



WSSA/EPA Webinar on registration review, DCPA, diuron, and fluometuron

Weed Science Society of America (WSSA) webinar

June 15, 2022

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U.S. Environmental Protection Agency

Presentation Outline

1. Overview of EPA's Pesticide Registration Review Process
2. DCPA registration review update
3. Diuron registration review overview and status
4. Q&A on DCPA, diuron, and fluometuron



Photo by U.S. EPA. 2014. <https://www.flickr.com/photos/usepagov/>



Overview of EPA's Registration Review Process

Photo by U.S. EPA. 2008 <https://www.flickr.com/photos/usepagov/>

U.S. Pesticide Regulatory Framework

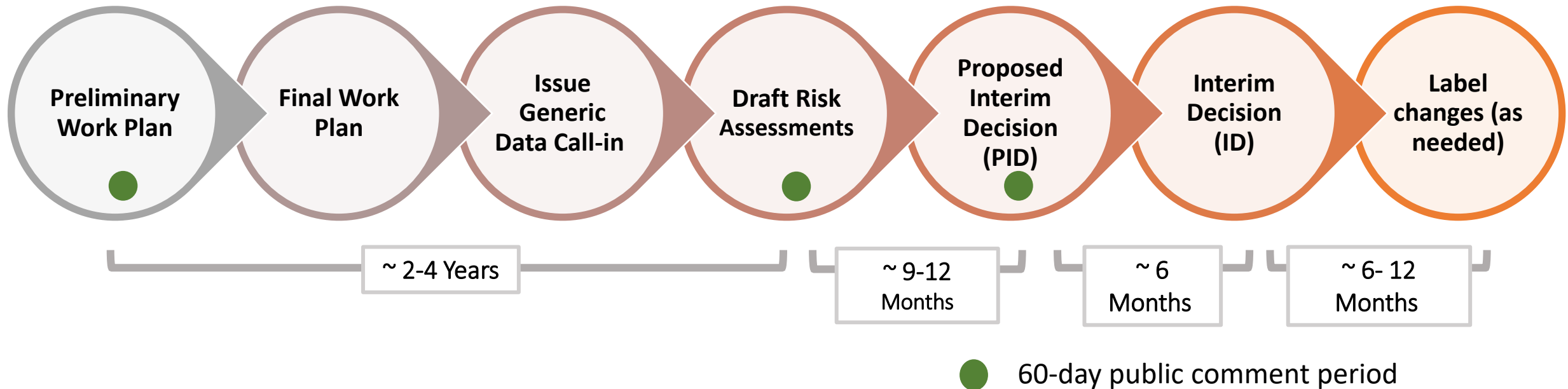
Federal Statute	Key Features
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	<ul style="list-style-type: none"> • All pesticides distributed or sold in the U.S. must be registered (licensed) by U.S. EPA. • Established risk/benefit standard for registering pesticide products (preventing “unreasonable adverse effects on the environment”); FIFRA risk mitigation must consider the benefits of pesticides to users. • Safety standard for occupational and residential exposures. • Grants U.S. EPA authority to obtain toxicity and exposure data from pesticide registrants. • Grants U.S. EPA ability to regulate pesticide labels and packaging.
Federal Food, Drug, and Cosmetic Act (FFDCA)	<ul style="list-style-type: none"> • Grants U.S. EPA authority to establish pesticide tolerances in or on foods and feeds. • Requires that FDA and USDA monitor and enforce tolerances. • FFDCA is a risk-only statute; FFDCA mitigation does not consider pesticide benefits to users.
Food Quality Protection Act (FQPA)	<ul style="list-style-type: none"> • Amended both FIFRA and FFDCA and mandated a health-based standard for pesticides used in foods. • Established a more health protective standard (“reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information”). • Requires consideration of aggregate pesticide exposure (food + drinking water + residential + other non-occupational exposure), cumulative effects of pesticides with common mode of toxicity, and special sensitivity of infants and children to pesticides. • EPA must fully mitigate risks from aggregate exposure and cannot balance risks against benefits.

