Q4 FY20 Registration Review FRNs

FRN #1, FRL TBD (Not submitted yet): Contains all black text chemicals in Preliminary Work Plan table. Timing: mid-October

Preliminary Work Plans (Red = AA briefing & fact sheet, Orange = Program review & fact sheet, Black = Summary)	
Antimicrobials:	N/A
Conventionals:	Aminocyclopyrachlor (ACP)***, Flutriafol***
Biopesticides:	N/A

*** Registration Review Round 2

FRN #2, FRL TBD (Not submitted yet): Contains all orange and black text chemicals (except for zinc phosphide) in Draft Risk Assessments table. Timing: mid-October
FRN #3 FRL TBD (Not submitted yet): Contains Chlorpyrifos DRA. Timing: mid- September
FRN #4 FRL TBD (Not submitted yet): Contains Zinc Phosphide DRA. Timing: mid- October
FRN #5 FRL TBD (Not submitted yet): Contains Sulfuryl Fluoride Residential Post-Clearance Assessment (and EFED DWA/DRA). Timing: September

Draft Risk Assessments (Red = AA briefing & fact sheet, Orange = Program review & fact sheet, Black = Summary)	
Antimicrobials:	Benzoic Acid, Dimethoxane, Organic Esters of Phosphoric Acid (OEPA)*, Polymeric Betaine
Conventionals:	4-Aminopyridine (4-AP), Benzyl benzoate* (HH only), Butoxypolypropylene glycol (BPG)*, Chlorpyrifos, Cycloate, Difenoconazole, Fenbuconazole, Ferbam, HPPD Inhibitors (Isoxaflutole, Mesotrione, Tembotrione, Topramezone, & Pyrasulfotole), Phorate (OP, eco only), Phosmet (OP, eco only), Sulfuryl Fluoride**, Thiram, Tolfenpyrad***, Zinc Phosphide, Ziram
Biopesticides:	N/A

* DRA and PID both are anticipated to publish in Q4; summaries appear in the PID section of this document
** Residential Post-Clearance Assessment and EFED DWA/DRA Only
*** Registration Review Round 2

FRN #6, FRL TBD (Not submitted yet): Contains all orange and black text chemicals in PID table. Timing: mid-October
FRN #7, FRL TBD (Not submitted yet): Contains Methomyl/Thiodicarb PID. Timing: mid-October
FRN #8, FRL TBD (Not submitted yet): Contains Paraquat PID. Timing: mid-October
FRN #9, FRL TBD (Not submitted yet): Contains Coumaphos PID. Timing: late-August

Proposed Interim Decisions (Red = AA briefing & fact sheet, Orange = Program review & fact sheet, Black = Summary)	
Antimicrobials:	DBNPA, Halohydantoins, Irgarol, *ortho*-Phenylphenol and Salts (O-PP and salts), Organic Esters of Phosphoric Acid (OEPA)*
Conventionals:	1,3-Dichloropropene (Telone), Benzyl benzoate*, Butoxypolypropylene glycol (BPG)*, Carboxin/Oxycarboxin, Commodity Fumigants* (Aluminum Phosphide,

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	Magnesium Phosphide, Phosphine, Propylene Oxide (PPO) & Inorganic Sulfites), Coumaphos, Cyhalothrins, Methomyl/Thiodicarb, Myclobutanil, Naphthalene Acetic Acid (NAA), Paraquat, Triphenyltin hydroxide (TPTH), Triallate, Triticonazole
Biopesticides:	1-Methylcyclopropene, *Beauveria bassiana,* Kaolin, *Paecilomyces* species, *Streptomyces lydicus* strain WYEC 108, Methoprene, Kinoprene, and Hydroprene (combined FWP/PID)

* DRA and PID both are anticipated to publish in Q4
** Residential Re-entry Assessment Only
*** Registration Review Round 2

FRN #10, FRL TBD (Not submitted yet): Contains all orange and black text chemicals in Interim Decisions table. Timing: mid-October
FRN #11, FRL TBD (Not submitted yet): Contains Triazine Interim Decisions. Timing: mid-October

Interim Decisions (Red = AA briefing & fact sheet, Orange = Program review & fact sheet, Black = Summary)	
Antimicrobials:	Chlorine gas, Phenol and Salt, Terbuthylazine
Conventionals:	Boscalid, Cyproconazole, Ethoxyquin, Etoxazole, Fluazifop-P-butyl, Gonadotropin Releasing Hormone (GnRH)***, MCPA, Mecoprop-p, Methyl bromide, Pinoxaden, Pymetrozine, Pyraclostrobin, Pyraflufen-ethyl, Pyrethroids (Bifenthrin, Cyfluthrins, Cyphenothrin, Deltamethrin, Esfenvalerate, Fenpropathrin, Imiprothrin, Permethrin, Phenothrin, Prallethrin, Tau-fluvalinate, Tefluthrin, Tetramethrin), Thiabendazole (dual use), Triazines (Atrazine, Propazine, & Simazine)
Biopesticides:	*Bacillus thuringiensis* Plant-incorporated Protectants in Cotton – Lepidopteran Pests, *Coniothyrium* species, Flower Oils, *Gliocladium* species, Vegetable Oils

* DRA and PID both are anticipated to publish in Q4
** Residential Re-entry Assessment Only
*** Registration Review Round 2

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Q4 Preliminary Work Plans

Q4 Conventional PWP Fact Sheets

None.

Q4 Conventional PWP Summaries

Aminocyclopyrachlor (ACP):
Release preliminary work plan, scoping document and problem formulation for round 2 of registration review. ACP is an herbicide that provides pre- and post- emergence control of susceptible weeds through applications to foliage or soil surface. ACP was recently registered for use on privately-owned and non-hayed rangelands in 2019. It is also used on non-agricultural land, uncultivated agricultural areas, outdoor industrial sites, wildlife management and natural areas, and vegetation management sites transecting areas grazed by livestock. ACP has no registered agricultural crop uses. The most recent human health and ecological risk assessments were conducted in 2020 to support an amended use on privately-owned non-hayed rangeland. The recent human health risk assessment found no human health risks of concern. The ecological risk assessment found risks of concern to non-target terrestrial plants. ACP is in the pyridine and pyrimidine carboxylic acid group of herbicides, which are very persistent and are known to cause non-target plant damage from compost contamination. Residues in treated plant matter can contaminate compost through turf clippings or manure from animals that have grazed on treated plants. ACP is even more persistent than other persistent pyridine/pyrimidine carboxylic acid herbicides like clopyralid, aminopyralid, and picloram. Anticipated Stakeholder Feedback: ACP is the most persistent of all the pyridine/pyrimidine herbicides. A large volume of comments is expected from the public on the potential for compost contamination. The US Composting Council has organized a mass mail campaign for clopyralid, another compost herbicide, previously, and is expected to be very vocal in advocating for more restrictive measures from EPA.

Flutriafol:
Release preliminary work plan, scoping document, and problem formulation for round 2 of registration review. Flutriafol is a contact and systemic Group 3 triazole fungicide which acts primarily as an inhibitor of ergosterol biosynthesis, thereby interfering with synthesis of fungal cell membranes. First registered in 2010, flutriafol is registered for use on a wide variety of agricultural sites (including corn, cotton, soybeans, grapes, hops, stone and pome fruit trees, tree nuts, vegetables, and wheat) and non-agricultural sites (including turfgrass, ornamentals, flowerbeds, and houseplants). The most recent human health risk assessment was completed in 2019 to support new uses on alfalfa, barley, sweet corn, rice, turf, and ornamentals. The HH RA incorporated the most recent drinking water assessment from 2018 and found no human health risks of concern. HED anticipates conducting a quantitative spray drift assessment as part of registration review. The most recent ecological risk assessment was completed in 2011 to support new uses on corn (field and pop), grapes, peanuts, pome and stone fruits, sugar beets, and wheat. The ERA found some slight LOC exceedances for birds and mammals foraging in short grass and for non-target aquatic vascular plants. EFED anticipates calling in the full suite of Tier I pollinator data as part of registration review. Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

