDA) are publishing new web content to provide an overview of the topics raised during the public comment period and to answer frequently asked questions about EPA and FDA's whitepaper, "A Modern Approach to EPA and FDA Product Oversight."

In February 2023, EPA and FDA released a whitepaper describing approaches for updating the agencies' oversight of various animal products regulated as either pesticides or new animal drugs. It describes challenges with the way EPA and FDA currently regulate these products and highlights the potential benefits of a modernized approach for oversight, particularly the transfer of product oversight for topically administered flea and tick products from EPA to FDA. Any change to regulatory jurisdiction, however, has not been formally proposed or finalized by the agencies. Rather, through the whitepaper, the agencies sought public input on whether to potentially transfer oversight of these products and, if so, how best to do so.

EPA and FDA opened a 60-day public comment period on Feb. 23, 2023. The agencies received over 18,000 comments from environmental organizations, veterinarians, industry, pet and livestock owners, and other members of the public. In addition to the comment period, the agencies also collected stakeholder feedback during a public meeting on March 22, 2023. All comments received during the comment period and the public meeting, are posted in docket EPA-HQ-OPP-2023-

0103.

In reviewing the comments, EPA and FDA identified common questions from stakeholders, such as:

- How do EPA and FDA currently regulate products and review animal safety and incident data?
- How could EPA and FDA coordinate more closely on animal health, environmental, and efficacy considerations for these products?
- If products are transferred to FDA, how would products—particularly those used to protect livestock and honeybees—move from EPA to FDA? What would it cost for product manufacturers, how could it impact consumer access to products, and what would the FDA approval process look like?

EPA and FDA also identified some general comments and concerns from stakeholders, including:

- Support for an approach that would enhance animal safety for products used on pets, such as flea and tick products applied to cats and dogs.
- Recognition that FDA has a more robust regulatory infrastructure for regulating products used on or in animals.
- Support for a modernized approach to regulate genetically engineered pest animals used for population control (such as genetically engineered mosquitoes).
- Desire for continued agency transparency and outreach as the modern approach is developed and possibly implemented.

As an initial step, the agencies have published a new website to answer some of the public's most frequently asked questions.

At this time, the agencies do not have a timeline for formalizing any of the approaches discussed in the whitepaper and anticipate that if the agencies implement any such changes, it could take several years to come to fruition. EPA and FDA appreciate the stakeholder engagement received to date and look forward to continuing the conversation.

**View the Q&A**

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# The Coordinated Framework for the Regulation of Biotechnology

*Plain language information on the biotechnology regulatory system*

**November 2023**

***The U.S. Department of Agriculture***
***The U.S. Environmental Protection Agency***
***The U.S. Food and Drug Administration***

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*The goal of this document is to provide plain language information that will be easily accessible to new entrants to the regulatory system and members of the public.*

## THE COORDINATED FRAMEWORK FOR REGULATION OF BIOTECHNOLOGY

The Coordinated Framework for the Regulation of Biotechnology outlines a comprehensive U.S. regulatory policy for ensuring the safety of biotechnology products. It was adopted in 1986 and most recently updated in 2017. This policy supports innovation, protects health and the environment, and promotes trust in the regulatory system. To help developers and the public better understand U.S. regulatory processes for biotechnology products, this document provides a high-level overview of the roles and responsibilities of U.S. regulatory agencies under the Coordinated Framework.

U.S. biotechnology regulatory policy is that regulation should be based on science, proportionate to the risks posed, and based on the product (not the process used to develop the product). It also states that existing laws provide necessary authorities for agencies to regulate biotechnology and agencies have separate responsibilities. Agencies coordinate as needed, and the regulatory status of a product with one agency does not affect the regulatory status of that product with other agencies. Meeting with regulatory agencies early in product development can help developers determine the process or processes that are most relevant for a product.

The United States uses existing laws to regulate products of biotechnology rather than a special biotechnology law. As a result, different agencies may regulate different aspects and uses of a product. The primary agencies involved in U.S. biotechnology regulation are the Animal and Plant Health Inspection Service (APHIS) in the U.S. Department of Agriculture (USDA); the Food and Drug Administration (FDA) in the Department of Health and Human Services (HHS); and the Environmental Protection Agency (EPA). Multiple offices, programs, and centers within the agencies are involved in biotechnology regulation (Table 1). New entrants to the regulatory system and members of the public can use Table 2 to determine which agency or agencies may regulate particular product types. Individuals with questions about the regulation of a particular product can submit their questions to one or more agencies via the Contact Us page on the Unified Website for Biotechnology Regulation. Examples of case studies describing how specific product types would be regulated by each agency are included for plants, plant cells, plant products of biotechnology in Table 3; for animals, animal cells, and animal products produced with biotechnology in Table 4; and for microorganisms produced with biotechnology, microbial cells, and microbial products produced with biotechnology in Table 5. These case study examples are not intended to be inclusive of all products of biotechnology.

**TABLE 1. U.S. GOVERNMENT AGENCIES, OFFICES, AND PROGRAMS THAT OVERSEE PRODUCTS OF BIOTECHNOLOGY**

| DEPARTMENT | AGENCY | OFFICE OR PROGRAM |
|---|---|---|
| **DEPARTMENT OF AGRICULTURE (USDA)** | Agricultural Marketing Service (AMS) | Food Labeling and Disclosure Division (FDLD) |
| | Animal and Plant Health Inspection Service (APHIS) | Biotechnology Regulatory Service (BRS) |
| | | Veterinary Services (VS) |
| | Food Safety and Inspection Service (FSIS) | Office of Field Operations (OFO) |
| | | Office of Policy and Program Development (OPPD) |
| | | Office of Public Health Science (OPHS) |
| **DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)** | Food and Drug Administration (FDA) | Center for Biologics Evaluation and Research (CBER) |
| | | Center for Drug Evaluation and Research (CDER) |
| | | Center for Devices and Radiological Health (CDRH) |
| | | Center for Food Safety and Applied Nutrition (CFSAN) |
| | | Center for Veterinary Medicine (CVM) |
| **ENVIRONMENTAL PROTECTION AGENCY (EPA)** | Office of Chemical Safety and Pollution Prevention (OCSPP) | Office of Pesticide Programs (OPP) |
| | | Office of Pollution Prevention and Toxics (OPPT) |

**TABLE 2. SUMMARY OF U.S. REGULATORY AGENCY ROLES IN REGULATING DIFFERENT CATEGORIES OF PRODUCTS PRODUCED WITH BIOTECHNOLOGY**

*Ensure you review the categories below to identify all the agencies that may be involved in regulating your product.*

| PRODUCT | AGENCY | PLANTS, PLANT CELLS, PLANT PRODUCTS | ANIMALS, ANIMAL CELLS, ANIMAL PRODUCTS | MICROORGANISMS AND OTHER PRODUCTS |
|---|---|---|---|---|
| **FOOD FOR HUMANS** | USDA-AMS | FDLD is responsible for enforcing compliance with bioengineered labeling requirements of human foods that contain recombinant DNA, including certain foods that are or contain plants, animal products, or microorganisms. Information can be found at National Bioengineered Food Disclosure Standard. | | |
| | USDA-APHIS | BRS regulates importation, interstate movement, and environmental release of modified plants that may pose a plant pest risk.<br><br>Information about this process can be found at Regulatory Exemptions and Confirmations, Regulatory Status Review, and Biotechnology Permits. | BRS regulates importation, interstate movement, and environmental release of modified animals that may pose a plant pest risk.<br><br>Information about this process can be found at Biotechnology Permits.<br><br>VS regulates importation of livestock (including poultry and aquatic animals) that may pose a health risk to | BRS regulates importation, interstate movement, and environmental release of modified microorganisms that may pose a plant pest risk.<br><br>Information about this process can be found at Biotechnology Permits and draft Guide for Submitting Applications for Microorganisms. |