History of Registration Review

- Under FIFRA section 3(g), each pesticide is required to be reviewed every 15 years after:
 - ...the date that the previous registration review was completed (*e.g.*, a Registration Review decision issued in 2018 must complete the next round of Registration Review by 2033), or
 - ...the date the chemical was first registered (*e.g.*, a new active ingredient registered in 2010 must complete Registration Review by 2025)
- Initial Registration Review represents chemicals registered prior to October 1, 2007:
 - Includes 726 “cases” encompassing over 1,100 pesticide active ingredients (some active ingredients are similar enough to rely on the same set of data).
 - Must be completed no later than October 1, 2022.
 - Endangered Species Act and Endocrine Disruptors Screening Program.

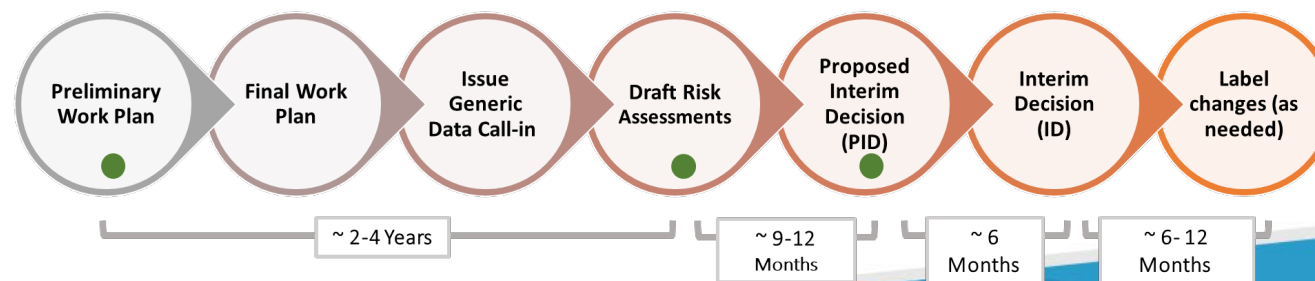
Registration Review Process

(see: <https://www.epa.gov/pesticide-reevaluation/registration-review-process>)



Preliminary/Final Work Plan and Data Call-In

- Opening of the public docket on regulations.gov
- Evaluation of Current Knowledge
- Registration Review builds upon previous assessments and decisions
 - Facts about the pesticide and its current use and usage
 - Anticipated risk assessments and data needs
 - An estimated timeline for the review
 - Focus meetings to narrow scope (with registrants and other stakeholders)
- EPA obtains any needed data from the technical registrants by issuing a Data Call-In (DCI)



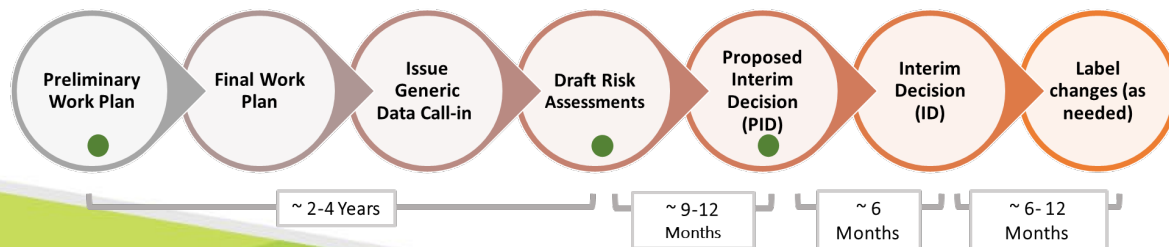
Draft Risk Assessments

- Human Health Assessments commonly comprise:
 - Hazard and Dose Response Assessment
 - Dietary Exposure Assessment (food and drinking water)
 - Residential Exposure Assessment
 - Aggregate Assessments
 - Occupational Exposure Assessments
 - Cumulative Assessments

<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>

- Ecological Risk Assessment evaluates risks to non-target organisms, including:
 - Mammals
 - Birds
 - Reptiles (birds usually as surrogate)
 - Fish
 - Amphibians (terrestrial and aquatic; birds or fish as surrogate)
 - Aquatic Invertebrates
 - Terrestrial Invertebrates (insects)
 - Aquatic Plants
 - Terrestrial Plants