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Q4 Draft Risk Assessments

Q4 Conventional DRA Fact Sheets

4-Aminopyridine (4-AP) DRA

Current Status

- Avicide that acts as a neurotoxin; member of the pyridine family
- Restricted use pesticide (RUP) that must be applied by certified applicators or those under their direct supervision
- Five end-use products are registered as bird control agents (treated bait) for nuisance birds
- Bait consists of coarse mixed grains, whole kernel corn, or pelleted corn
- Application sites are on or in bird feeding, nesting, and roosting sites across urban, rural, agricultural, and non-agricultural locations

Key Points

- PRD negotiated with the 4-AP registrants to make changes to their labels to minimize potential environmental exposures and associated eco risks that could result from rainfall interaction
- Improved label language will allow waiver of the data requirements listed in the GDCI
- Similarly, drinking water assessment for human health was not conducted due to limited environmental exposures

Human Health Risk Assessment Conclusions

- No dietary exposure from food or water is expected based on the use patterns
- Residential applicator exposure is not expected since 4-aminopyridine can only be applied by certified applicators
- The occupational applicator combined MOE is 240 (LOC = 30) and is not of concern

Ecological Risk Assessment Conclusions

- Potential risk concerns for birds and mammals on an acute basis (chronic risk uncertain)
- Low potential risk for fish, aquatic invertebrates, and aquatic and terrestrial plants
- Risk to terrestrial invertebrates not expected due to limited exposure pathway from limited application methods (bait by tray)

Communications—No additional communications are planned. This chemical has attracted attention over the potential risk to non-target species, particularly those protected by the Migratory Bird Treaty Act.

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Chlorpyrifos DRA

Current Status

- Chlorpyrifos is an OP insecticide registered for a large variety of ag uses and non-ag uses.
- Residential registrations are limited to roach bait products with child resistant packaging and ant mound treatments which may only be applied by commercial applicators.
- The PID is currently scheduled for October 2020. As such, OPP anticipates establishing the public comment for the DRAs concurrently with the PID.
- DRA Publication Target: on or before 9/21/20[1]
- On August 7, 2019, the petitioners from the 2007 petition, in addition to several states, petitioned the Ninth Circuit Court to review orders issued by the EPA denying the 2007 petition to ban food uses on chlorpyrifos ("LULAC 2").

Key Points

- On July 28, the Ninth Circuit heard oral arguments for LULAC 2. Based on the timelines for other cases, the ruling could potentially be issued approximately 70 days later.

Human Health Risk Conclusions

- Dietary and residential risk assessments will be presented both with and without retention of the 10X FQPA safety factor. There are no residential risks of concern.
    - Dietary risks of concern were identified for water only with and without retention of the 10X FQPA Safety Factor; no dietary risks of concern were identified from food only.
    - Drinking water dietary assessment does not include non-agricultural uses. As it stands, non-agricultural uses would not fit into the risk cup.
    - For aggregate risks, the lowest/most protective DWLOC is 4 ppb (for infants) with the 10X retained and 43 ppb with the 10X removed. These values can be compared to the multiple EDWCs generated by EFED (in progress) to determine risk.
- In the updated drinking water exposure assessment, early indications are that modeled concentrations pass for the subset of uses under consideration, but there may be concerns with monitoring data concentrations, relative to the DWLOCs.
- Occupational scenarios of concern were identified both with and without retention of a 10X database uncertainty factor (UF_{DB}).

Ecological Risk Assessment Summaries

- Potential risks of concern for mammals, birds, fish and terrestrial/aquatic invertebrates based on RQs.
- Use on citrus and cherries result in some of the highest RQs, but RQs exceed the LOC for all uses.
- No tier I chronic bee data available.
- Numerous incidents in all taxa, including plants, have been reported as associated with the use of chlorpyrifos.

Communications

- Anticipate separate rollout; OCSPP/OPA will have a desk statement on-hand for any press inquiries
- Some press for the DRAs is possible

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[1] In its response to objections on the chlorpyrifos petition, EPA committed to a revised human health risk assessment by summer of 2020 and PID by October 2020.

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Commodity Fumigant DRAs - Aluminum phosphide, Magnesium Phosphide, Phosphine & Propylene Oxide (PPO)

The DRAs and PIDs for the commodity fumigants (Aluminum phosphide, Magnesium Phosphide, Phosphine & Propylene Oxide (PPO)) will be released together in Q4, however the inorganic sulfite (another commodity fumigant) DRAs were uploaded into the docket on May 4, 2020 (part of the FY2020 Q2 DRA Package). See the fact sheet for these cases under the [HYPERLINK \l "_Commodity_Fumigants_DRAs_1"] below.

Cycloate DRA

Current Status

- Cycloate is a systemic, broad-spectrum, and pre-emergent herbicide registered for control of certain grasses and broadleaf weeds on three agricultural use sites: table beets, spinach, and sugar beets.
- Ecological Risk Assessment was signed July 9, 2020 and the Human Health Risk Assessment will be signed by the end of July 2020.

Key Points

- About 40 percent of spinach is treated with cycloate, suggesting that this herbicide is important in U.S. production. With no usage data on table beet, and annual acres grown were near 15,000 in the last Census of Agriculture, cycloate use could be similarly important. Sugar beet usage is very low.
- 92 percent of average yearly (reported) usage of cycloate was in California spinach.
- The average annual use dropped drastically from 2001-2005 average (237,000 lbs/yr) to 2008-2012 average (45,000 lbs/yr) entirely due to usage in sugarbeet. Data from 2018 indicate that use on sugarbeet continues to be insignificant.
- The development of genetically modified sugarbeet varieties with resistance to gylphosate may have contributed to the reduction of cycloate usage on sugarbeet production.

Human Health Risk Assessment Conclusions

- In 2014, a 10X UF_{DB} was added to both acute and chronic dietary exposures for lack of a DNT. Request to waive that DNT was recently denied. The agency will also apply a 10x to dermal occupational scenarios.
- The acute PAD has been refined (from 20 mkd to 27 mkd) by using benchmark dose analysis, resulting in an update to both the POD and safety factors. There are no acute dietary risks of concern. However, chronic dietary exposures were above the level of concern, 270% of the cPAD for all infants and 100% of the cPAD for the general population. Major contributor is drinking water.
- There are risks of concern for occupational handler scenarios (dermal and inhalation), as well as occupational applicator scenarios (inhalation). Risks for some, but not all, scenarios are mitigated with PPE.
- There are no residential exposures, so aggregate risks are equivalent to the dietary (food + drinking water) analyses.
- Non-occupational spray drift was not conducted.

Ecological Risk Assessment Conclusions

- The ecological DRA identified risks to mammals, terrestrial invertebrates, aquatic plants, and potentially terrestrial plants based on registered uses.
- For all uses (garden beets, sugar beets, and spinach), potential risk was similar for all application types (broadcast/band application with mechanical or irrigation incorporation treatment, and soil injection and/or combined with fertilizer).
- Mortality in the chronic adult honeybee toxicity study results in the potential for risk to bees on treated fields for garden and sugar beet crops grown for seed. No colony-level effects data are available for honeybees, but PRD will work with EFED to determine if additional data are needed.

Communications – In addition to posting in the FR for public comment, the agency plans to develop a desk statement due to the DNT requirements.

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HPPD Inhibitor DRAs - Isoxaflutole, Mesotrione, Tembotrione, Topramezone, & Pyrasulfotole

Current Status

- Draft registration review risk assessments scheduled for Q4 FY20
- Draft cumulative risk assessment scheduled for Q2 FY21
- PIDs are scheduled for Q3 FY21; IDs are scheduled for Q1 FY22

Key Points

- The HPPD inhibitors are systemic herbicides that inhibit the enzyme p-hydroxyphenyl pyruvate dioxygenase (HPPD).
- The HPPD inhibitors are used in agricultural, non-agricultural, and residential settings for control of broadleaf and grass weeds.
- No human health risks of concern are expected. A screening-level cumulative human health risk assessment is slated for Q2 FY21.
- Ecological risks of concern are expected primarily for non-target terrestrial plants.