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| | | | livestock, as well as importation of their cell lines and germplasm, and materials derived from them. (VS also regulates, or supports regulation of, interstate movement of livestock, including poultry, and germplasm in conjunction with each State's regulations.<br><br>Information including VS guidance and permitting for importing animal products, live animals (includes semen and embryos), and veterinary biologics, as well as VS guidance and permitting for import and interstate movement for organisms and vectors, can be found at Imports: Animal and Animal Products. Additional information about APHIS VS regulatory authority is codified in 9CFR Subchapter I. | |
| | USDA-FSIS | OPPD and OFO verify the labeling of meat, poultry, Siluriformes fish and egg products, including those containing ingredients developed with modified plants if FDLD requires disclosure.<br><br>Information about this process can be found at labeling and label approval. | FSIS ensures domestic and imported meat (including Siluriformes fish), poultry, and egg products are safe, wholesome, and properly labeled, including products made from modified animals and products made from animal cells.<br><br>FSIS has a collaborative role with FDA following FDA's safety assessment, where FDA determines whether meat, poultry, and egg products derived from the intentional genomic alterations are safe for food.<br><br>FSIS reviews and approves products of new technologies, including products | FSIS is responsible for determining the suitability of ingredients, including those developed with microorganisms and that they are properly labeled, including use of processing aids for use in meat (including Siluriformes fish), poultry, or egg products.<br><br>OPPD and OFO verify the labeling of meat (including Siluriformes fish), poultry, and egg products, including those containing ingredients developed with modified microorganisms.<br><br>Information about this process can be found at labeling and label approval. |

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| | | | developed with biotechnology, and ensures the suitability of all ingredients used in meat and poultry products. Suitability relates to the effectiveness of the ingredient in performing the intended purpose of use and the assurance that the conditions of use will not result in a product that is adulterated or misbranded (labeled in a manner that misleads the consumer). Substances recognized as safe and suitable under the approved conditions of its intended use are those listed in 9 CFR 424.21(c) and those that are listed in FSIS Directive 7120.1, "*Safe and Suitable Ingredients in Meat, Poultry, and Egg Products*."<br><br>Further information can be found at FSIS Compliance Guideline Procedures for New Technology Notifications and Protocols \| Food Safety and Inspection Service (usda.gov), and FSIS Directive 7800.1- FSIS Responsibilities in Establishments Producing Cell-Cultured Meat and Poultry Food Products \| Food Safety and Inspection Service (usda.gov). | |
| | HHS-FDA | CFSAN oversees the safety of all plant food products for humans.<br><br>Information can be found at Food Ingredients & Packaging \| FDA. Food from New Plant Varieties \| FDA. | CFSAN oversees the safety of dairy products, eggs (but not egg products), and fish other than Siluriformes (e.g., catfish).<br><br>Information can be found at Food Ingredients & Packaging \| FDA.<br>CFSAN oversees food safety of human food products made from cultured | CFSAN oversees the safety of all microbial food products for humans. Information can be found at Food Ingredients & Packaging \| FDA. |

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| | | | animal cells during cell collection, selection, and growth, when the cells are from animals whose food safety is regulated by FSIS (livestock, poultry, Siluriformes).<br><br>CFSAN also oversees the subsequent processing, packaging, and labeling when the cells are derived from animals not regulated by FSIS. Information about this program can be found at Human Food Made with Cultured Animal Cells \| FDA.<br><br>CVM reviews human food safety of IGAs in food products derived from modified animals and of drug residues in human food products from animals treated with biotech (and non-biotech) animal drugs.<br><br>Information about the IGA program can be found at Intentional Genomic Alterations (IGAs) in Animals \| FDA.<br><br>Information about evaluating the food safety of animal drug residues in human food can be found at Evaluating the Human Food Safety of New Animal Drugs \| FDA. | |
| | EPA-OCSPP | OPP regulates PIPs produced by plants for safety of dietary exposure to pesticide residues in human and animal food.<br><br>Information on regulation of PIPs under FIFRA and FFDCA can be | OPP regulates genetic modifications in pest animals intended for use as a pesticide for safety of dietary exposure in human and animal food.<br><br>Information on regulation of emerging biotechnology pesticides can be found | OPP regulates microbial pesticides for safety of dietary exposure to residues in human and animal food.<br><br>Information on regulation of emerging biotechnology pesticides can be found at Regulation of Biotechnology under TSCA and FIFRA. |

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| | | found at Overview of Plant Incorporated Protectants | at Regulation of Biotechnology under TSCA and FIFRA. | |
| **FOOD FOR ANIMALS** | HHS-FDA | CVM oversees the safety of all plant food products for animals. Information about its programs can be found at Food from New Plant Varieties \| FDA. Animal Food & Feeds \| FDA. | CVM oversees the safety of all animal-derived food products for animals. CVM also oversees food safety of animal food products made from cultured animal cells during cell collection, selection, and growth, as well as subsequent processing, packaging, and labeling. Information about CVM's procedures for animal food products generally is available at Animal Food & Feeds \| FDA.<br><br>CVM reviews animal food safety of IGAs in food products derived from modified animals.<br><br>Information about this program can be found at: Intentional Genomic Alterations (IGAs) in Animals \| FDA. | CVM oversees the safety of all microbial food products for animals. Information about CVM's procedures for animal food products generally is available at Animal Food & Feeds \| FDA. |

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| | USDA-APHIS | BRS regulates importation, interstate movement, and environmental release of modified plants that may pose a plant pest risk.<br><br>Information about this process can be found at Regulatory Exemptions and Confirmations, Regulatory Status Review, and Biotechnology Permits. | BRS regulates importation, interstate movement, and environmental release of modified animals that may pose a plant pest risk.<br><br>Information about this process can be found at Biotechnology Permits.<br><br>VS regulates importation of livestock (including poultry and aquatic animals) that may pose a health risk to livestock, as well as importation of their cell lines and germplasm, and materials derived from them. VS also regulates, or supports regulation of, interstate movement of livestock (including poultry) and germplasm in conjunction with each State's regulations.<br><br>Information including VS guidance and permitting for importing animal products, live animals (includes semen and embryos), and veterinary biologics, as well as VS guidance and permitting for import and interstate movement for organisms and vectors, can be found at Imports: Animal and Animal Products.<br><br>Additional information about APHIS VS regulatory authority is codified in 9CFR Subchapter I. | BRS regulates importation, interstate movement, and environmental release of modified microorganisms that may pose a plant pest risk,<br><br>Information about this process can be found at Biotechnology Permits and draft Guide for Submitting Applications for Microorganisms. |

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| | EPA-OCSPP | OPP regulates PIPs produced by plants for safety of dietary exposure to pesticide residues in human and animal food.<br><br>Information on regulation of PIPs under FIFRA and FFDCA can be found at Overview of Plant Incorporated Protectants. | OPP regulates genetic modifications in pest animals intended for use as a pesticide for safety of dietary exposure in human and animal food.<br><br>Information on regulation of emerging biotechnology pesticides can be found at Regulation of Biotechnology under TSCA and FIFRA. | OPP regulates microbial pesticides for safety of dietary exposure to residues in human and animal food.<br><br>Information on regulation of emerging biotechnology pesticides can be found at Regulation of Biotechnology under TSCA and FIFRA. |
| **PESTICIDES** | EPA-OCSPP | OPP regulates PIPs produced by plants for human and environmental risks, including dietary exposure to pesticide residues in human and animal food.<br><br>Information on regulation of PIPs under FIFRA and FFDCA can be found at Overview of Plant-Incorporated Protectants. | OPP regulates genetic modifications in pest animals intended for use as a pesticide for human and environmental risks, including dietary exposure to pesticide residues in human and animal food.<br><br>Information on regulation of emerging biotechnology pesticides can be found at Regulation of Biotechnology under TSCA and FIFRA. | OPP regulates pesticides that are made from or include microorganisms for human and environmental risks, including dietary exposure to pesticide residues in human and animal food. OPP also regulates pesticides that consist of nucleic acids or peptides for human and environmental risks.<br><br>OPPT regulates chemicals (including intergeneric microorganisms) used as pesticide intermediates.<br><br>Information on regulation of chemicals under TSCA can be found at Reviewing New Chemicals under the Toxic Substances Control Act (TSCA).<br><br>Additional information on TSCA regulation of microorganisms can be found at Overview of Biotechnology under TSCA.<br><br>Information on regulation of emerging biotechnology pesticides can be found at Regulation of Biotechnology under TSCA and FIFRA. |