<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/factsheet-ecological-risk-assessment-pesticides>



Draft Risk Assessments

- If the risk assessment indicates there are risk exceedances, it also includes context and characterization:
 - Is the risk assessor confident that the risk exceedance is indicative of risk? What gives them that confidence?
 - What is driving the exceedance, and what refinements are available/warranted?
 - What is the magnitude, frequency, duration, timing, and location/spatial extent of risk?
 - Example: Although a pesticide label might allow use on a particular crop everywhere it is grown, usage data might indicate that a chemical is predominantly used in one area.
- Use/usage data are used to inform the DRAs
 - Label use summaries aid risk assessors in determining use parameters and modeling scenarios.
 - Additional information on pesticide usage and use practices (*e.g.*, typical rates, geography) can be used to refine and characterize risk estimates.

Evaluating Benefits to Pesticide Users

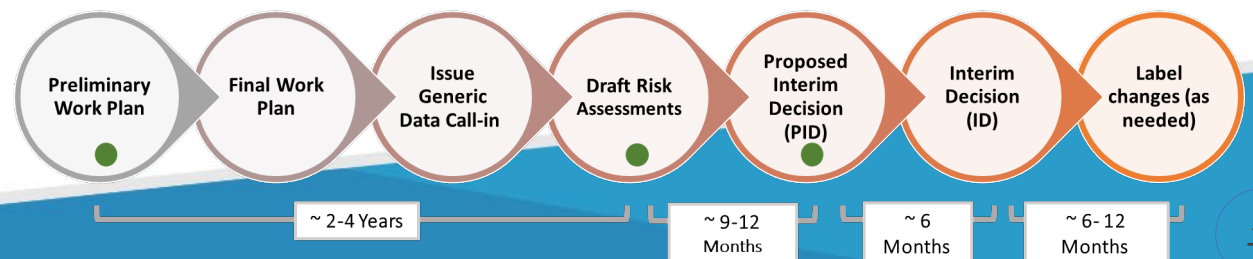
- What are the target pests of the AI?
- Are there regional differences in target pests?
- Are there cost-effective alternatives for the pests controlled?
- If there are alternatives, does this pesticide have a different mode of action needed to manage/delay resistance?
- Are there public health benefits from use?
- Does use of this chemical result in lower/higher human health risks than alternatives?



Photo by U.S. EPA. 2007. <https://www.flickr.com/photos/usepagov/>

Proposed and Interim Decisions

- Chemical-specific considerations
 - What are the risks of concern?
 - What are the benefits to pesticide users?
 - Note that benefits are not considered in FFDCA/FQPA safety finding: applies to dietary risks (food + drinking water), residential/non-occupational, and aggregate human health risk.
 - Is there feasible and enforceable language that can be placed on the label to mitigate the risks of concern (e.g., use cancellation, reduce application rate, reduce number of applications per year)?
 - What are the impacts of risk mitigation to pesticide users and to society?
 - What comments were received from stakeholders on DRA (and PID)?
- Cross-chemical considerations
 - What are the risk profiles of potential alternatives, and how would the decision shift the market?
 - What is the impact on pesticide resistance management?
 - Is the mitigation equitable across active ingredients?
- Most decisions made to date are interim
 - Registration review is not complete until final decision is made.





Questions?