Human health risks

- HED has been reviewing toxicity data for the HPPD inhibitors to determine the appropriate animal model for risk assessment.
    - HPPD inhibitors cause a build-up of tyrosine in the body, and humans and mice have greater capability for clearing the excess tyrosine than rats and rabbits. Rats and rabbits are not appropriate animal models for human health risk assessment; therefore, rat and rabbit toxicity studies will be excluded.
    - Dogs also have a lower capacity for clearing excess tyrosine; however, it was not found to be consistently more sensitive than mice and there was uncertainty as to whether all effects seen in dogs are attributable to the build-up of tyrosine. As a result, dog studies will be considered for endpoint selection.
    - A white paper is now being drafted to describe HED's evaluation of mode-of-action and species differences, as well as provide the basis for the HPPD cumulative risk assessment.
- A screening-level cumulative risk assessment is scheduled for completion in Q2 FY21 for the group.

Ecological risks

- Ecological risks vary across the HPPD Inhibitors, however potential risks are primarily for non-target terrestrial/aquatic plants. Past risk assessments have also identified risks of concern to mammals for pyrasulfotole, tembotrione, and topramezone and risks to birds for topramezone. Some of the Tier 1 honeybee studies have not yet been submitted for isoxaflutole.

Communications

- No significant opposition from stakeholders is anticipated.
- No communications are planned beyond posting in the FR and the public comment period.

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Phosmet and Phorate DRAs (eco only)

Current Status

- Phosphorodithioate organophosphates that kill via contact and ingestion, acting through inhibition of the acetylcholinesterase (AChE) enzyme.
- Phosmet insecticide uses on alfalfa, orchard crops, blueberries, citrus, cotton, grapes, ornamental and non-bearing fruit trees, potatoes, vegetable crops, fire ant mounds and field margins.
- Phosmet may be applied in liquid formulations by aircraft and ground spray or through irrigation equipment. Phosmet can also be applied as a dust for postharvest storage of potatoes.
- Phorate is used at plant (with soil incorporation) on crops including beans, sugar beets, corn, peanuts, potatoes, sorghum, soybeans, and sugarcane, sweet corn and non-food crops lilies, cotton, and seed radishes.
- Phorate - systemic acaricide/insecticide/nematicide targets soil borers, beetles, rootworms, and nematodes.
- Phorate only available as RESTRICTED USE 10-20% soil-incorporated granular EUP, 85-95% EC MUP.

Key Points

- Human health risk assessments will be completed for phorate and updated for phosmet after the SAP meeting this fall. A human health risk assessment for phorate is scheduled for Q2 21.
- Comparative Cholinesterase Assay data are in development for both a.i.s; submissions expected sometime after November 2020 for phosmet oxon and in March 2021 for phorate. CCA data may result in changes to the 2016 phosmet human health assessment

Phosmet Ecological Risk Assessment Conclusions

- Classified as non-volatile and slightly to moderately mobile. Hydrolyzes rapidly and is slightly persistent in soil. Residues of concern include phosmet and phosmet oxon.
- Very highly toxic to aquatic vertebrates, aquatic invertebrates, and terrestrial invertebrates and moderately toxic to mammals and birds on an acute exposure basis; DRA identified risk to birds, mammals, reptiles, amphibians, terrestrial invertebrates, fish, and aquatic invertebrates for currently registered use patterns of phosmet.
- 11 incidents are reported in the IDS. 10 involved bees and one was an accidental misuse resulting in a fish kill.
- Eco RA including endangered species risk assessment. Phosmet is on initial EDSP list.

Phorate Ecological Risk Assessment Conclusions

- Highly toxic to mammals, birds, aquatic and terrestrial invertebrates, and fish.
- Residues of concern include phorate and two degradates (phorate sulfoxide and phorate sulfone); available data suggests similar toxicity of the three compounds
- EFED anticipates overall primary risk conclusions for DRA will be similar to those previously identified (specific details and characterization may differ)
- potential risk concerns for birds/reptiles/terrestrial phase amphibians, mammals, terrestrial invertebrates, fish/aquatic-phase amphibians, and aquatic invertebrates.
- 18 incidents for birds and mammals, 3 for aquatic animals; phorate residues associated with these incidents. Two incidents reported for plants, although a co-applied herbicide was more likely cause.

Communications—Significant stakeholder reaction not anticipated at this time.

Sulfuryl Fluoride Residential Post-Clearance Assessment (& DWA/Eco DRA)

Current Status

- Structural and commodity fumigant, methyl bromide replacement, and only fumigant with residential uses
- Restricted use pesticide (RUP) registered for dwellings, buildings, construction materials, furnishings, vehicles, and food commodities (e.g., grains, dried fruit, dried beans). Used to control several pests, including termites, beetles, borers, bedbugs, moths, cockroaches, rats, and mice

Key Points

- After several incidents, the 2016 Office of the Inspector General Report recommended that EPA validate the effectiveness of sulfuryl fluoride (SF) clearance devices (e.g., handheld detectors) in detecting the clearance level of 1 ppm and implement new device clearance guidance (if needed).
- BEAD completed the clearance device testing and EPA will publish these results, the residential post-clearance assessment, and the updated incident report to the registration review docket in September.
- A separate assessment (FY21 Q2) will be conducted for occupational, bystander, and ambient exposures for all uses and dietary exposure to sulfuryl fluoride and fluoride from food commodities.

Human Health Risk Assessment Conclusions (Residential Post-Clearance Only)

- Since the last assessment, a special inhalation neurotoxicity study was received and selected for the acute and short-term inhalation endpoints. However, other studies are being considered. Once the endpoint is established, the exposure assessment will be updated.
- HED analyzed residential post-clearance (5 ppm or 1 ppm) SF air concentration data from three studies to predict potential inhalation exposure after re-entry.
    - In the 3 studies, all fumigated structures were furnished, and were aerated according to California Aeration Plan (CAP). The clearance level used (i.e., 1 or 5 ppm) does not affect the measured post-clearance SF concentrations when aerating following CAP.
    - HED will provide an acute and a short-term assessment detailing if additional time to re-entry is needed, once the toxicity endpoints and HECs have been finalized.
- HED also updated the Tier I incident review. While there were up to 168 incidents reported, 81-91% were low severity. Several fatalities were reported (most due to breaking/entering during fumigation). Majority (60%) of non-lethal incidents occurred post-clearance, several involved young children.

Ecological Risk Assessment Conclusions

- The drinking water assessment and ecological risk assessment were qualitative and also evaluated inorganic sulfites and metal phosphides & phosphine, other structural and commodity fumigants.
- Due to its high volatility, registered use patterns primarily within closed structures or containers, and rapid degradation, SF is not expected in surface water or ground water drinking sources.
- Additionally, the indoor use patterns limit the potential for environmental exposure, thus, there is a minimal potential for risk to non-target terrestrial and aquatic organisms.

Communications

- Before publication, PRD and BEAD will brief the registrant, device manufacturers, and potentially other stakeholders (e.g., California, Florida, NPMA, ASPCRO) on the results of the clearance device testing. Tentatively scheduling for second week of September.
- FEAD is drafting an OPP Update, an email newsletter to send to stakeholders, announcing the release of the assessment and comment period.

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Zinc Phosphide DRA

Current Status

- Moved to Q4 to align with phosphine PID.
- Zinc phosphide is an inorganic compound registered as a rodenticide for agricultural use and non-agricultural use such as golf courses, rangeland, airports, industrial plants, lawns, right of ways, etc.
- Unique among rodenticides in having tolerances
- Can be applied in a variety of methods including aerial broadcast

Key Points

- High risk/high benefit
- The compound is formulated as tracking powder or bait, which when combined with stomach acids produces phosphine gas resulting in death.

Human Health Risk Assessment Conclusions

- HED is taking a qualitative dietary assessment approach based on low presence of residues and consistency with the phosphine dietary assessment
- The ORE assessment will be similar to the anticoagulant rodenticides. Exposure is anticipated; however, a qualitative assessment will be conducted. This strategy aligns with the agency's risk management goals to minimize non-target (human) exposure.
- Dermal toxicity data are outstanding but are not required for registration review given that the ORE assessment will be qualitative.