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| | HHS-FDA | Any tolerances for pesticide chemical residues or exemptions from the requirement of a tolerance in or on human or animal food are enforced by FDA.<br><br>Information about FDA's oversight of pesticide residues in foods is available at Pesticides \| FDA. | Any tolerances for pesticide chemical residues or exemptions from the requirement of a tolerance in or on human or animal food are enforced by FDA.<br><br>Information about FDA's oversight of pesticide residues in foods is available at Pesticides \| FDA. | Any tolerances for pesticide chemical residues or exemptions from the requirement of a tolerance in or on human or animal food are enforced by FDA.<br><br>Information about FDA's oversight of pesticide residues in foods is available at Pesticides \| FDA.<br><br>Any product with pesticide claims that is also intended for use in the "diagnosis, cure, mitigation, treatment, or prevention of disease" and/or intended to affect the structure or any function of the human body, would also be regulated as a human medical product by FDA.<br><br>Information about FDA oversight of drugs and biologics can be found at Development & Approval Process \| Drugs; Therapeutic Biologics Applications (BLA) \| FDA; About CBER \| FDA; Biologics Regulated Products \| FDA and Jurisdictional Information \| FDA. |

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| | USDA-APHIS | BRS regulates importation, interstate movement, and environmental release of modified plants that may pose a plant pest risk.<br><br>Information about this process can be found at Regulatory Exemptions and Confirmations, Regulatory Status Review, and Biotechnology Permits. | BRS regulates importation, interstate movement, and environmental release of modified animals that may pose a plant pest risk.<br><br>Information about this process can be found at Biotechnology Permits. | BRS regulates importation, interstate movement, and environmental release of modified microorganisms that may pose a plant pest risk.<br><br>Information about this process can be found at Biotechnology Permits and draft Guide for Submitting Applications for Microorganisms. |
| | USDA-APHIS | BRS regulates importation, interstate movement, and environmental release of plants modified to express pharmaceutical substances.<br><br>Information about this process can be found at Biotechnology Permits. | | BRS regulates importation, interstate movement, and environmental release of modified microorganisms that may pose a plant pest risk.<br><br>Information about this process can be found at Biotechnology Permits and draft Guide for Submitting Applications for Microorganisms. |
| **HUMAN MEDICAL PRODUCTS** | HHS-FDA | CDER regulates drugs for humans, including products made from modified plants or plant cells. Information about FDA oversight of drugs can be found at Development & Approval Process \| Drugs.<br><br>CDRH regulates medical devices (including diagnostics) for humans and radiation-emitting electronic products.<br><br>Information about oversight of medical devices can be found at Overview of Device Regulation, | CDER regulates drugs for humans, including some products made from modified animals or animal cells. Information about FDA oversight of drugs can be found at Development & Approval Process \| Drugs.<br><br>CDRH regulates medical devices (including diagnostics) for humans, including some made from modified animal cells or tissues, and radiation-emitting electronic products.<br><br>Information about oversight of medical devices can be found at: Overview of Device Regulation, and at How to | CDER and/or CBER regulate drugs for humans, including products made from, composed of, or containing microorganisms (modified or unmodified).<br><br>Information about these programs is available at Therapeutic Biologics Applications (BLA) \| FDA and Biologics Regulated Products \| FDA.<br>CDRH regulates human medical devices (including diagnostics) for humans.<br><br>Information about oversight of medical devices can be found at Overview of |

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| | | and at How to Determine if Your Product is a Medical Device.<br><br>CBER and CDER each have regulatory responsibility for certain human biological products.<br><br>Information about these programs is available at Therapeutic Biologics Applications (BLA) \| FDA and Biologics Regulated Products \| FDA.<br><br>FDA has post-market authority that could be applied if plants modified to express pharmaceutical substances, or materials from these plants, entered the food supply and resulted in the adulteration of food.<br><br>Information can be found at section 402 of the FD&C Act (21 USC 342: Adulterated food). | Determine if Your Product is a Medical Device.<br><br>CBER and CDER each have regulatory responsibility for certain human biological products including those made from, containing, or composed of modified animal cells or tissues. Information about these programs is available at Therapeutic Biologics Applications (BLA) \| FDA, About CBER \| FDA, and Biologics Regulated Products \| FDA. | Device Regulation, and at How to Determine if Your Product is a Medical Device. |
| **VETERINARY** | USDA-APHIS | VS regulates veterinary biologics, including those made from modified plants or plant cells. Information including veterinary biologics can be found at Imports: Animal and Animal Products.<br><br>Additional information about APHIS VS regulatory authority is codified in 9CFR Subchapter I. | VS regulates veterinary biologics, including those made from modified animals or animal cells.<br><br>Information including veterinary biologics can be found at Imports: Animal and Animal Products.<br><br>Additional information about APHIS VS regulatory authority is codified in 9CFR Subchapter I. | VS regulates veterinary biologics, including those made from modified microorganisms.<br><br>Information about veterinary biologics can be found at Imports: Animal and Animal Products.<br><br>Additional information about APHIS VS regulatory authority is codified in 9CFR Subchapter I. |

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| | | BRS regulates importation, interstate movement, and environmental release of modified plants that may pose a plant pest risk.<br><br>Information about this process can be found at the following links: Regulatory Exemptions and Confirmations, Regulatory Status Review, and Biotechnology Permits. | | |
| | HHS-FDA | CVM regulates animal drugs and medical devices for animals, including any made from modified plants, and biological products for animals if the product is not regulated by VS as a veterinary biologic.<br><br>Information about these programs is available at Animal & Veterinary \| FDA. | CVM regulates animal drugs and medical devices for animals, including any made from modified animals, and biological products for animals if the product is not regulated by VS as a veterinary biologic.<br><br>Information about these programs is available at Animal & Veterinary \| FDA. | CVM regulates animal drugs and medical devices for animals, including any made from modified microorganisms, and biological products for animals if the product is not regulated by VS as a veterinary biologic.<br><br>Information about these programs is available at Animal & Veterinary \| FDA. |
| **INDUSTRIAL OR CONSUMER CHEMICALS AND OTHER COMMERCIAL USES** | USDA-APHIS | BRS regulates environmental release of plants expressing pharmaceuticals, industrials, or plants for phytoremediation.<br><br>Information about this process can be found at Biotechnology Permits. | | BRS regulates importation, interstate movement, and environmental release of modified microorganisms that may pose a plant pest risk.<br><br>Information about this process can be found at Biotechnology Permits and draft Guide for Submitting Applications for Microorganisms. |
| | HHS-FDA | FDA has post-market authority that could be applied if, for example, plants expressing | CVM reviews animal and human safety, and effectiveness (e.g., that the industrial product is made) of IGAs in | |

