

Benefits, ESA & the Pesticide Registration and Re-evaluation Process

**Louisiana Agricultural Consultants
Association Annual Meeting 2023**

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Office of Pesticide Programs

Biological and Economic Analysis Division



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2002 Recipient of LACA Scholarship

Louisiana Agricultural
Association Annual

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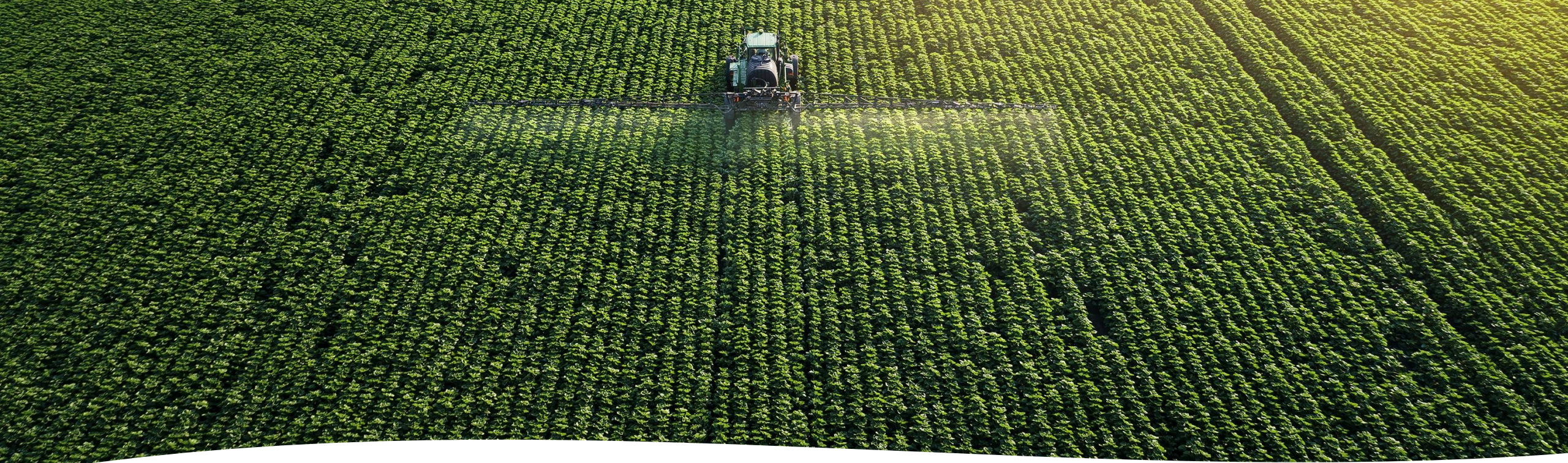
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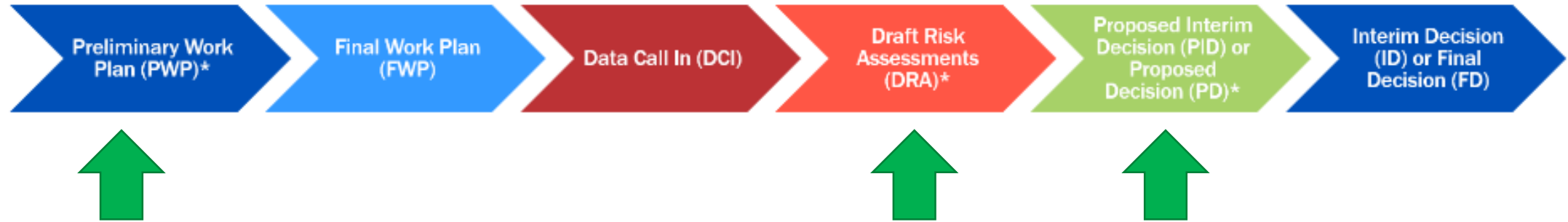