For more information, please visit:

<https://www.epa.gov/pesticide-reevaluation>



DCPA Registration Review Update

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Diuron Registration Review Update

Weed Science Society of America (WSSA) webinar

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Pesticide Re-evaluation Division

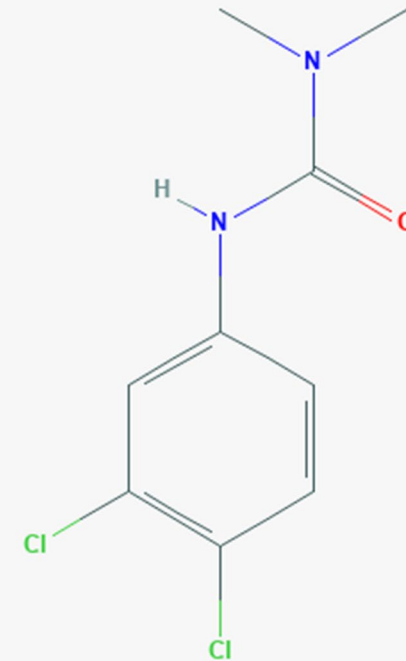
U.S. Environmental Protection Agency

Key Points for Diuron Registration Review

- The [2021 refined human health risk assessments](#) identified potential cancer risks from food exposure and drinking water exposure (from all conventional herbicide uses) and from residential handler painting exposure (from exterior paint uses). Food and residential painting exposure are each nearly of concern on their own while drinking water exposure presents risks of concern on its own.
- Given these risks, EPA cannot make an aggregate safety determination (food + drinking water + residential exposures).
- In the Proposed Interim Decision (PID), EPA has proposed termination of nearly all conventional uses (including all food/feed uses and conventional herbicide uses) to resolve dietary risks of concern. EPA considered conventional use rate reductions or use restrictions (*e.g.*, spot treatments) to resolve dietary risks, but the resulting use patterns would not be efficacious for users.
- For residential handler painting exposure, EPA has proposed rate reductions for all paints and building material products to mitigate aggregate risks of concern.
- EPA welcomes public comments on the PID (through July 27, 2022) including information on usage practices and minimum efficacious rates, highest-benefit sites, mitigation impacts, and alternative mitigation proposals. EPA will fully review and consider public comments before issuing its Interim Decision.

Background

- Diuron is a systemic phenylurea herbicide, algaecide, mildewcide, and antimicrobial preservative first registered in 1967. Reregistration was completed in 2003.
- Diuron is used to control annual and perennial broadleaf and grassy weeds in a variety of agricultural sites, ornamentals, and non-agricultural sites, as well as a harvest aid in cotton and algaecide in commercial fish production.
- Diuron also has antimicrobial uses as a mildewcide and materials preservative in paints, stains, coatings, adhesives, and sealants.
- Its relatively low cost contributes to its widespread use.



Diuron Use/Usage

- Sites with high percent crop treated (PCT) include asparagus, cotton (harvest aid and herbicide uses), and citrus.
- Regionally high PCT sites include alfalfa, pear, peach, blueberries, and tree nuts.
- Limited data for aquaculture and rights-of-way sites.
- Top antimicrobial sites: paints and coatings, adhesives, and sealants (237,200 lbs a.i. total usage in 2016)

Conventional Usage			
	Average Total Acres Treated	Average Pounds Applied	Average Application Rate (lbs. a.i./acre)
Herbicide Uses	2,896,000	2,300,000	0.794
Cotton Harvest Aid	1,541,000	41,000	0.026
National Total	4,437,000	2,341,000	

All values are averaged over 5 years, from 2015 to 2019, Kynetec (2020)

Human Health Risk Assessment (Aggregate)

Conventional Uses

- The cancer dietary risk is 2×10^{-5} , driven by drinking water (2×10^{-5}) and food exposure (3×10^{-6}).
 - Highest contributors include drinking water (83%), asparagus (5%), freshwater fish (2%), citrus (2%), cereal grains (2%), pears (1%), and livestock products (<1%).
 - The [dietary assessment](#) was partially refined with:
 - Average percent crop treated (PCT) estimates
 - Field trial data for the highest contributing commodities (beef, pork, fish, asparagus, and bananas).
 - Further refinements are not expected to significantly improve risk estimates.
 - The drinking water assessment (DWA) is highly refined (all residues of concern and typical application rates). All use sites at typical rates present potential risks of concern, and additional characterizations explored would not resolve dietary risks due to contribution from food.