Ecological Risk Assessment Conclusions

- The DRA provided multiple lines of evidence indicating risk of mortality to terrestrial vertebrates through direct consumption of bait and secondary poisoning via consumption of contaminated prey.
- There are many incident reports involving wildlife and pets.
    - Birds: Since the RED (1998), there have been 34 incidents reported.
        - These incidents involve mortalities of thousands of geese and hundreds of turkeys.
        - All incidents involve primary exposure.
        - The certainty index is often highly probably due to detections of zinc phosphide or phosphine.
        - The most recent incident was reported in 2019.
    - Mammals: Since the RED, there have been 4 incidents reported, with the most recent incident in 2008.
        - One incident report involves secondary exposure.
    - Aggregate wildlife incident reports: Since the RED, 4 incidents were reported.
    - Pets: There were 505 incidents involving domestic animals.
        - 41 were fatalities.
- Risks are considered low for:
    - Aquatic animals;
    - Aquatic and terrestrial plants; and
    - Terrestrial invertebrates.

Communications – None expected beyond posting in the FR and public comment period. A high volume of comments are expected.

Ziram DRA

Current Status

- A dimethyldithiocarbamate fungicide (conventional) and materials preservative (antimicrobial)
- Registered for conventional use on almond, apple, apricot, blackberry, blueberry, cherry, grapes, nectarine, peach, pear, pecan, tomato, christmas tree plantations, conifers, ornamentals
- Registered for antimicrobial use as: materials preservatives for adhesives, wallboard joint compounds, emulsion paints, paper and paperboard, paper coatings, caulks and sealants
- Applications are made by air, ground boom, air blast sprayer, and high-pressure hand wand Applications of ziram include dormant and foliar treatments.
- Thiram is the common metabolite of both ziram and ferbam. DRAs for thiram, ferbam, and ziram are all due at the same time.

Key Points

- The biggest agricultural use is on almonds, peaches and apples; 50% to 80% of treated acreage of almonds, peaches, and apples is treated at maximum label application rate
- The ziram risk assessment for the conventional uses relies heavily on thiram/ferbam risk assessments.
- An antimicrobial end use product results in food and residential uses that need to be assessed.

Human Health Risk Assessment Conclusions

- The DRA includes updated endpoints/PODs and dermal absorption factor (10%).
- *Conventional uses*:
  - Dietary Risk: The acute and chronic assessments were refined. There were no risk estimates of concern.
  - Spray Drift: Risk estimates are of concern for adults and children at the field edge.
  - Occupational Handler: Assessed assuming PPE and, in some cases, with engineering controls.
    - Dermal Exposure: there were many scenarios of concern.
    - Inhalation Exposure: all scenarios were of concern with one exception: aerial applicator for nurseries.
  - Occupational Post-Application
    - Risk estimates were of concern on Day 0, except for hand weeding of tomatoes and blueberries.
    - Risk estimates were of concern on Day 0 and on Day 23 for bird control, hand weeding, orchard maintenance, and propping activities for apple/cherry/pear applications.
    - Use of DFR data did not substantially improve the risk picture.
- *Antimicrobial uses*: The risk assessment for the paint use results is an inhalation risk of concern for residential painters.

Ecological Risk Assessment Conclusions

- Eco assessment currently being drafted, but preliminary results show risks to birds, mammals, bees, fish, aquatic invertebrates, and non-vascular plants (terrestrial plants and aquatic vascular plants not at risk). Because ziram rapidly breaks down to thiram (within days) a total toxic residues approach was used which conservatively considered exposure and toxicity considerations of both compounds.
- The eco assessment for the AD uses are still being determined.

Communications—Registrants and end users likely to provide comments on risk assessment conclusions based on scope and degree of risk, and implications for mitigation. There are 3 registrants for ziram.

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Q4 Conventional DRA Summaries

Benzyl benzoate Human Health DRA:
Benzyl benzoate is scheduled for both a draft human health risk assessment and a proposed interim decision this quarter, and the summaries for both appear under the [HYPERLINK \l "_Benzyl__benzoate"] below. The ecological risk assessment for benzyl benzoate was posted in the docket in 2016, with a "no effects" determination for listed species.

Butoxypolypropylene glycol (BPG):
BPG is scheduled for draft ecological and human health risk assessments and a proposed interim decision this quarter, and the summaries for both appear under the [HYPERLINK \l "_Butoxypolypropylene_glycol_(BPG)"] below.

Difenoconazole:
Release human health and ecological risk assessments. Difenoconazole is a broad-spectrum systemic triazole fungicide that works by inhibiting cell membrane formation. It is registered for use on plants and seeds of various fruits, vegetables, cereals, and field crops. Non-agricultural uses include landscape ornamentals, parks, institutional sites, golf courses and residential properties. The human health risk assessment is currently under development. Updates to the hazard profile include removal of dermal endpoints and upward revisions to all other endpoints except for the acute dietary endpoint. Dietary, residential, aggregate, and occupational risks are not anticipated to be of concern. For the ecological risk assessment, which is currently under review, there are potential chronic risks of concern to birds, mammals, fish, invertebrates, and aquatic plants and acute risks of concern for saltwater invertebrates. With a log K_{ow} of 4.2, difenoconazole has the potential to bioaccumulate in the aquatic food web and be of an exposure concern to piscivorous birds and mammals. Based on minimum and maximum annual EECs and a refined metabolism elimination rate, there were no acute or chronic LOC exceedances in the aquatic food-web based model (KABAM). Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

Fenbuconazole:
Release human health and ecological risk assessments. Fenbuconazole is a broad-spectrum systemic fungicide of the triazole (conazole) chemical class. It is currently registered for use on almonds, apples, bananas, blueberries, citrus fruits, cranberries, pecans, peanuts, peppers, stone fruits, sugar beets and wheat. There are no registered residential uses. Fenbuconazole is classified as a Group C, or possible human carcinogen, therefore EPA is evaluating potential cancer and non-cancer human health risks of concern. The toxicological and residue chemistry databases are complete. The DRA will include updated toxicity endpoints/PODs. No human health risk estimates of concern are anticipated. The fenbuconazole eco assessment is still in-preparation but it is anticipated that there are risks to the following taxa; chronic risk to mammals, acute risks to larval bees, acute and chronic risk to freshwater and estuarine/marine fish, chronic risk to freshwater (water-column) invertebrates, risk to estuarine/marine sediment-dwelling invertebrates; and potential risks to mammalian species via consumption from aquatic organisms. Anticipated stakeholder feedback: Minimal stakeholder feedback is anticipated.

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Ferbam:
Release human health risk assessment. Ferbam is a dimethyldithiocarbamate fungicide on grapefruits and oranges in Florida to control scab disease. It is also used to control anthracnose disease on mangoes in Florida (as a special local need registration). Other agricultural use sites for ferbam include apples, citrus, cranberries, pears, peaches, and nectarines. There are no non-agricultural use sites and no residential uses for ferbam. Ferbam rapidly degrades to the more persistent thiram, so no DCI was issued for ferbam. All the data needed is called in on thiram. Human health assessment currently being drafted, but preliminary results show no acute or chronic dietary (food and drinking water) risks of concern for ferbam. Acute and chronic aggregate risk estimates include food and drinking water only and are not of concern. Most occupational handler scenarios result in dermal and/or inhalation risk estimates of concern even with additional PPE or engineering controls. Most occupational post-application scenarios result in dermal risk estimates of concern at the current label REI of 24 hours (one day after treatment). Some scenarios are still of concern at 30 days, or longer, after treatment. Indirect exposures to ferbam as a result of spray drift are not of concern. The ecological risk assessment is currently being drafted, but preliminary results show potential risks to: birds, mammals, bees, fish, and aquatic invertebrates (terrestrial plants and aquatic plants not at risk). Because ferbam rapidly breaks down to thiram (within minutes to hours), a total toxic residues approach was used which conservatively considered exposure and toxicity considerations of both compounds. Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

Thiram:
Release human health risk assessment. Thiram is a dimethyldithiocarbamate fungicide registered for use on the following: apples, strawberries, peaches; non-bearing trees, shrubs, nursery stock, and ornamentals as an animal repellent to protect crops from damage by rabbits, rodents, and deer; golf course turf tees and greens; and as a seed treatment (non-food). The human health risk assessment is currently being drafted. The ecological risk assessment is also currently being drafted, but preliminary results show potential risks to birds, mammals, bees, fish, and aquatic invertebrates (terrestrial plants and aquatic plants not at risk). Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

Tolfenpyrad:
Release human health and ecological risk assessments. Tolfenpyrad is a broad-spectrum pyrazole insecticide and fungicide registered for agricultural uses. Products containing tolfenpyrad are registered for use on a variety of crops, on greenhouse and outdoor ornamental plants, and to control horn flies and face flies on beef and dairy cattle. The human health hazard assessment for tolfenpyrad is being updated, and the dietary, residential, and occupational exposure and risk assessments are in development. Based on previous assessments and preliminary exposure modeling, potential ecological risks are anticipated for all taxa except for terrestrial and aquatic vascular plants. Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

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Q4 Antimicrobial DRA Fact Sheets

None.