Overview

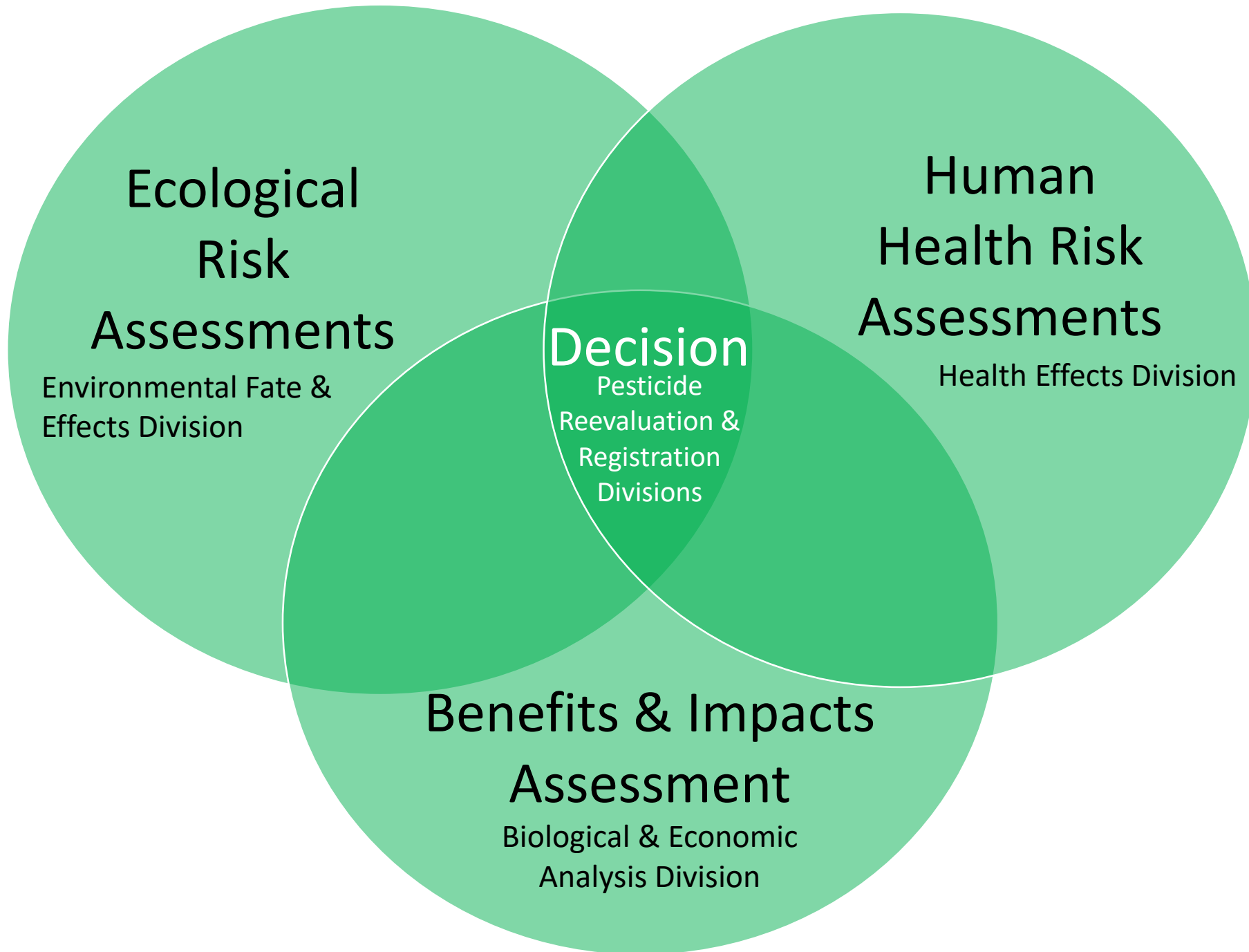
- Registration Review process and Benefit Assessments
- Endangered Species Act (ESA)
- EPA's ESA Workplan
- How ESA affects Registration Review and Registration Activities
- Chemical updates

Overview of Registration Review Process



- There are multiple opportunities for public comment during registration review.
- Feedback from stakeholders is important to get feedback on our risk assessments and mitigation proposals to ensure they are based on the best available information.
- ESA mitigation would generally first appear in a Proposed Interim Decision (PID) or a Proposed Amendment to PID for public comment.