Antimicrobial Uses

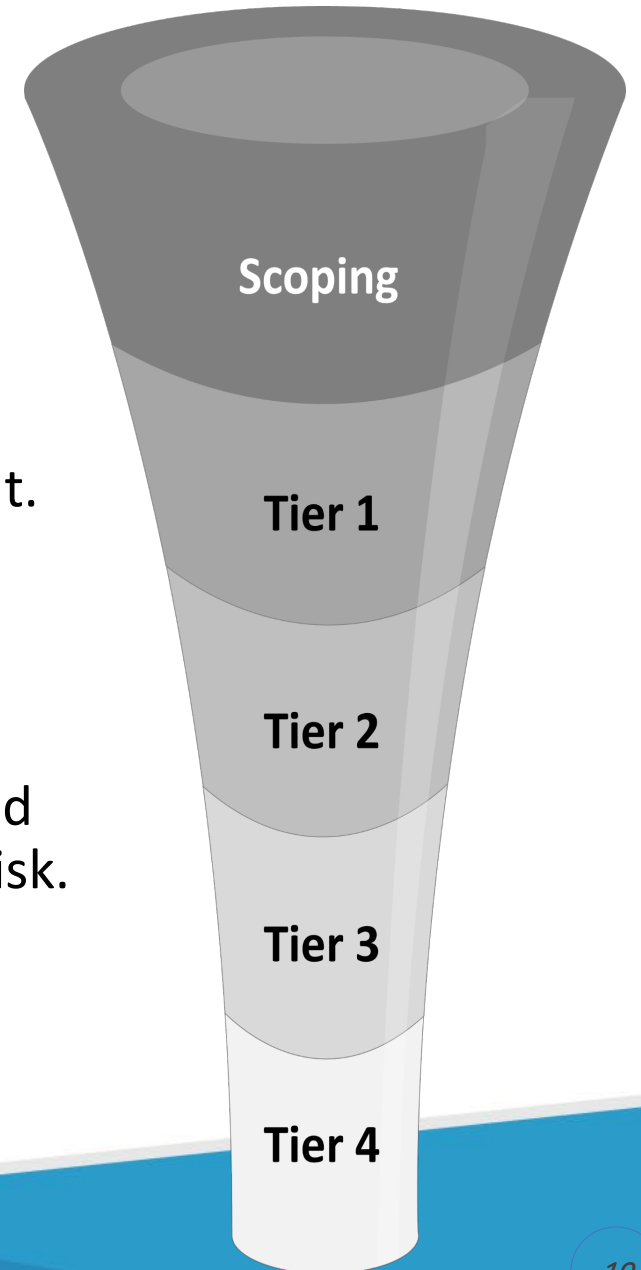
- Residential handler cancer risk estimates from “Do It Yourself” (DIY) painting using preserved house paints:
 - 3×10^{-6} for airless spray (used in aggregate) and 2×10^{-6} for brush/roller painting.

Aggregate cancer risk (food + water + residential painting): 2×10^{-5}

DWA Tiered Assessment Approach

- Tiered approach is used to prioritize resources
 - Low tiers are easy to use; simple input and output.
 - High tiers require more input; more complex and detailed output.
 - Allows chemical team to focus efforts on challenging pesticides, vulnerable exposure locations.
- Upper-bound estimate of exposure
 - If acute and/or chronic risk level of concern (LOC) is not exceeded using the screening exposure estimate, high confidence of low risk.
 - If LOC is exceeded, there could be risk, or it may be the result of overestimating exposure – refinements are considered.

[Tiered Drinking Water Assessment Framework](#)



DWA Highlights and Refinements

- EPA's drinking water assessment (surface water-driven) is highly refined; incorporates typical application rates and characterizations and considers available monitoring data.
- DWA is based on the parent and two degradates (diuron, DCPMU, and mCPDMU).
- The Estimated Drinking Water Concentrations (EDWCs) from the non-agriculture scenario was the highest value and initially used in the cancer dietary risk assessment. However, refined EDWCs based on typical application rates for all other herbicide use sites (considered individually) would also lead to dietary and aggregate cancer risks of concern.
- Additional characterizations, including mean degradation rates, parent-only runs, reduced percent crop area (PCA) adjustments, buffer distances, and drinking water treatment options were explored but would not resolve dietary or aggregate risks of concern.
- Surface and ground water monitoring detections would still be of concern in the context of aggregate exposure.
- Comprehensive analyses of the available monitoring data did not reduce EDWCs below a level of concern in the context of aggregate exposure.
- See DWA for additional details: [regulations.gov/document/EPA-HQ-OPP-2015-0077-0043](https://www.regulations.gov/document/EPA-HQ-OPP-2015-0077-0043).