Q4 Antimicrobial DRA Summaries

Benzoic Acid:
Release human health and ecological risk assessments. Benzoic acid is a bactericide and is formulated for use as a preservative of food-grade lubricating oils in industrial facilities and in textiles, polymers, and plastics. Human dietary exposure to residues of benzoic acid from pesticidal sources is expected to be minimal compared to the direct food-additive uses regulated by FDA. Therefore, a qualitative dietary assessment has been performed. Occupational dermal risk is not expected for the registered use of benzoic acid. The inhalation risk to benzoic acid will be determined after the available inhalation study is taken to HED's ToxSAC for review in early August 2020. The risk to terrestrial and aquatic organisms (including plants) is expected to be negligible. At this time, the Agency concluded that based on low hazard and exposure, the registered uses of benzoic acid will have a "no effects" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitats for such species. Anticipated stakeholder reaction: minimal stakeholder feedback is anticipated.

Dimethoxane:
Release human health and ecological risk assessments. Dimethoxane is a bacteriostat and fungistat. It is registered as a materials preservative for use in industrial adhesives, paints, coatings, emulsions, slurries, inks, textile chemicals, leather processing, and distillation fuels. There are no oral exposures from uses of dimethoxane products. There are no residential handler risks of concern for dimethoxane. There are no occupational dermal or inhalation risk of concerns for dimethoxane. Dimethoxane and its degradates are not expected to result in risk to terrestrial or aquatic species (including pollinators). Based on the low exposure potential from antimicrobial uses of dimethoxane as well as low toxicity to non-target terrestrial and aquatic organisms, the Agency has made a "no effects" determination for dimethoxane under the Endangered Species Act (ESA) for all listed species and designated critical habitats for such species. Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

Polymeric Betaine:
Release human health and ecological risk assessments. Polymeric betaine is a wood preservative, borate ester, that breaks down to DDAC and boric acid when applied to wood. It is registered as a microbiocide, fungicide, and insecticide applied through pressure treatment. Dietary exposure to polymeric betaine via food is not expected because the labels prohibit use on wood that may come into contact with food or feed. Residential post-application dermal and incidental oral exposures to polymeric betaine are of concern. Occupational dermal and inhalation exposures for composite wood workers and pressure treatment are not of concern. Occupational inhalation exposure for sapstain control worker are also not of concern. Occupational dermal exposure for sapstain control worker are of concern. There are no ecological risks of concern from the wood preservation use from polymeric betaine, DDAC, or boric acid from the registered uses of polymeric betaine. The assessment is still being conducted, but the Agency will likely be able to make a 'no effects' call for listed species and their designated critical habitats for the

current uses of polymeric betaine. Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

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Q4 BPPD DRA Fact Sheets

None.

Q4 BPPD DRA Summaries

None.

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Q4 Proposed Interim Decisions

Q4 Conventional PID Fact Sheets

Note: The commodity fumigants are scheduled for combined draft risk assessments/proposed interim decisions this quarter, and the summaries for both appear in this section.

1,3-D (Telone) PID

Current Status

- 1,3-D is a non-selective soil fumigant registered for preplant use with a range of agricultural and non-agricultural crops and for post-plant use in vineyards.
- The main agricultural crops include: strawberries, peppers, tobacco, carrots, potatoes, and tomatoes.
- 1,3-D is a Restricted Use Pesticide and may only be applied by certified applicators or under the supervision of a certified applicator.
- OCSPP intends to publish the proposed interim decision for the registration review of 1,3-D for public comment.
- Publication Target (flexible): October 2020

Key Points

- For all soil fumigants, OPP implemented significant risk mitigation during reregistration. Mitigation included: personal protective equipment, water seals, tarping, restricted entry periods, and buffer zones.
- From 2013-2017, usage averaged 33,755,000 pounds active ingredient (a.i.) applied annually on 320,000 acres. Application rates and number of acres treated with 1,3-D have increased over time.
- 1,3-D is considered to have high benefits because it effectively controls nematodes leading to improvements in crop production and reduced management time to grow a crop. Alternatives for 1,3-D are other soil fumigants.
- The National Marine Fisheries Service Biological Opinion for Pacific Salmonids is currently due December 2020.

DRA Human Health Conclusions

- Based on newly submitted data, a recent review by the Cancer Assessment Review Committee (CARC) re-classified 1,3-D from "Likely to be Carcinogenic to Humans" to "Suggestive Evidence of Carcinogenic Potential" and concluded that quantification of human cancer risk is not required as the non-cancer reference dose (RfD) would be protective of all chronic toxicity, including carcinogenicity.
- The human health DRA identified some potential non-cancer risks of concern to occupational handlers and bystanders. HED is currently revising the risk assessment, which is expected to address these risks.
- There are no dietary risks of concern based on a refined drinking water assessment assuming typical application rates, one application every three years, and model parameterization using a prospective groundwater monitoring study.

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- The human health DRA also incorporated the Soil Fumigant Exposure Assessment (SOFEA4) modeling for ambient air developed by the registrant. HED is still validating SOFEA4 and expects to complete validation before publication of the ID (FY21 Q2).

DRA Ecological Conclusions

- The EPA conducted a streamlined ecological DRA and identified potential risks to fish, aquatic invertebrates, birds, mammals, and uncertain risk to pollinators.

Proposed Mitigation in PID

- Include a Fumigant Management Plan (FMP) for all labels (1,3-D does not currently have an FMP)
- Update respirator language

Communications

- Minimal press anticipated, however, on the DRAs we received a letter from eight state Attorneys General questioning the cancer reclassification and approach for cancer risk assessment.
- No rollout is proposed; OCSPP/OPA will have a desk statement on-hand for any press inquiries.

Carboxin/Oxycarboxin Registration Review PID

Current Status

- Carboxin and oxycarboxin are oxathiin-carboxamide class systemic fungicides used to control primarily basidiomycete pathogens such as rusts, smuts, and bunts.
- Carboxin was first registered in 1968 and oxycarboxin was first registered in 1971. The RED for both chemicals was completed in 2004.
- Carboxin is used mostly as a seed treatment for a variety of food crops (including wheat, barley, oats, corn, soybeans, safflower, beans, onions, rice, sorghum, soybeans, and triticale) and as a dip for ornamental roots/bulbs. Oxycarboxin is only applied to ornamental plants inside greenhouses.
- There are no residential uses for carboxin or oxycarboxin.
- Publication Target (flexible): October 2020

Key Points

- Four labels are listed with approved uses on peas and rye but do not have tolerances established for these commodities. PRD and OECA are preparing a SSURO, will work with the registrant to recall and relabel these products, and have asked them to submit tolerance petitions or use deletions.
- A sub-chronic inhalation study was waived with the addition of a PF10 respirator to several occupational scenarios.

DRA Human Health Conclusions

- Potential inhalation risks of concern were identified for:
  - Eight occupational handler scenarios in commercial seed treatment facilities (cleaning and maintenance of seed treatment equipment and mixing/loading activities).
  - One occupational handler scenario involving the application of oxycarboxin inside greenhouses using mechanically pressurized handguns.

DRA Ecological Risk Conclusions

- Potential chronic risks of concern were identified for birds and mammals consuming treated seeds left exposed in fields.