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| | | pharmaceuticals or industrials, or materials from these plants, entered the food supply and resulted in the adulteration of food.<br><br>Information can be found at section 402 of the FD&C Act (21 USC 342: Adulterated food). | animals, including those for producing substances for industrial and other uses.<br><br>Information about FDA's oversight of IGAs can be found at Intentional Genomic Alterations (IGAs) in Animals \| FDA. | |
| | EPA-OCSPP | OPPT regulates chemicals derived from plants if they are intended for uses other than food, food additives, drugs, cosmetics, medical devices, tobacco, nuclear material, firearms, or pesticides (but not pesticide intermediates). TSCA requires submission of a notice to EPA before commercial manufacture of a new chemical, including chemicals derived from plants, and EPA takes steps to address risk before the new chemical can enter commerce.<br><br>Information on regulation of chemicals under TSCA can be found at Reviewing New Chemicals under the Toxic Substances Control Act (TSCA). | OPPT regulates chemicals derived from animals if they are intended for uses other than food, food additives, drugs, cosmetics, medical devices, tobacco, nuclear material, firearms, or pesticides (but not pesticide intermediates). TSCA requires submission of a notice to EPA before commercial manufacture of a new chemical, including chemicals derived from animals, and EPA takes steps to address risk before the new chemical can enter commerce.<br><br>Information on regulation of chemicals under TSCA can be found at Reviewing New Chemicals under the Toxic Substances Control Act (TSCA). | OPPT regulates chemicals, including those derived from microorganisms, intended for uses other than food, food additives, drugs, cosmetics, medical devices, tobacco, nuclear material, firearms, or pesticides (but not pesticide intermediates). OPPT also regulates microorganisms intended for uses that are not excluded from TSCA coverage (e.g., food, food additives, drugs, cosmetics, medical devices, tobacco, nuclear material, firearms, or pesticides). TSCA requires submission of a notice to EPA before commercial manufacture of a new microorganism or of a new chemical derived from a microorganism, and EPA takes steps to address risk before the new microorganism can enter commerce.<br><br>Information on regulation of chemicals under TSCA can be found at Reviewing New Chemicals under the Toxic Substances Control Act (TSCA). Information on TSCA regulation of microorganisms can be found at Overview of Biotechnology under TSCA. |

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| **ORGANISMS INTENDED FOR AGRICULTURAL USE OR OTHER ENVIRONMENTAL RELEASE THAT DO NOT FALL INTO A CATEGORY LISTED ABOVE** | USDA-APHIS | BRS regulates importation, interstate movement, and environmental release of modified plants that may pose a plant pest risk, regardless of intended use.<br><br>Information about this process can be found at Regulatory Exemptions and Confirmations, Regulatory Status Review, and Biotechnology Permits. | VS regulates importation of livestock (including poultry and aquatic animals) that may pose a health risk to livestock, as well as importation of their cell lines and germplasm, and materials derived from them. (VS also regulates, or supports regulation of, interstate movement of livestock (including poultry) and germplasm in conjunction with each State's regulations.<br><br>Information including VS guidance and permitting for importing animal products, live animals (includes semen and embryos), and veterinary biologics, as well as VS guidance and permitting for import and interstate movement for organisms and vectors, can be found at Imports: Animal and Animal Products. Additional information about APHIS VS regulatory authority is codified in 9CFR Subchapter I. | BRS regulates importation, interstate movement, and environmental release of modified microorganisms that may pose a plant pest risk, regardless of intended use.<br><br>Information about this process can be found at Biotechnology Permits and draft Guide for Submitting Applications for Microorganisms. |
| | HHS-FDA | FDA has post-market authority that could be applied if these plants, or materials from these plants, entered the food supply and microorganisms resulted in the adulteration of food.<br><br>Information can be found at section 402 of the FD&C Act (21 USC 342: Adulterated food). | CVM reviews animal and human safety, and effectiveness of intentional genomic alterations (IGAs) in animals.<br><br>Information about FDA's oversight of IGAs can be found at Intentional Genomic Alterations (IGAs) in Animals \| FDA. | FDA has post-market authority that could be applied if these microorganisms resulted in the adulteration of food.<br><br>Information can be found at section 402 of the FD&C Act (21 USC 342: Adulterated food). |

## THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS

Each regulatory agency has developed regulations and guidances for the regulation of products of biotechnology under existing laws.

### U.S. DEPARTMENT OF AGRICULTURE

Agencies within the U.S. Department of Agriculture (USDA) regulate aspects of food and agriculture, including products developed with biotechnology.

#### USDA Animal and Plant Health Inspection Service

USDA's Animal and Plant Health Inspection Service (APHIS) safeguards plant and animal health, including protecting agriculture and agriculturally important resources. To ensure biotechnology products are safe for plant health and agriculture, APHIS Biotechnology Regulatory Service (BRS) regulates the importation, interstate movement, and environmental release of:

- Modified plants and plant parts capable of propagation that may pose a plant pest risk, regardless of the intended use.
  BRS regulations for modified plants have three key elements: First, individuals can determine whether their modified plant meets the criteria for an exemption from regulation or can request APHIS' confirmation of the plant's exempt status. Additional information about this process and expected timelines can be found at Regulatory Exemptions and Confirmations. Second, applicants can request a regulatory status (RSR) review to determine if their modified plant is subject to the regulations. Additional information about this process and expected timelines can be found at Regulatory Status Review. Third, applicants must apply for a permit to move or release a modified organism that is not exempt or found through the RSR process to be not subject to APHIS's biotechnology regulations. Additional information about this process and expected timelines can be found at Biotechnology Permits.
- Modified invertebrates and microorganisms that are plant pests or that may pose a plant pest risk, regardless of intended use.
  Applicants must apply for a permit to move or release modified invertebrates or microorganisms that are not exempt. Additional information about this process and expected timelines can be found at Biotechnology Permits and Draft Guide for Submitting Applications for Microorganisms.
- Certain plants and plant parts capable of propagation that are modified to express pharmaceuticals or industrial compounds.
  Applicants must apply for a permit to move or release plants modified to express pharmaceuticals or industrial compounds. Additional information about this process and expected timelines can be found at Biotechnology Permits.

APHIS Veterinary Services (VS) regulates the importation of all livestock, birds (including poultry) and their hatching eggs, and certain fish; cell lines and germplasm (e.g., embryos, oocytes, semen, and cloning tissue) from such animals; materials derived from such animals; livestock and poultry pathogens or disease vectors and any cell line containing a livestock or poultry pathogen or gene from a livestock or poultry pathogen. VS also regulates, or supports regulation of, interstate movement of livestock and poultry, including germplasm, in conjunction with each individual State's regulations; livestock and poultry pathogens or disease vectors; and cell lines that contain a livestock or poultry pathogen. VS also regulates veterinary biologics (e.g., vaccines and diagnostic products), some of which are developed with biotechnology, including veterinary biologics that are, or are derived from, modified plants or plant cells, modified animals or animal cells, and modified microorganisms.

Information including VS guidance and permitting for importing animal products, live animals (includes semen and embryos), and veterinary biologics, as well as VS guidance and permitting for import and interstate movement for organisms and vectors, can be found at Imports: Animal and Animal Products. Additional information about APHIS VS regulatory authority is codified in 9CFR Subchapter I.

**USDA Agricultural Marketing Service**
The USDA Agricultural Marketing Service (AMS) Food Disclosure and Labeling Division (FDLD) is responsible for ensuring that certain foods produced with biotechnology are labeled according to the National Bioengineered Food Disclosure Standard. The Standard requires labeling of bioengineered foods, which are defined as those foods that contain detectable genetic material that has been modified through certain lab techniques and cannot be created through conventional breeding or found in nature. AMS maintains a List of Bioengineered Foods to identify the food or crops that are available in a bioengineered form throughout the world and for which regulated entities must maintain records. Foods are considered for addition to the List when AMS identifies that they are in legal commercial production somewhere in the world. Regulated entities include food manufacturers, importers, and certain retailers who label human food for retail sale.