 Denotes a 60-day comment period





Considerations Given when Describing Benefits

Generally, the benefits of a pesticide are the advantages it brings *to the user*, compared to other methods of controlling pests

- Why are people using the pesticide in the first place?
 - Prevent yield/quality losses, controlling specific pests, resistance management
- What would users do without the pesticide?
 - Alternative pesticides, cultural/mechanical control, accept losses in yield/quality, etc.
- What is the magnitude of benefit?
 - Benefits are considered as crop-specific

Considerations Given when Describing Impacts

Generally, the impacts of risk mitigation are potential consequences incurred by the user as a result of OPP regulation on a pesticide

- How does the proposed mitigation impact users?
- Typically crop specific
 - Considers primary pests, application rates/timing/ method
- Assess on a per acre basis
 - Effects on yield/quality, costs of production
- Other potential impacts
 - predatory arthropods, resistance management, general convenience, etc.



Recent Court Decisions

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

Cyantraniliprole decision. *In re: Center for Biological Diversity and Center for Food Safety* (Nov. 2022), DC Circuit.

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

4 new Als. *Center for Biological Diversity v. EPA* - (Dec. 2022) - DC Circuit.

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

Sulfoxaflor decision. *Center for Food Safety v. Regan* (Dec. 2022), 9th Circuit

Endangered Species Act (ESA)

- “The Services” administer ESA:
 - U.S. Fish and Wildlife Service (FWS)
 - National Marine Fisheries Service (NMFS)
- **Consultation (ESA § 7(a)(2))**: In consultation with the Service(s), Agencies must ensure that any "agency action" is not likely to **jeopardize** the continued existence of a listed species or result in destruction or **adverse modification** of habitat designated by the Services as critical (**J/AM**)
- **What FIFRA Actions are ESA “Agency Actions”**: Includes certain registration and registration review decisions

Roles and Responsibilities

- **EPA:** Conducts an effects determination, often encompassed in a biological evaluation (BE) and, as appropriate, initiates consultation with one or both of the Services.
- **U.S. Fish and Wildlife Service (FWS):** Species expert for all non-marine species (~1,800 species). Provides biological information and species' ranges. Issues Biological Opinion (BiOp) at the end of consultation.
- **National Marine Fisheries Service (NMFS):** Same role as FWS, but for marine and anadromous species. They oversee ~100 species (*e.g.*, salmon). They also issue a BiOp.
- **U.S. Department of Agriculture (USDA):** Provides agricultural information, usage data, spatial data, and agricultural perspective.

EPA's Responsibilities Under the ESA

No Effect (NE)

Action is not expected to result in effects to a member of a listed species/designated critical habitat.

**No Consultation
Required**

Not likely to adversely affect (NLAA)

Action not expected to result in any adverse effects to a member of a listed species/designated critical habitat.

Initiate informal consultation with the responsible Service(s). If the Service(s) do not concur, then initiate formal consultation.