Proposed Mitigation in PID

- The agency is proposing the addition of a PF10 respirator for the 9 identified inhalation scenarios of concern to bring MOEs above the LOC of 1000.
- The agency is proposing updated mandatory seed management and planting language to reduce risk of birds and mammals consuming treated seeds left exposed in fields.
- Proposed label changes include requiring a minimum 4-month plant-back interval for unregistered crops (carboxin labels only) and updated pesticide resistance management language.
- BEAD is currently reviewing impacts of proposed mitigation measures and label changes.

Communications

- Minimal stakeholder feedback is expected on most proposed mitigations and label changes. PRD is currently reviewing a comment from the registrant on whether the PF10 respirator requirement should apply to all scenarios.
- No rollout is proposed beyond the normal public notice and comment period.

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Commodity Fumigants DRAs and PIDs – Aluminum Phosphide, Magnesium Phosphide, Phosphine, Propylene Oxide (PPO) & Inorganic Sulfites

Current Status

- Aluminum (Al) phosphide was first registered for use in the US in 1958, followed by magnesium (Mg) phosphide in 1979, and phosphine, formulated as a gas, in 2002.
- PPO was first registered in 1982.
- Sulfur dioxide (SO_2) was first registered for use in the US in 1988, followed by sodium metabisulfite in 1989.
- The commodity fumigants are used to prevent spoilage on food commodities in storage and packaging, following harvest. Al phosphide and Mg phosphide are also registered for use outdoors in burrows for rodent control. Sodium metabisulfite products are also contained in semi-sealed pads which are added to containers holding grapes prior to shipping. It is also used as an antimicrobial agent, embedded into packaging stickers for use in shipping consumer goods.
- The risk assessment and management strategy was briefed up to the AA in April 2019.
- Publication Target (flexible): October 2020

Key Points

- The commodity fumigants are high risk/high benefit active ingredients with critical applications in agriculture, trade and other industries. There are often no alternatives to these active ingredients for their registered uses.
- Significant data requirements of the commodity fumigant DCIs were not addressed by the registrants. As a result, OPP was not able to conduct quantitative human health risk assessments for occupational handler scenarios. Qualitative assessments of worker exposure were instead conducted. Monitoring data to assess bystander exposure to ambient air concentrations of PPO and phosphine were also not submitted. In lieu of these data, the agency used statistical models to assess bystander ambient air exposure.

DRA Human Health Conclusions

- Dietary (food + water) risks: No potential risks of concern identified.
- Occupational handlers: Qualitatively assessed.
- Occupational post-application: Qualitatively assessed.
- Residential handlers and post-application: All commodity fumigant products are Restricted Use (RUP) and are not applied to residential areas, so residential assessments were not conducted.
- Bystander (drift and/or volatilization): Quantitative buffer assessments using the PERFUM model were conducted. PERFUM recommended buffers ranging from 0 m to 2,500 m, based on the fumigant in question and various assumptions about the treatment facility.
- Bystander ambient air: Monitoring data not available; exposure assessed using modeling and no potential bystander ambient air risks of concern expected.
- SO_2 is regulated by EPA's Office of Air Quality Planning and Standards (OAQPS).

DRA Ecological Conclusions

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- Limited risk to the environment is expected from registered uses of these active ingredients. The commodity fumigants are volatile and expected to disperse quickly in the environment, mitigating exposure.
- There have been six ecological incidents reported with Al phosphide and one incident with phosphine. One aggregate incident involving plant damage was also reported for Al phosphide. No incidents were reported for Mg phosphide, PPO, sodium metabisulfite or sulfur dioxide.

Proposed Mitigation in PID

- Aluminum phosphide, Magnesium Phosphide, Phosphine, Sulfur Dioxide & Propylene Oxide (PPO): To protect workers and bystanders, EPA is proposing revised/requiring fumigation management plans (FMPs). Based on the results of the buffer assessments, EPA may also propose buffer zones around treatment sites. FMPs describe how and when a fumigant will be applied, include plans to respond to leaks or accidents, specify storage guidelines, and outline other protective measures such as active monitoring of fumigant air concentrations. A buffer zone is a radius around an application site that personnel may enter only if wearing personnel protective equipment (PPE) during application and aeration times. Buffer zones are calculated on site depending on chamber size, application rate, stack height and configuration, and other factors.
- Sodium Metabisulfite: No mitigation is proposed for the antimicrobial use of sodium metabisulfite as no human health or ecological risks were identified.

Communications – No rollout is proposed beyond the normal public notice and comment period. OPP has been actively communicating with commodity fumigant product registrants throughout the risk assessment and mitigation development process.

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Coumaphos Registration Review Revised PID

Current Status

- Coumaphos is a member of the organophosphate (OP) insecticide class that primarily affects the nervous system through cholinesterase (ChE) inhibition.
- Coumaphos is registered to control arthropod pests on beef and dairy cattle, goats, horses, sheep and swine by sprays, dips, and dust as well as by a strip in bee hives.
- OCSPP intends to publish a revised PID for the registration review of coumaphos for public comment. The original PID was published in 2018.
- Publication Target (flexible): Moved from Q3. Now anticipated late-August, 2020

Key Points

- Coumaphos is important in the USDA APHIS Cattle Fever Tick Eradication Program (CFTEP) along the Texas/Mexico border to control cattle fever tick and prevent cattle fever from spreading into the United States.
- Since the 2018 PID was published, EPA has been made aware of:
    - Potential on-going lapses with following label instructions by USDA Animal and Plant Health Inspection Service (APHIS) (e.g., PPE, product misuse, improper disposal)
    - A lawsuit between a cattle rancher in Texas and USDA over cattle deaths allegedly caused by coumaphos use within the program.
    - Several application methods identified by USDA and the technical registrant, Bayer Animal Health (BAH) that were not originally evaluated in the risk assessments (e.g., spray-box and vehicle-mounted sprayer uses).
    - Received comments about the need to retain horse uses of coumaphos.

DRA Human Health Conclusions

- The human health risk assessment retains the FQPA 10x safety factor consistent with recent chlorpyrifos and other OP assessments.
- Unlike other OPs, EPA decided to move forward with the coumaphos registration review as most risks identified would remain even if the FQPA 10x safety factor was removed.
- Potential risks to occupational handlers were identified for all use sites except ear tags and bee hive strips.

DRA Ecological Conclusions

- The ecological risk assessment identified potential risks to aquatic invertebrates and to bees, as well as to birds and mammals from secondary exposure to contaminated prey.

Proposed Mitigation in PID

- Prohibition of the following application methods:
    - Flowable concentrates for hydraulic-type or swim-type dip vats (except for USDA quarantine program use)
    - All dust shaker can uses
    - All liquid spray products, except for 1) manually pressurized hand-wand uses on horses; 2) the USDA quarantine program, and 3) vehicle-mounted spray uses

- For vehicle-mounted sprayers, propose clear label directions and propose closed mixing/loading/ applicator systems. Request additional information about the amount handled per day.
- For dust bags, reduce application rate and propose PPE for mixers/loaders; specific PPE varies with size of cattle operation
- For manually-pressurized hand-wand applications to horses, propose a maximum daily amount handled of 10 gallons and propose double layer, gloves, and a PF10 respirator for mixers/loaders/applicators
- Revise references/statements about USDA APHIS on the USDA label to improve clarity
- Propose including spray-dip boxes on the USDA label in conjunction with dip vats (same rates and PPE).
- Propose limiting application methods to only those specified on labels.

Communications

- OPP worked with USDA while developing the PID and briefed USDA on the proposed mitigation.
- OCSPP/OPA will work on communications, including joint communication with USDA.
- Some press anticipated; previously received input on the importance of coumaphos as a pest control tool and alternative to pyrethroids and previously received input from several concerned parties on the potential secondary exposure of birds and mammals to coumaphos, particularly endangered birds and mammals whose habitat is near cattle farms.

Myclobutanil Registration Review PID

Current Status

- Myclobutanil is a systemic fungicide in the conazole class, first registered in 1984. There are a large variety of agricultural uses including field crops, row crops, orchard, and vineyard crops. There are also ornamental, forestry, and residential/commercial turf uses.
- PID Publication Target (flexible): October 2020, carry over from Q3.