**USDA Food Safety and Inspection Service**
The USDA Food Safety and Inspection Service (FSIS) ensures domestic and imported meat (including Siluriformes fish), poultry, and egg products are safe, wholesome, and properly labeled. To achieve its mission, FSIS:

- FSIS has a collaborative role with the Food and Drug Administration (FDA) following FDA's safety assessment, where FDA determines whether the safety of meat, poultry, and egg products derived from the intentional genomic alterations are safe for food. FSIS reviews and approves products of new technologies, including products developed with biotechnology, and ensures the suitability of all ingredients used in meat and poultry products. Suitability relates to the effectiveness of the ingredient in performing the intended purpose of use and the assurance that the conditions of use will not result in a product that is adulterated or misbranded (labeled in a manner that misleads the consumer).
- Verifies an establishment's compliance with the Hazard Analysis and Critical Control Point regulations, Sanitation Standard Operating Procedures (Sanitation SOPs), or other prerequisite program.
- Conducts sampling of meat and poultry products comprised of or containing cultured cells to assess potential hazards and verify food safety.
- Verifies the labeling of meat, poultry, Siluriformes fish, and egg products, including those containing ingredients developed with modified plants or microorganisms.

**FOOD AND DRUG ADMINISTRATION**
Centers and an Office within the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) evaluate safety of human and animal foods, human and animal drugs, veterinary biologics not regulated by USDA Veterinary Services, human biologics and medical devices, and other products, including those developed with biotechnology. Meeting with FDA early in the product development process can help developers determine the program most relevant to a product.

**HHS FDA Center for Food Safety and Human Nutrition**
Within FDA, the Center for Food Safety and Applied Nutrition (CFSAN) focuses on the safety of human food, other than meat, poultry, catfish, and egg products (which are regulated by USDA-FSIS).

CFSAN offers several programs that help developers ensure their biotechnology-derived foods meet the relevant safety and legal requirements.
Substances added to food require premarket review and approval unless their intended use is generally recognized as safe (GRAS). CFSAN operates petition programs that provide for the premarket review and approval of food additives and color additives. For substances whose intended use is GRAS, CFSAN offers a voluntary GRAS notice program where developers can provide CFSAN with their basis for a GRAS conclusion for the intended use of an ingredient. CFSAN evaluates the submission and responds with a letter indicating whether CFSAN has questions about the firm's GRAS conclusion. CFSAN has information on these programs on its website at Food Ingredients & Packaging | FDA.

CFSAN operates a voluntary consultation program for foods from biotechnology-derived new plant varieties In this program, FDA works with developers to help ensure that foods from new plant varieties meet all relevant pre- and post-market legal requirements (such as whether the new food contains an unapproved food additive or color

additive). FDA has more information about the new plant variety consultation program for both human and animal food on its website at Food from New Plant Varieties | FDA.

CFSAN oversees human food safety of products made from cultured animal cells during cell collection, selection, and growth. CFSAN also oversees subsequent processing, packaging, and labeling for cells derived from animals that are not regulated by USDA. CFSAN has more information about this program on its website at Human Food Made with Cultured Animal Cells | FDA.

**HHS FDA Center for Veterinary Medicine**
The FDA Center for Veterinary Medicine (CVM) focuses on the safety of products for animals, including animal foods and drugs.

Substances added to animal food require premarket approval if the added substances are unapproved food additives or unapproved color additives. CVM partners with CFSAN in the voluntary food safety consultation process for foods from new plant varieties. CVM also has several other regulatory programs through which firms can submit information regarding the safety and regulatory status of a product in animal food. FDA has more information about the new plant variety consultation process for both human and animal food on its website at Food from New Plant Varieties | FDA. FDA has more information about premarket approval and other regulatory programs for products in animal food on its website at Animal Food & Feeds | FDA. CVM regulates animal drugs, including any made from modified plants, animals, or microorganisms. CVM regulates intentional genomic alterations (IGAs) in animals, including those used to produce a drug product derived from an animal, as well as animal cells, tissues, and cell- and tissue-based products (ACTPs), unless they are used to produce a DNA vaccine or a live vaccine that stimulates a protective immune response (such products are regulated by VS). CVM reviews IGAs in animals for animal safety, human safety (e.g., could proximity to the animals pose a risk to handlers or others), food safety, environmental impacts, and efficacy of the IGA. CVM has more information on its oversight of IGAs in animals on its website at Intentional Genomic Alterations (IGAs) in Animals | FDA.

**HHS-FDA Centers that Regulate Human Medical Products**
The Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH) each regulate articles (drugs, biological products (biologics) and devices) used in human medicine, including those that are produced with biotechnology. Some human medical products are combination products (e.g., a combination of a drug and a device). The Office of Combination Products issues classification (which type of product is it) and jurisdiction (which FDA Center regulates the product or is the Lead Center regulating it) assignments for human medical products. More information on this process can be found at Jurisdictional Information | FDA.

- CDER regulates drugs and some biological products for humans, including, but not limited to, products made from plants, animals, or microorganisms, or from plant or animal cells. More information can be found at Development & Approval Process | Drugs and Therapeutic Biologics Applications (BLA) | FDA.
- CBER regulates many biologics for humans, including products that are cell-based or tissue-based products, blood and blood products, vaccines, allergenics, human tissues, xenotransplantation products, and gene therapies. CBER also regulates some devices used for blood and blood products, and for human tissues and cellular products. More information can be found at About CBER | FDA and Biologics Regulated Products | FDA.
- CDRH regulates human medical devices (which include diagnostics), including products derived from animal and human tissues. More information can be found at Overview of Device Regulation and How to Determine if Your Product is a Medical Device.

**ENVIRONMENTAL PROTECTION AGENCY**
The Environmental Protection Agency (EPA) regulates pesticides and chemicals, including those developed with biotechnology.

**EPA Office of Pesticide Programs**
EPA's Office of Pesticide Programs (OPP) evaluates the risks to the environment and humans from exposure to pesticides, including dietary exposure to pesticide residues in human and animal food. For products developed with biotechnology, OPP regulates plant-incorporated protectants (PIPs) (such as Bt corn), genetically engineered microbial pesticides, genetic modifications in pest animals intended for use as a pesticide (such as for mosquito and rodent population control), pesticides that consist of nucleic acids (such as exogenous/sprayable dsRNA) and peptides. More information is available at Regulation of Biotechnology under TSCA and FIFRA

**EPA Office of Pollution Prevention and Toxics**
EPA's Office of Pollution Prevention and Toxics (OPPT) evaluates potential risks from new and existing chemicals (including microorganisms) and acts to address any unreasonable risks they may have on human health and the environment. Food, food additives, drugs, cosmetics, medical devices, tobacco, nuclear material, firearms, and pesticides (but not pesticide intermediates) are excluded from regulation under TSCA. For purposes of regulation any chemical or microorganism that is not listed on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory is considered a "new chemical" or "new microorganism."

Developers are required to submit a notice to EPA prior to commercial manufacture of a new chemical or a new microorganism, and EPA makes a risk determination and takes steps to address risk before the new chemical or new microorganism can enter commerce. Some commercial uses of new microorganisms are fully or partially exempt from notification to EPA, such as research and development activities conducted inside a building, manufacture for test marketing, and commercial manufacture of certain exempt taxa under predetermined conditions of use. Some commercial uses of new chemicals are fully or partially exempt from notification to EPA, such as research and development activities, manufacture for test marketing, and commercial uses with low annual production volumes or low releases and exposures. Products developed with biotechnology that are reviewed by OPPT include new microorganisms, new chemicals produced from microbial fermentation, and new chemicals produced from genetically engineered plant and animal cells. Common examples include intergeneric microorganisms used in biofuel or ethanol production, bioremediation, biosensor and biofertilizer applications, production of bioplastics, and the manufacture of enzymes for various commercial and industrial uses. More information is available at Reviewing New Chemicals under the Toxic Substances Control Act (TSCA); Overview of Biotechnology under TSCA.