For Formal Consultation: Develop BE

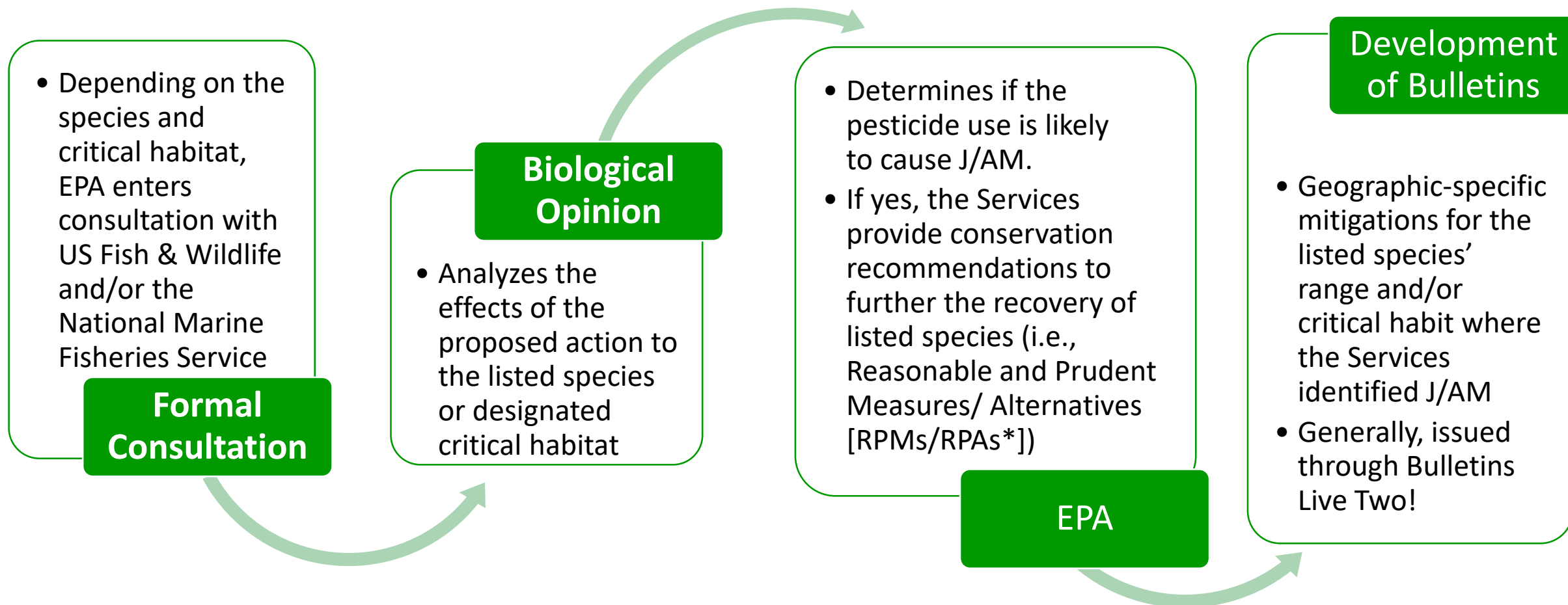
Consider the effects to ~1,800 listed species and ~800 designated critical habitats.

Likely to adversely affect (LAA)

Action may result into a direct or indirect adverse effect to a member of a listed species/designated critical habitat.