Results of Benefits Assessments

- Sites with high benefits (limited alternatives)
 - Cotton: as a harvest aid (Pima cotton regions: southwest and west)
 - Aquaculture (catfish and striped bass)
 - Pineapple
- Sites with moderate benefits (more costly alternatives available)
 - Cotton: as an herbicide (southeast cotton production)
 - Asparagus
 - Alfalfa
 - Citrus (and other tree crops)
 - Blueberries
 - Rights-of-way weed management
- For details, see *Assessment of Diuron (PC #035505) Usage and Benefits in Agricultural and Non-Agricultural Use Sites*: [regulations.gov/document/EPA-HQ-OPP-2015-0077-0063](https://www.regulations.gov/document/EPA-HQ-OPP-2015-0077-0063)

Proposed Mitigation in the PID

Conventional use mitigations

1. Proposed termination of all herbicide uses on food and feed crops to address dietary and aggregate risks of concern to the general public and ecological risks of concern. Rate reductions necessary to resolve risks of concern from drinking water would not be efficacious for users.
2. Revoke all food and feed tolerances to address dietary risks of concern to the general public (except for a single tolerance to support the remaining cotton harvest aid use).
3. Proposed termination of all herbicide use on non-food/non-feed agricultural sites (*e.g.*, ornamental nurseries) and non-agricultural use sites (*e.g.* rights-of-way, utilities, roadways); reduced application rates or use restrictions (*e.g.*, spot treatments) would not be efficacious for users.
4. EPA has not proposed cancellation of the following, which do not present dietary or aggregate risks of concern:
 - Cotton defoliant/harvest aid use (0.026 lbs a.i./A application rate)
 - Residential aquariums/containerized ponds (applying tablets)

Antimicrobial use mitigations

- Occupational and residential painting risk: rate reductions
- Occupational risk: PPE and stewardship language
- Ecological risks: rate reductions

Current status and timeline

- The public comment period on the PID was extended to July 27, 2022.
- Types of comments useful to EPA:
 - Use sites that are highest priority/highest benefit for growers and other stakeholders.
 - Availability of alternatives and strengths/weaknesses relative to diuron.
 - Data on minimum effective use rates, application practices, or other data from the field that may not be reflected in EPA's documents, and which can help inform the interim decision.
 - Alternative mitigation proposals that allow EPA to make a safety finding: EPA will consider them in a manner consistent with its risk assessment guidelines.
 - Coordinated comments on these issues that represent views of a set of stakeholders/constituency can be helpful to EPA's review of diuron.
- Comments on diuron can be submitted to:
 - Diuron docket: <https://www.regulations.gov/document/EPA-HQ-OPP-2015-0077-0061>
- EPA will prepare and issue an interim decision after comments and stakeholder feedback have been fully considered.

Submitting comments on the Proposed Interim Decision (PIDs)

- Diuron:

- Diuron PID: <https://www.regulations.gov/document/EPA-HQ-OPP-2015-0077-0065>
- Submit comments: <https://www.regulations.gov/document/EPA-HQ-OPP-2015-0077-0061>

- Fluometuron:

- Fluometuron PID: <https://www.regulations.gov/document/EPA-HQ-OPP-2015-0746-0038>
- Submit comments: <https://www.regulations.gov/document/EPA-HQ-OPP-2015-0746-0031>

- For additional guidance on submitting comments to EPA's public dockets, see: <https://www.epa.gov/dockets/commenting-epa-dockets>



Questions?



Q&A on DCPA, Diuron and Fluometuron

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