**CASE STUDIES**
The tables below provide case study examples of how products would be regulated by each agency. They are not intended to be inclusive of all products of biotechnology. Other examples of product types not specifically listed in a category may require review by different regulatory agencies. This is an area of developing technology and regulation. Additional case studies may be added to this list of examples in the future.

**Case study examples for plants, plant cells, plant products of biotechnology (Table 3)**

In Table 3 below,

- **EPA-OPP** regulates the sale, distribution, and use of all pesticides including those produced through genetic engineering and evaluates risks to humans and the environment from exposure to pesticides, including dietary exposure to pesticide residues in human and animal food. EPA-OPP requires developers to register pesticides in order to sell or distribute a pesticide product with particular conditions of use. EPA-OPP requires the establishment of a pesticide tolerance (maximum residue levels) or tolerance exemption for residues of a pesticide in or on both domestic and imported foods (for humans and animals). EPA-OPP requires Experimental Use Permits (EUPs) for field testing. Experimental tests are typically presumed not to need an EUP when conducted on a cumulative total of no more than 10 acres of land or less or one surface acre of water or less per pest tested. However, when field testing PIPs at 10

acres or less, developers should consider that PIPs, unlike other types of pesticides, can spread in the environment and enter the food supply, e.g., through gene flow from the test field to crops in surrounding fields, and consult EPA guidance regarding the use of additional containment measures to limit the potential for PIPs to move from the trial plot.

- **EPA-OPPT** determines the likelihood that chemicals produced from the plant for a commercial purpose pose unreasonable risk to human health or the environment if they are intended for uses other than food, food additives, drugs, cosmetics, medical devices, tobacco, nuclear material, firearms, or pesticides (but not pesticide intermediates). EPA requires submission of a notice to EPA before commercial manufacture of a new chemical, including chemicals derived from plants, or before engaging in a significant new use of an existing chemical, and EPA takes steps to address risk before the new chemical can enter commerce or before the significant new use can occur.
- **FDA-CFSAN** offers a voluntary food safety consultation process to help ensure the food is safe for human consumption. Food manufacturers have an obligation to ensure that the foods they market are safe and lawful. FDA has more information about the consultation process for both human and animal food on its website at Food from New Plant Varieties | FDA.
- **FDA-CVM** partners with FDA-CFSAN in the voluntary food safety consultation process to help ensure the food is safe for animals to consume. Food manufacturers have an obligation to ensure that the foods they market are safe and lawful. FDA has more information about the consultation process for both human and animal food on its website at Food from New Plant Varieties | FDA.
- **USDA-BRS** will determine if the plant poses a plant health risk compared to conventional plants. To import a modified plant (or modified germ plasm), move it interstate, or conduct a field trial, you will need permit from USDA-BRS, unless your modified plant is exempt or has successfully completed a Regulatory Status Review process. In the event you no longer wish to operate under permit, you may request a Regulatory Status Review. More information on these processes is available at Biotechnology Permits, Regulatory Exemptions and Confirmations, Regulatory Status Review.
- **USDA-FDLD** will oversee bioengineered labeling if resulting food for human consumption contains detectable modified genetic material produced with recombinant DNA technologies and cannot be created through conventional breeding or found in nature. Consult with USDA-FDLD to see whether your food product may require a BE disclosure. Information can be found at National Bioengineered Food Disclosure Standard.

For a complete list of an agency's roles and responsibilities, see Table 2.

**TABLE 3: CASE STUDY EXAMPLES FOR PLANTS, PLANT CELLS, PLANT PRODUCTS OF BIOTECHNOLOGY**

| | INSECT RESISTANT FOOD PLANT | HERBICIDE TOLERANT FOOD PLANT | ALTERED NUTRITIONAL CONTENT IN FOOD PLANT | FUNGAL RESISTANT PLANT NOT FOR HUMAN FOOD | ALTERED APPEARANCE OF ORNAMENTAL NON-FOOD PLANT |
|---|---|---|---|---|---|
| *Examples of each product type* | *Rootworm-resistant corn* | *Glyphosate-tolerant soybean* | *Soybeans producing increased levels of oleic acid* | *Fusarium-resistant bentgrass* | *Blue petunia* |
| **EPA** | | | | | |
| **OPP** | X | X[1] | | X | |
| **FDA** | | | | | |
| **CFSAN** | X | X | X | | |
| **CVM** | X | X | X | X[2] | |
| **USDA** | | | | | |
| **BRS**[3] | X | X | X | X | X |
| **FDLD** | X | X | X | | |

[1] To determine the safety of herbicide to be used on the plant.

[2] If product goes into animal food.

[3] For products where the modification does not qualify for an exemption. See Regulatory Exemptions and Confirmations.

**Case study examples of animals, animal cells, and animal products produced with biotechnology (Table 4)**

In Table 4 below,

- **EPA-OPP** regulates the sale, distribution, and use of all pesticides including those produced through genetic engineering and evaluates risks to humans and the environment from exposure to pesticides, including dietary exposure to pesticide residues in human and animal food. EPA-OPP requires developers to register pesticides in order to sell or distribute a pesticide product with particular conditions of use. EPA-OPP requires the establishment of a pesticide tolerance (maximum residue levels) or tolerance exemption for residues of a pesticide in or on both domestic and imported foods (for humans and animals). EPA-OPP requires Experimental Use Permits (EUPs) for field testing. Experimental tests are typically presumed not to need an EUP when conducted on a cumulative total of no more than 10 acres or less of land or one surface acre or less of water per pest tested. However, for genetic modifications in pest animals intended for use as a pesticide, the applicant should notify EPA-OPP when testing is at 10 acres or less of land or one surface acre or less of water in order to confirm an EUP is not required.
- **EPA-OPPT** determines the likelihood that chemicals produced from the animal cells/products for a commercial purpose pose unreasonable risk to human health or the environment if they are intended for uses other than food, food additives, drugs, cosmetics, medical devices, tobacco, nuclear material, firearms, or pesticides (but not pesticide intermediates). EPA requires submission of a notice to EPA before commercial manufacture of a

new chemical, including chemicals derived from animals, or before engaging in a significant new use of an existing chemical, and EPA takes steps to address risk before the new chemical can enter commerce or before the significant new use can occur.

- **FDA-CFSAN** offers a voluntary food safety consultation process for developers of foods from cultured animal cells (columns 4 and 5) to help ensure the food is safe for human consumption. For cells of animals of amenable species (livestock, poultry and Siluriformes fish), the consultation covers cell collection, selection, growth and removal from cell culture. For cells of all other animals, the consultation covers cell collection, selection, growth, removal from cell culture, processing, packaging, and labeling of the final product. Food manufacturers have an obligation to ensure that the foods they market are safe and lawful. CFSAN has information about the consultation process at Human Food Made with Cultured Animal Cells | FDA.
- **FDA-CVM** oversees safety (including food safety for humans and animals, animal safety and human safety), effectiveness (e.g., it achieves its growth claim), and environmental impacts of products such as fast-growing salmon in column 2. CVM has information on its procedures and requirements for such products on its website at Intentional Genomic Alterations (IGAs) in Animals | FDA. CVM recommends that developers contact CVM early in their development of such products to discuss regulatory requirements and data expectations to support review of the intentional genomic alteration in the animal. FDA-CVM uses its existing regulatory programs to oversee cultured animal cell products for use in animal food (column 6). Its oversight covers cells from all animal species and all aspects of the cell culture process: cell collection, selection, growth, removal from cell culture, processing, packaging, and labeling of the final product. Developers of such products should contact CVM at animalfood-premarket@fda.hhs.gov to discuss submissions and setting up consultation meetings. Food manufacturers have an obligation to ensure that the foods they market are safe and lawful. CVM has information on its regulatory programs for animal foods at Animal Food & Feeds | FDA.
- **USDA-FSIS** ensures domestic and imported meat (including Siluriformes fish), poultry, and egg products are safe, wholesome, and properly labeled. FSIS reviews and approves products of new technologies, including products made from modified animals and products made from animal cells. For animal cell products derived from amenable species (livestock, poultry, and Siluriformes fish (catfish)) and intended for human food, FSIS oversees the harvesting from cell culture, processing, packaging, and labeling of the final product. Further information about this program can be found at FSIS Compliance Guideline Procedures for New Technology Notifications and Protocols | Food Safety and Inspection Service (usda.gov). **USDA-VS** will ensure safe importation of livestock, birds and their hatching eggs, and certain fish (not including salmon); cell lines from such animals; animal pests; and veterinary biologics. Developers should consult with USDA-VS to understand the permitting requirements for the importation of live animals.
- **USDA-FDLD** will oversee bioengineered labeling if resulting food for human consumption contains detectable modified genetic material produced with recombinant DNA technologies and cannot be created through conventional breeding or found in nature. Consult with USDA-FDLD to see whether your food product may require a BE disclosure. Information can be found at National Bioengineered Food Disclosure Standard.