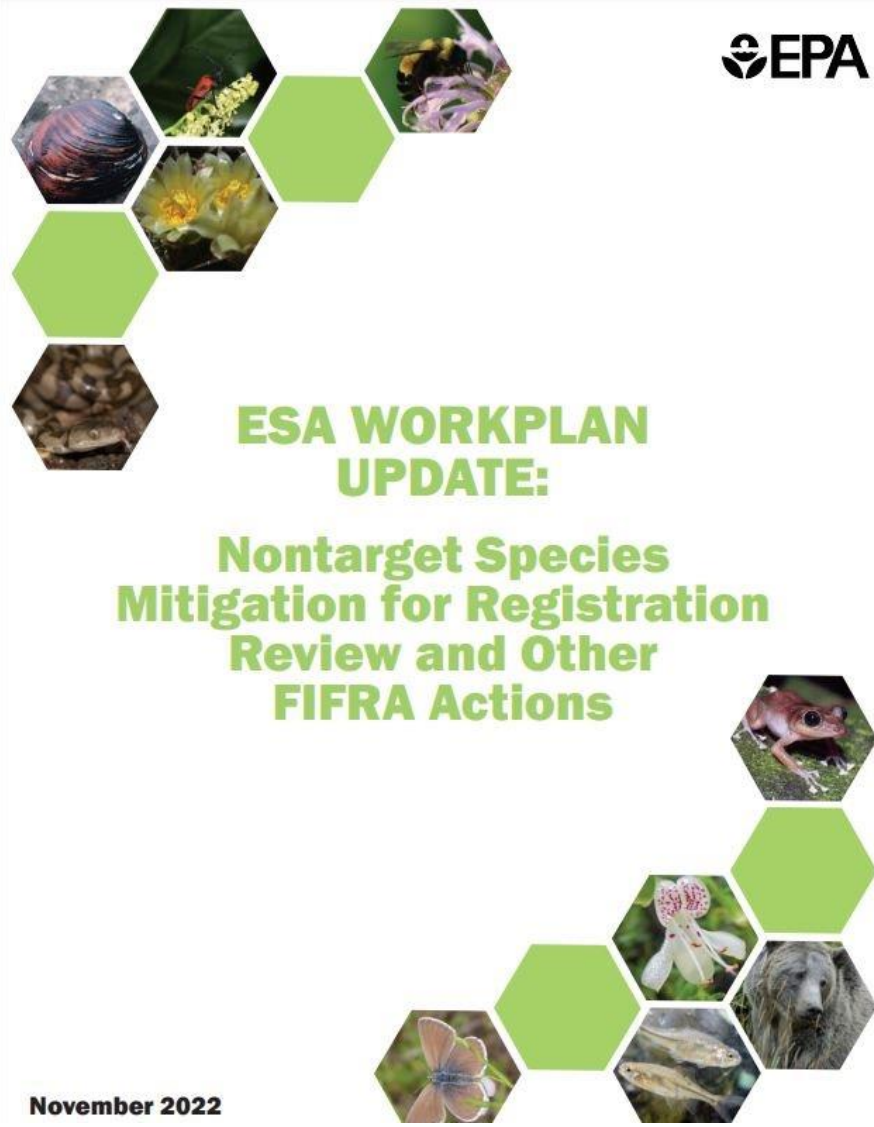

Initiate formal consultation with the Service(s).

Next Steps After the Biological Evaluation



*RPM – intended to minimize any "take" of listed species; RPA – alternative actions that would avoid jeopardy

ESA Workplan Update – November 2022



**ESA WORKPLAN
UPDATE:**

**Nontarget Species
Mitigation for Registration
Review and Other
FIFRA Actions**

November 2022

- FIFRA Interim Ecological Mitigation
- Endangered Species Protection Bulletins and Bulletins Live Two!
- Additional ESA Strategies
- Public comment period on appendix closes Feb 14 (EPA-HQ-OPP-2022-0908)



Ecological Mitigations in the Nov. 2022 ESA Workplan Update

- **FIFRA Mitigations (Interim Ecological Mitigation)**
 - FIFRA mitigation intended to reduce risks to all non-target species, including but not limited to listed species
 - Found on the “paper label”
 - Apply to all locations where the pesticide is applied
 - Benefits are weighed against the risks
- **Endangered Species Mitigations (Bulletins)**
 - Intended to reduce exposure specifically to listed species
 - Primarily found on Bulletins Live! Two
 - Apply to specific geographic areas where listed species’ range and/or critical habit exists
 - Product/application/formulation information
 - Bulletins can be converted into a ‘printable’ pdf



FIFRA Interim Ecological Mitigation

- A menu of FIFRA Interim Ecological Mitigation measures
 - Focuses on agricultural crops uses of conventional and biological pesticides
 - Proposing in registration review, to be adapted to new use registrations
 - To be adjusted to account for varying risks and benefits of the pesticide
 - Proposed for inclusion on product labels (not Bulletins)
- FIFRA Interim Ecological Mitigation measures do not include
 - Pesticide-specific measures (e.g., application rate reductions)
 - Listed species-specific mitigation measures being developed for the Vulnerable Species Pilot
 - Mitigation measures being developed for listed species under Additional ESA Strategies