Key Points

- EPA found myclobutanil to be likely to adversely affect (LAA) the California red-legged frog in 2009 and recommended a formal consultation with USFWS under section 7 of the ESA.

DRA Human Health Conclusions

- Residential post-application risks identified for turf scenarios for all lifestages which included averaging TTR data over 4 days. Occupational handler risks of concern were identified for on-farm cotton seed treatment.
- Using chemical specific study data (DFR and TTR), post-application risks of concern were identified for sod operations and grapes.
- Potential risks identified for dust application.
- Based on the proposed cancellation of residential turf uses HED is currently revising the aggregate and occupational risk estimates.

DRA Ecological Conclusions

- Some chronic risk to birds and mammals, especially from high rate turf uses.
- The highest turf rate has a chronic risk to freshwater fish and an acute risk to aquatic invertebrates after 5 years accumulation.

Proposed Mitigation in PID

Mitigation measures being discussed include:

- Cancellations of residential turf use, dust product formulation, and on-farm cotton seed treatment.
- Requiring a 24-hour REI for sod uses, and up to a 2-day REI on turning girdling table grapes.
- Requiring "chemical-resistant headgear" (instead of currently listed "hat") for airblast applications.
- Requiring double layer of clothing and gloves with all backpack and mechanically pressurized handgun equipment uses.
- Adding advisory spray drift language.
- PRD is currently negotiating these mitigation measures with the registrants.

Communications

- No rollout is proposed beyond the normal public notice and comment period.

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Paraquat Dichloride Registration Review PID

Current Status

- Paraquat dichloride is a fast-acting, non-selective herbicide used for the control of broadleaf and grass weeds in agricultural and non-agricultural use sites. It is a contact herbicide that desiccates and destroys plant cell membranes within hours of application.
- Paraquat is a restricted use pesticide that can only be used by certified applicators and there are no paraquat products registered for homeowner or residential use.
- Paraquat is extremely toxic and as little as 1.5 teaspoons can be fatal if ingested.
- In 2016, EPA amended paraquat registrations to impose several additional restrictions intended to prevent accidental ingestion incidents. All requirements from this human health mitigation will be implemented on labels by December 30, 2020.
- Incident recently reported in North Carolina involving workers who suffered skin reactions (rash/blistering/possibly burns) while performing weed removal in a sweet potato field 5 days after the field was treated with paraquat via a rope wick application.
    - It is currently unclear whether the workers' injuries are attributable to paraquat; OPP will stay in touch with NC Dept of Ag as they gather more information.
- Publication Target: October 2020

Key Points

- Paraquat is one of the most widely used herbicides in the U.S., with an average of 7 million pounds applied annually to over 14 million acres. The crops with the highest number of acres treated are cotton, soybeans, and corn.
- There are a limited number of alternatives to paraquat.
- Human health and ecological risks of concern were identified for numerous use scenarios.
- Very high benefit/very high risk

DRA Human Health Conclusions

- Occupational handler risks of concern for most scenarios, including mixers/loaders and applicators.
- Occupational post-application risks of concern for cotton and alfalfa.
- Bystander risks are of concern up to 150 feet beyond the field edge for aerial applications.
- Weight of evidence from systematic review of paraquat open literature is insufficient to link paraquat exposure from pesticidal use of U.S. registered products to Parkinson's disease in humans.

DRA Ecological Risk Conclusions

- Potential acute and chronic risks to mammals and birds.
- Potential acute risks to adult honeybees.
- Potential risks to terrestrial plants.
- No potential risks to aquatic taxa, except for algae and benthic species (but bioavailability may be limited).

Proposed Mitigation in PID

- Prohibit aerial application for all use sites except for cotton (desiccation use only)
- Require 75-ft buffer for cotton desiccation

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- Prohibit pressurized handgun and backpack sprayer application methods on the label
- Limit maximum application rate for alfalfa to 1.0 lb a.i./A
- Require enclosed cabs if area treated in 24-hr period is more than 80 acres
- Require enclosed cabs or PF10 respirators if area treated in 24-hr period is 80 acres or less
- 48-hr Restricted Entry Interval (REI) for all crops/uses except for cotton desiccation
- 7-day REI for cotton desiccation
- Mandatory spray drift management
- PID will propose label changes to exempt truck drivers from the current requirement to be a certified applicator in order to transport paraquat
- Registrants have agreed to the proposed mitigation measures.
- Positive stakeholder feedback is expected from the cotton industry, due to prior communication with cotton growers and extension specialists regarding paraquat's use on cotton.

Communications – Web update, desk statement, OPP update, Qs & As

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Pyrethroids (gamma-Cyhalothrin & lambda-Cyhalothrin) Registration Review PIDs

Current Status

- Gamma-cyhalothrin and lambda-cyhalothrin (which are isomers of the cyhalothrin molecule) are part of the pyrethroids group of pesticides. More information about the pyrethroids is available in the [HYPERLINK \l "_Pyrethroids_Registration_Review"] of this document.
- Gamma- and lambda-cyhalothrins are formulated as ready-to-use sprays, liquids and granules.
- Major agricultural uses, primarily for lambda, include alfalfa, corn, onions, rice, soybeans, sunflowers, sweet corn, tree nuts, vegetables and other crops.
- Non-agricultural insecticide uses include indoor and outdoor residential/commercial and industrial spaces and structures, cattle ear tags, ornamental gardens, lawns, landscapes, turf, golf courses and general insect control (spot treatments and crack and crevice treatment).
- PID publication target (flexible): October 2020

Key Points

- The 2017 DRA and response to comments were revised in 2020, with an addendum addressing the occupational handler risks of concern for both gamma-cyhalothrin and lambda-cyhalothrin.
- Both gamma-cyhalothrin and lambda cyhalothrin pose human health risks (see human health conclusions below).
- The cyhalothrins are labeled for agricultural uses which pose potential risks to pollinators, and therefore the PID will propose updated environmental hazards, and information on incident reporting, managed pollinator protection plans, and pollinator best management practices. The OCSPP IO was briefed on and approved these proposed pollinator protection measures on 1/22/20.
- Proposing to prohibit certain application methods and require additional PPE to address risks of concern identified in the residential and occupational assessment.

Gamma Human Health Conclusions

- Residential Handler: risks of concern from several handheld equipment scenarios.
- Residential Post-Application: risks of concern for adults and children from dermal exposure from indoor and outdoor applications.
- Aggregate: most aggregate exposures were not of concern except for the residential exposure scenarios listed above and indoor spot application to hard flooring.
- Occupational Handler: potential risks of concern for several application scenarios (backpack, manually-pressurized equipment, and mechanically-pressurized equipment) even with additional PPE (i.e., gloves, double-layer clothing, and PF10 respirators).
- Occupational Post-Application: Using chemical-specific data, risks of concern on the day of application for a variety of crops, with days needed for the MOE to be greater than the LOC ranging from 2 days to greater than 30 days.

Lambda Human Health Conclusions

- Residential Post-Application: potential risks are of concern to children (1 to < 2 years old) from indoor applications and lawn/turf application (liquid/solid).

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- Aggregate: most aggregate exposures were not of concern except the residential exposure scenarios listed above.
- Occupational Handler: potential risks of concern for several application scenarios even with additional PPE (i.e., gloves, PF10 respirator, or engineering control)
- Occupational Post-Application: Using chemical-specific data, risks of concern on the day of application, with days needed for the MOE to be greater than the LOC ranging from 2 to 14 days.

Ecological Risk Assessment Conclusions

- Risk to pollinators: There are potential acute risks of concern identified for bees from agricultural uses of pyrethroids. Bee mortality incidents confirm these findings.
- Tier 1 bee data set for cyhalothrins are complete. The RQs identify risks to bees and Tier 2 bee data set may be requested.
- Risks to aquatic invertebrates and fish: There are potential risks to aquatic organisms because pyrethroids bind tightly to soil and aquatic organisms can be exposed from runoff and erosion.