For a complete list of an agency's roles and responsibilities, see Table 2.

**TABLE 4: CASE STUDY EXAMPLES OF ANIMALS, ANIMAL CELLS, AND ANIMAL PRODUCTS PRODUCED WITH BIOTECHNOLOGY**

| | GROWTH TRAITS IN A FOOD ANIMAL THAT IS NOT REGULATED BY FSIS | POPULATION SUPPRESSION IN A PEST ANIMAL | CELLS FROM AMENABLE SPECIES FOR HUMAN FOOD | CELLS FROM NON-AMENABLE SPECIES FOR HUMAN FOOD | CELLS FROM ANY SPECIES FOR ANIMAL FOOD |
|---|---|---|---|---|---|
| *Examples of each product type* | *Fast growing Salmon* | *Self-limiting mosquito* | *Pig* | *Salmon* | *Pet Food* |
| **EPA** | | | | | |
| **OPP** | | X | | | |
| **FDA** | | | | | |
| **CFSAN** | | | X | X | |
| **CVM** | X | | | | X |
| **USDA** | | | | | |
| **FSIS** | | | X | | |
| **VS** | * | | | | |
| **FDLD** | X | | X[1] | | |

[1] For final food products subject to the Federal Food, Drug, and Cosmetic Act that contain detectable modified genetic material.

* Certain fish, not including salmon.

**Case study examples of microorganisms produced with biotechnology, microbial cells, and microbial products produced with biotechnology (Table 5).**

In Table 5 below,

- **EPA-OPP** regulates the sale, distribution, and use of all pesticides including those produced through genetic engineering and evaluates risks to humans and the environment from exposure to pesticides, including dietary exposure to pesticide residues in human and animal food. EPA-OPP requires developers to register pesticides in order to sell or distribute a pesticide product with particular conditions of use. EPA-OPP requires the establishment of a pesticide tolerance (maximum residue levels) or tolerance exemption for residues of a pesticide in or on both domestic and imported foods (for humans and animals). EPA-OPP requires Experimental Use Permits (EUPs) for field testing. Experimental tests are typically presumed not to need an EUP when conducted on a cumulative total of 10 acres or less of land or one surface acre or less of water per pest tested. However, for genetically engineered microorganisms, the applicant must notify EPA-OPP when testing is 10 acres or less of land or one surface acre or less of water in order to confirm an EUP is not required.
- **EPA-OPPT** evaluates human health and environmental safety of the microorganism and chemicals derived from the microorganism. The developer must submit a notice to EPA prior to commercial manufacture of a new chemical or new microorganism, before engaging in a significant new use of an existing chemical or microorganism, or prior to use of a new microorganism in research and development activities resulting in environmental release. Prior to commercial manufacture, EPA must make a risk determination and take steps to address risk before the new microorganism can enter commerce. For research and development activities resulting in environmental release of a new microorganism, EPA must review and approve any proposed activities prior to commencement of field trials.

- **FDA-CFSAN** operates both mandatory (for food additives or color additives) and voluntary programs that oversee the safety of substances added to food (including substances from microbes, or any other source). FDA has information about these programs at Food Ingredients & Packaging | FDA. Food manufacturers have an obligation to ensure that the foods they market are safe and lawful.
- **FDA-CVM** offers several regulatory programs through which firms can submit information regarding the safety and regulatory status of a product in animal food, including products of microbes. FDA has information about these programs on its website at Animal Food & Feeds | FDA. Food manufacturers have an obligation to ensure that the foods they market are safe and lawful.
- **USDA-BRS** will ensure safe shipment, contained production, and/or confined field release of microorganisms that are plant pathogens or could pose a plant pest risk, or are biocontrol organisms for plant pests. To import a modified microbe, move a modified microbe interstate, or conduct a field trial, you will need a permit from USDA-BRS. Information can be found at Biotechnology Permits.

For a complete list of an agency's roles and responsibilities, see Table 2.

**TABLE 5: CASE STUDY EXAMPLES OF MICROORGANISMS PRODUCED WITH BIOTECHNOLOGY, MICROBIAL CELLS, AND MICROBIAL PRODUCTS PRODUCED WITH BIOTECHNOLOGY**

| | INTERGENERIC MICROORGANISM FOR ENVIRONMENTAL RELEASE | CONTAINED PRODUCTION OF AN INTERGENERIC MICROORGANISM NOT EXCLUDED UNDER TSCA [1] | CONTAINED PRODUCTION OF A FOOD INGREDIENT IN A MICROORGANISM | CONTAINED PRODUCTION OF A DIETARY SUPPLEMENT IN A MICROORGANISM | FIELD TESTING OR COMMERCIAL USE OF A MICROORGANISM USED AS A PESTICIDE |
|---|---|---|---|---|---|
| *Examples of each product type* | *Nitrogen-fixing soil bacteria* | *Intergeneric yeast modified for ethanol production* | *Vanillin produced by bacteria* | *Vitamin D produced in yeast* | *Bacillus thuringiensis* |
| **EPA** | | | | | |
| **OPP** | | | | | X |
| **OPPT** | X[1] | **X** | | | |
| **FDA** | | | | | |
| **CFSAN** | | | X | X | |
| **CVM** | | X[5] | X | X[2] | |
| **USDA** | | | | | |
| **BRS[3]** | X | X[4] | X[4] | X[4] | X |

[1]EPA's OPPT regulates chemicals, including microorganisms, under TSCA excluding those intended for use in food, food additives, drugs, cosmetics, medical devices, tobacco, nuclear material, firearms, or pesticides (but not pesticide intermediates).
[2] If the ingredient is used in animal food.
[3] BRS permit is required if the microorganisms are plant pathogens or could pose a plant pest risk, or biocontrol organisms for a plant pest that could pose a plant pest risk.
[4] BRS permit is required for contained production if the organisms are being imported or moved interstate.
[5] If byproducts of fermentation, such as devitalized biomass or dried distillers grains, are used in animal food.

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# EPA Proposes Updates to Strengthen the Safer Choice Standard

Yesterday EPA announced proposed updates to the Safer Choice Standard, which identifies the requirements that products and their ingredients must meet to earn EPA's Safer Choice label or Design for the Environment (DfE) logo. The Agency is requesting public comments on the proposed updates by Jan. 16, 2024, and will hold a webinar on Dec. 19, 2023, to provide information on proposed updates to the Standard.

**Register Here for the Webinar**

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The Safer Choice program helps consumers and purchasers for facilities, such as schools and office buildings, find cleaners, detergents, and other products made with chemical ingredients that are safer for human health and the environment. Similarly, the DfE program helps people find disinfectants that meet high standards for human health and the environment.