FIFRA Interim Ecological Mitigation

- To reduce off-field ecological risks from **surface water runoff or soil erosion**:
 - Surface water protection statements users would follow when precipitation occurs or (for runoff) is forecasted
 - Pick list of conservation buffers and other conservation measures
- To reduce off-field ecological risks from **spray drift**:
 - Droplet size, windspeed, and release height limits
 - Spray drift buffers from aquatic habitats
 - For example, lakes, reservoirs, rivers, permanent streams, wetlands or natural ponds, estuaries, and commercial fish farm ponds
 - Spray drift buffers from conservation areas
 - For example, public lands and parks, Wilderness Areas, National Wildlife Refuges, reserves, and conservation easements



FIFRA Interim Ecological Mitigation

Other Proposed Label Language

- Bulletins Live! Two (BLT) system web link
- Advisory language for insect pollinators
 - Pollinator Hazard Statement
 - Best Management Practices for Pollinator Protection
- Incident reporting language
- Treated seed language
 - Labeling for Products with Seed Treatment Uses
 - Instructions for Seed Bag Tags

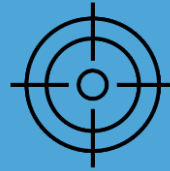


Mitigation Approach for Bulletins (ESA Mitigations)



Avoidance

The Services prefer that EPA first limit potential pesticide effects by avoiding pesticide use where they might impact listed species and/or designated critical habitat



Minimization

Where avoidance is not feasible, then EPA looks to minimize exposure and/or impacts to protected species from pesticides using mitigations like: spray drift and/or runoff measures, geographic and/or timing restrictions, etc.



Conservation Offsets

Where neither avoidance nor minimization are feasible, or adequate to reduce impacts to listed species, conservation offsets can be considered



Strategies to Expedite Progress on ESA Workplan Initiatives Being Developed

Group assessments and mitigations based on:

- Pesticide type or use
 - Ex. Herbicides - broad approach to address spray drift and runoff from treated fields to minimize exposure to listed plants avoiding jeopardy/ adverse modification.
- Region
 - Develop a cross-pesticide approach to address listed species and designated critical habitats in Hawaii
- Vulnerable Species
 - Identify mitigation measures for ~25 listed species with limited ranges and where pesticides identified as a stressor

Offsets and Compensatory Measures

- Creation of new habitat, rearing and releasing listed species, etc.
- Consult with the Services to identify species that may be amenable to offsets



How Do Benefits and Impacts Fit into Determining Interim Ecological Mitigations?

- EPA will continue to conduct a review of use site-specific benefits to support the FIFRA decision
 - Risk/benefit balancing will occur

How Do Benefits and Impacts Fit into Determining ESA Mitigations?

- Consistent with ESA, EPA will evaluate the feasibility and the impacts of mitigation (avoidance, minimization)
- Goal is to develop mitigation that is protective of listed species while minimizing impacts on pesticide users where possible



What Does this Mean for Registration Review?

Interim Ecological Mitigation (IEM)

- Public comment period closes Feb 14 and comments will be reviewed
- Changes resulting from public comments will be incorporated into future Proposed Interim Decisions (PIDs), as appropriate
- IEM was included in recent PIDs were published for public comment in Dec 2022. Comment periods close Mar 8
 - Dicloran (DCNA)
 - Etofenprox
 - Norflurazon
 - Thiophanate-methyl/carbendazim (TM/MBC)



What Does this Mean for Registration Review?

ESA Mitigation

- Registration review conventional chemical pilots: methomyl, carbaryl, certain neonicotinoids, and rodenticides*
 - Propose mitigation for a subset of listed species that EPA predicts would avoid jeopardy/adverse modification (J/AM)
 - Help our stakeholders to better understand how EPA identified J/AM species and mitigation measures
 - Address protections for listed species faster and streamline future consultations
 - Opportunity for stakeholder feedback on proposed mitigation in the proposed interim registration review decision (PID) or an amended PID
- Implement the terms of existing pesticide Biological Opinions
- Vulnerable Species Pilot Effort and the Herbicide Strategy expected to be released in 2023 for public comment

* All but 'certain neonicotinoids' have gone out for public comment

What Does this Mean for Conventional New Active Ingredients?

New Conventional Active Ingredient (A.I.) Policy (Jan. 2022)

- Prior to registration, EPA will conduct ESA assessment when registering new conventional A.I.
- Where EPA makes one or more LAA determinations, EPA plans to predict the likelihood of J/AM
 - EPA will identify and implement mitigations, with a focus on addressing predicted likelihood of J/AM and the following:
 - mandatory references to Bulletins Live! Two (BLT) on the label
 - clause in registration notice stipulating that the registration will be appropriately amended according to the outcome of consultation
- EPA will initiate consultation with the Services if appropriate (i.e., not necessary for a No Effects determination)

Other Updates

- Congress extended the registration review deadline for certain chemicals by 4 years
- Pesticide Registration Improvement Act (PRIA) 5 passed
- Chemical Updates
 - Organophosphates (OPs)
 - Atrazine
 - Glyphosate

Glyphosate (Docket EPA-HQ-OPP-2009-0361)

- Feb 2020 - Glyphosate Interim Decision (ID) published for registration review
- March 2020, several petitioners challenged the ID in the Ninth Circuit
 - Challenged the human health and ecological risk analysis, the weighing of ecological risk against the benefits under FIFRA, and interim risk mitigation measures and alleged that EPA violated the ESA in issuing the ID before completion of ESA consultation
- Nov 2020 – Draft Biological Evaluation (BE) published
- May 2021 - EPA filed motion for voluntary remand without vacatur of the ecological portion of the ID, so that EPA could revisit certain aspects of its analysis based in part on the draft BE and recent court decisions for other herbicides
- Nov 2021 – EPA released the final BE and initiated formal consultation with Services
 - EPA found that glyphosate is Likely to Adversely Affect (LAA) 1,676 listed species and 759 critical habitats



Glyphosate (Docket EPA-HQ-OPP-2009-0361)

- June 2022, the Ninth Circuit:
 - Vacated and remanded the human health portion of the ID for further explanation and analysis.
 - Held that EPA's failure to make effects determinations before issuance of the ID violated the ESA.
 - Granted EPA's motion to remand the ecological portion of the ID, but imposed a deadline of October 1, 2022 for issuing a new ecological portion.
- Sept 2022 – EPA withdrew all remaining portions of the ID in consideration of the 9th Circuit's June 2022 decision
 - Unable to finalize a new ecological portion by the court-imposed deadline due to the time needed to address the issues for which EPA sought remand of the ecological portion and satisfy ESA requirements.
 - Products remain on the market as EPA works towards a final registration review decision for glyphosate in accordance with the court's decision.
- Next steps
 - Registration review decision expected in 2026, for which EPA intends to revisit and better explain the evaluation of glyphosate's carcinogenic potential, address the ecological portion of the ID, complete ESA consultation, make a determination under the Endocrine Disruptor Screening Program, and respond to an administrative petition. The Agency's position on the cancer reclassification has not changed.



Atrazine (Docket EPA-HQ-OPP- 2013-0266)

- Sept 2020 – EPA released the Interim Decision (ID)
- Oct 2020 – Several petitioners challenged the ID in the Ninth Circuit, arguing that EPA lacked evidence supporting the decision
- Aug 2021 – EPA sought voluntary partial remand
- Nov 2021 – EPA released the Biological Evaluation
- Dec 2021 – Ninth Circuit granted voluntary partial remand
- June 2022 – Additional mitigation proposed to protect aquatic plant communities
 - EPA is reviewing public comments
 - Scientific Advisory Panel (SAP) will be held in 2023. EPA will:
 - Seek peer review of the risks to the aquatic plant community that underlie the proposed risk management strategy
 - Evaluate whether the 3.4 $\mu\text{g}/\text{L}$ CE-LOC should be updated based on feedback from the 2023 SAP
 - Publish notice in the Federal Register approximately five months prior to the scheduled date