"The Safer Choice program continues to encourage safer and greener chemistry in the marketplace to safeguard human health and protect the environment," **said EPA Office of Chemical Safety and Pollution Prevention Deputy Assistant Administrator for Pollution Prevention Jennie Romer**. "These proposed updates to

the Safer Choice Standard will increase transparency, safety, and sustainability in consumer and commercial products."


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EPA's proposed updates to the Standard include:

- New certification for cleaning service providers that use Safer Choice- and DfE-certified products to help protect workers that use cleaning products all day as well as the people who live or work in the spaces they clean.
- Strengthening sustainable packaging requirements in response to consumer demand and innovations in packaging materials and technologies.
- Expanded criteria specific to pet care products to ensure such products use only the safest possible ingredients for both humans and pets.
- Clarifying language on EPA's process for entering product classes and exiting those that pose unexpected risks despite safer chemistry.
- Clarifying language regarding the use of data from New Approach Methodologies during Safer Choice chemical review.
- New, optional energy efficiency or use reduction criteria to encourage companies to reduce water use and carbon-based energy consumption.
- Updated criteria for wipe products to help reduce damage to wastewater treatment systems.
- Potential creation of a new alternate logo, similar to the Fragrance-Free logo, to distinguish products used outdoors that meet additional EPA criteria for environmental safety.

EPA periodically updates the Standard to keep current with the state of scientific and technological innovation; increase transparency and reduce redundancy; and expand the scope of the program as appropriate. This will be EPA's fourth update of the

Standard since its inception in 2009, and the first since 2015.

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On **Dec. 19, 2023, 2-3 p.m. ET**, EPA will hold a webinar to provide further information on the proposed updates to the Standard. The webinar may be of interest to stakeholders interested in commenting on the updates, including manufacturers and distributors, retailers, community groups and representatives from states, Tribal Nations, non-profit organizations, trade associations, and others. Register here for the webinar.

Upon publication of the Federal Register notice, comments should be submitted to docket EPA-HQ-OPPT-2023-0520 on Regulations.gov by Jan. 16, 2024.

EPA will use the written comments to guide updates to the Standard.

**Safer Choice**

Safer Choice encourages chemistry that meets EPA's stringent criteria for human health and the environment and provides opportunities for companies to differentiate their products in the marketplace with the Safer Choice label. With thousands of certified products, the Safer Choice label is a reliable way for people to find products whose chemical ingredients have met EPA's criteria for being safer without sacrificing performance. Visit the Safer Choice program website for more information.

**Design for the Environment**

Similar to the Safer Choice label, EPA's DfE logo helps people identify antimicrobial products like disinfectants that meet the health and safety standards of the normal pesticide registration process required by the Federal Insecticide, Fungicide and Rodenticide Act as well as meeting the DfE certification criteria (as described in the Safer Choice Standard). When a person sees EPA's DfE logo on a product, they can feel confident that the product performs and meets stringent EPA criteria for human health and the environment. Visit the Design for the Environment website for more information.

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# EPA Approves Strengthened Pesticide Safety Plans for Certifying Applicators

The U.S. Environmental Protection Agency (EPA), in collaboration with state and tribal co-regulators, is strengthening the protection of human health and the environment and reaffirming its commitment to environmental justice by announcing the final approval of 67 updated plans for certifying applicators of Restricted Use Pesticides (RUPs). RUPs are pesticides that are the most acutely toxic pesticides or those needing to be applied with special care. With this announcement, all areas of the U.S. will be able to continue certifying applicators of RUPs, but now must also begin the process of holding RUP applicators to higher safety standards.

On January 4, 2017, EPA updated the Certification of Pesticide Applicators (CPA) regulations to set stronger standards for those who apply RUPs, which can only be used by certified applicators or individuals under a certified applicator's direct supervision, not by the general public. Applicators are certified by federal agency, state, territory, and tribal certifying authorities with an EPA-approved certification plan by completing a comprehensive training program and/or passing a written exam.

The 2017 CPA rule required that authorities certifying RUP applicators submit revised plans to EPA for approval by an extended deadline of November 4, 2023 that include:

- *Enhanced competency requirements and assessment*: Applicators must demonstrate they are competent to use RUPs through the completion of more comprehensive training programs and/or passing a written exam. Competency standards now include more specific information on pesticide application and safe use.

- *New specialized categories*: A certification is now required for aerial, fumigation, and predator control RUPs. These high-risk pesticides now require specific training due to the difficulty of application without exposing people to the pesticides
- *Minimum age restrictions*: Applicators and noncertified applicators under a certified applicator's direct supervision must be at least 18 to apply RUPs (with a limited age exemption (16) for some uses on family farms by noncertified applicators under the direct supervision of a certified applicator who is an immediate family member).
- *Noncertified applicator qualifications and supervisor requirements*: Those applying RUPs under the direct supervision of a certified applicator must receive safety training in a manner they can understand. Applicators must verify training records for those working under their direct supervision prior to applying RUPs.
- *Recertification*: Recertification programs must ensure that applicators continue to maintain a level of competency necessary to use RUPs without causing unreasonable adverse effects. Certifications are now valid for a maximum of only five years, whereas previously there was no federal limit.

EPA and certifying authorities from all 50 states, 5 territories, 6 federal agencies, 6 tribes, and the District of Columbia have been coordinating throughout the plan approval process for over 3 years, an effort which has resulted and will continue to result in modified plans that protect the environment and human health, including the health of certified pesticide applicators and those under their direct supervision, and will ensure that certified applicators are trained to prevent bystander and worker exposures. Plans have been approved on a rolling basis since spring of 2022. EPA has approved five tribal plans, with one remaining tribal plan currently being finalized for approval. In the interim, applicators certified under the tribe's existing plan will be transitioned to EPA federal certification under the EPA Plan for applicators of RUPs in Indian country until the revised plan is approved. The next phase for the CPA has begun as certifying authorities enhance certification programs according to the standards and implementation schedules in their plans.

Upon publication of the Federal Register notice detailing the approval of the certification plans, a list of the plans will be available in docket EPA-HQ-OPP-2022-0509 at www.regulations.gov. Copies of EPA-approved certification plans can be found on the Certification Plan and Reporting Database (CPARD). For more information regarding the reviews and approvals of these certification plans, visit EPA's Certification Standards for Pesticide Applicators website or read more about the 2023 EPA Plan to Certify Pesticide Applicators in Indian Country.

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# AG GROUPS WELCOME APPEALS COURT REVERSAL OF CHLORPYRIFOS BAN

November 3, 2023 By Mark Dorenkamp Filed Under: Ag litigation, Crops, crops, Environment, EPA, Minnesota, News, Soybeans

Ag groups are applauding a circuit court ruling that vacates a rule restricting the use of a commonly used pesticide.

Minnesota Soybean Growers Association president Bob Worth tells Brownfield the 8th Circuit Court of Appeals has reversed the EPA's ban on chlorpyrifos.

"There are other products, but they just don't work nearly as good as this. So this is really good news for us as farmers."

American Farm Bureau president Zippy Duvall says the decision sends a message to EPA that it must use sound science when drafting rules.

Worth says he scrambled during the growing season to find an alternative product to control soybean aphids.

“It was very difficult to find one that worked. It did work, but was it as good? No. So that’s another reason that we are excited about having this product back.”

But Worth says he is concerned about chlorpyrifos being available for the 2024 growing season because manufacturers were told to stop making the pesticide.

“It might be available legally for 2024, but are we going to be able to physically have it available for us? That’s going to be a big challenge.”

American Sugarbeet Growers Association president Nate Hultgren says growers experienced much higher costs without chlorpyrifos last year, and the court ruling allows the industry to safely use the crop protection tool to help keep farmers economically viable.