Organophosphates

- In various stages of the Reg. Review process
- Scientific Advisory Panel (SAP) held in Sept 2020
 - Use of New Approach Methodologies (NAMs) to derive extrapolation factors and evaluate developmental neurotoxicity for human health assessments
- Agency is reviewing recommendations from SAP
 - Findings may inform the chemical-specific safety factors
 - Anticipated Agency response to the SAP in 2023
- A petition from Earthjustice to revoke tolerances was published for public comment (EPA-HQ-OPP-2022-0490)
 - EPA is reviewing comments and considering how to respond

Current Registration Review Schedule for OPs

Active Ingredient	Action*	Year	Docket Number
Acephate	PID	2024	EPA-HQ-OPP-2008-0915
Bensulide	PID	2026	EPA-HQ-OPP-2008-0022
Chlorethoxyfos	PID	2024	EPA-HQ-OPP-2016-0037
DDVP	PID	2025	EPA-HQ-OPP-2009-0209
Diazinon	PID	2026	EPA-HQ-OPP-2008-0351
Dicrotophos	PID	2023	EPA-HQ-OPP-2008-0440
Dimethoate	PID	2023	EPA-HQ-OPP-2009-0059
Ethoprop	PID	2025	EPA-HQ-OPP-2008-0560
Malathion	PID	2024	EPA-HQ-OPP-2009-0317
Naled	PID	2025	EPA-HQ-OPP-2009-0053
Phorate	DRA, PID	2025	EPA-HQ-OPP-2009-0055
Phosmet	PID	2026	EPA-HQ-OPP-2009-0316
Phostebupirim	PID	2025	EPA-HQ-OPP-2008-0940
Terbufos	PID	2025	EPA-HQ-OPP-2008-0119
Tetrachlorvinphos	PID	2022	EPA-HQ-OPP-2008-0316
Tribufos	PID	2024	EPA-HQ-OPP-2008-0883
Trichlorfon	PID	2025	EPA-HQ-OPP-2009-0097

* **PID** – Proposed Interim Decision; **DRA** – Draft Risk Assessments



How Do You Know Where a Chemical Is in the Registration Review Process?

<https://www.epa.gov/pesticide-reevaluation/upcoming-registration-review-actions>



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Upcoming Registration Review Actions

EPA reviews each registered pesticide at least every 15 years to ensure that each pesticide can carry out its intended function(s) without creating unreasonable adverse effects to human health and the environment. EPA always

Related Information



How Do You Know Where a Chemical Is in the Registration Review Process?

<https://www.epa.gov/pesticide-reevaluation/upcoming-registration-review-actions>

Show entries

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Search:

Case Name	Case Number	Division	Action	Year	Quarter	Docket Number	Public Comment
2,4-D	73	Pesticide Reevaluation Division	Proposed Interim Decision	22	3	EPA-HQ-OPP-2012-0330	
2,4-D	73	Pesticide Reevaluation Division	Interim Decision	23	N/A	EPA-HQ-OPP-2012-0330	
4-Aminopyridine	15	Pesticide Reevaluation Division	Proposed Interim Decision	22	3	EPA-HQ-OPP-2016-0030	

For More Information

- **Registration Review Program:** <https://www.epa.gov/pesticide-reevaluation/registration-review-process>
- **Upcoming Registration Review Actions:** <https://www.epa.gov/pesticide-reevaluation/upcoming-registration-review-actions>
- **2022 ESA Workplan and Workplan Update:** <https://www.epa.gov/endangered-species/epas-workplan-and-progress-toward-better-protections-endangered-species>
- **ESA Policy for New Pesticides:** <https://www.epa.gov/newsreleases/epa-announces-endangered-species-act-protection-policy-new-pesticides>
- **Vulnerable Species Pilot:** <https://www.epa.gov/endangered-species/implementing-epas-workplan-protect-endangered-and-threatened-species-pesticides#species>
- **Bulletins Live! Two:** <https://www.epa.gov/endangered-species/bulletins-live-two-view-bulletins>

Questions?

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