Proposed Mitigation in PID

Lambda

- Residential post-application: (1) Prohibit indoor use on mattress (2) Restrict turf uses to golf courses only
- Occupational handlers: (1) Prohibit use of different types of handheld equipment for several use sites such as nurseries, landscapes/turfs, orchards and vineyards, greenhouses, industrial/commercial settings, and typical field crops. (2) Require a combination of additional PPE such as gloves, double layer clothing, and PF10 respirator.
- Occupational post-application: Adjust REIs for some activities (up to 9 days).

Gamma

- Residential handlers: Prohibit use of manually-pressurized hand-wand, hose-end sprayers, backpack sprayers and sprinkler applications.
- Residential post-application: (1) Prohibit indoor coarse spray and pin-stream applications to carpets. (2) Restrict outdoor use to direct ground application.
- Occupational handlers: (1) Prohibit aerial broadcast sprays to typical field crops. (2) Prohibit use of different types of handheld equipment for several use sites. (3) Prohibit use of flaggers. (4) Require a combination of additional PPE such as gloves, double layer clothing, PF10 respirator, and engineering control.
- Occupational post-application: Adjust REIs for several activities (maybe up to 30 days).
- Not widely used in agriculture; restrictions/cancellations may have limited effect.
- Impacts are uncertain for non-agricultural uses.

Communications – No rollout is proposed beyond the normal public notice and comment period.

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Triphenyltin Hydroxide (TPTH aka Fentin Hydroxide) PID

Current Status

- Triphenyltin hydroxide (TPTH; aka fentin hydroxide) is a non-systemic fungicide registered for use on pecans, potatoes and sugar beets. It's an organotin compound formulated as wettable powder and a flowable concentrate.
- TPTH is a Restricted Use Pesticide (RUP) that can only be used by certified applicators and there are no TPTH products registered for homeowner or residential use.
- Publication Target (flexible): October 2020

Key Points

- Between 2008 and 2017 there was an average of 260,000 pounds of TPTH applied to agricultural sites annually. Nationally, an average of 20% of pecan acres, 10% of potato acres, and 30% of sugar beet acres were treated with TPTH.
- Approximately 80 comments on the benefits of TPTH were received in response to the DRAs. These comments noted the importance of TPTH in combating Cerospora leafspot disease in sugar beets and pecan scab in pecans. They also noted that TPTH is critical due to its low potential for resistance.
- TPTH is a highly effective resistance management pesticide based on its mode of action.
- Current TPTH labels already include significant mitigation (PPE, closed M/L systems, REI, mandatory spray drift language, and buffers to water bodies) implemented during reregistration.
- Not all risks identified during reregistration were mitigated given the benefits of TPTH. Proposed mitigation measures do not eliminate all potential ecological risks but uses were retained because of high benefits.

DRA Human Health Conclusions

- Dietary cancer risks were identified for the most highly exposed subgroup, however, based on refinements to the drinking water assessment all dietary cancer risk estimates are no longer a risk of concern.
- Occupational handler cancer and non-cancer risks of concern for numerous scenarios including mixing/loading aerial applications to sugar beets and potatoes, all mixing/loading water-soluble packets (WSP) scenarios, and mixing/loading/applying with backpack/mechanically pressurized handgun scenarios on pecans.
- Potential bystander risks are of concern up to 75 ft beyond the field edge for aerial applications using medium or coarser droplet size.

DRA Ecological Risk Conclusions

- Potential acute and chronic risks to mammals and birds for all forage items, including bioaccumulation in fish.
- Potential acute and chronic risks to freshwater fish and invertebrates and estuarine/marine invertebrates.
- Potential chronic risks to estuarine/marine benthic invertebrates.
- Potential risks to aquatic plants.

Proposed Mitigation in PID

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- Use deletion of water-soluble packets (WSP).
- Prohibit backpack and mechanically pressurized handgun applications to pecans.
- Standardize type of closed mixing loading system on all labels: Mechanical Transfer System.
- Mandatory spray drift restrictions:
  - Increase droplet size restriction to medium or coarser.
  - Boom height: 3 ft from the canopy for ground applications.
- Spray drift buffers to residential and commercial areas (75 ft).
- Update surface water advisory language.
- Change 'seasonal use rates' to 'annual'.
- Registrants have agreed to all mitigation measures.

Communications – No rollout is proposed; OCSPP/OPA will have a desk statement on-hand for any press inquiries.

Q4 Conventional PID Summaries

Note: Benzyl benzoate and butoxypolypropylene glycol are scheduled for combined draft risk assessments/proposed interim decisions this quarter, and the summaries for both appear in this section.

Benzyl benzoate (benylate) Human Health DRA and PID:
Release draft human health risk assessment and Proposed Interim Decision. Benzyl benzoate is an insecticide/miticide with only one registered conventional pesticide product, a spray for treatment for sarcoptic mange mite on dogs. No dietary exposures are expected. The agency is currently evaluating the potential inhalation risk. For ecological effects, at the time of the Problem Formulation, the agency previously concluded that benzyl benzoate is not expected to pose risks of concern, and also made a "no effects" determination for listed species. These conclusions are based on the limited potential for environmental exposure, limited extent and diffuse nature of use, and the low toxicity of benzyl benzoate as demonstrated by available toxicity test data and corroborated by structural activity information. No mitigation is proposed for benzyl benzoate due to the absence of risks of concern from the use of this chemical. Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

Butoxypolypropylene glycol (BPG) Ecological DRA and PID:
Release draft risk assessments and Proposed Interim Decision. BPG is used to repel flies, mosquitoes, fleas, and ticks in areas where animals live and for direct application to companion and equine animals. There are no food uses, no uses on animals intended for slaughter, and outdoor misting systems are prohibited. There are no dietary, residential, aggregate, spray drift, or occupational risks of concern. No potential ecological risks of concern are anticipated. Some label clarification will be proposed. Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

Triallate:
Release Proposed Interim Decision. Triallate is a pre-emergent selective herbicide in the thiocarbamate class. It is registered for use on barley, peas, lentils, sugar beets, triticale, wheat, and Bermuda grass (grown for seed/hay). There is also an impregnated fertilizer use. There are no residential uses of triallate. Risks of concern were identified for occupational handlers mixing/loading and applying impregnated fertilizers. However, usage data and updated breathing rate assumptions were incorporated to refine the assessment and there are no longer risks of concern for mixer/loaders or applicators. Potential environmental risks of concern were identified for estuarine/marine invertebrates, mammals and terrestrial plants. Proposed mitigation includes updated non-target advisory statements, updated spray drift language, and mandatory soil incorporation (already recommended on labels). Anticipated stakeholder reaction: Minimal stakeholder feedback is expected.

Triticonazole:
Release Proposed Interim Decision. Triticonazole is a broad-spectrum, triazole fungicide registered for control of certain pathogenic fungal diseases on outdoor and greenhouse ornamentals (commercial and residential settings), golf courses, sod farms, and as a seed treatment for cereal grain crops. Triticonazole end-use products are formulated as foliar sprays, granules, and as a seed treatment. There are no human health risks of concern. Potential ecological risks of concern were identified for freshwater fish, estuarine/marine invertebrates, birds, mammals, terrestrial invertebrates and terrestrial plants. Proposed

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mitigation focuses on standardizing advisory label language, including: handling of treated seed; advisory spray drift management; and fungicide resistance management. Anticipated stakeholder reaction: Minimal stakeholder feedback is expected.

Naphthalene Acetic Acid (NAA):
Release Proposed Interim Decision. Naphthalene acetic acid, its salts, ester, and acetamide, are assessed as a group and are referred to as NAA, this group includes six active ingredients. The NAA compounds are systemic plant growth regulators registered for use on various orchard and fruit crops, ornamental trees, and turf/grass. Potential human health risks of concern were identified for occupational workers. Potential ecological risks of concern were identified for birds, mammals, and terrestrial plants. For human health, proposed mitigation includes requiring additional PPE (respirators) for occupational workers. For ecological, proposed mitigation includes changes to application rates for pomegranate and mandarin uses (reducing number of total applications per year), requiring mandatory and advisory spray drift language, and non-target advisory statements. Anticipated stakeholder reaction: minimal stakeholder feedback is anticipated.

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Q4 Antimicrobial PID Fact Sheets

Irgarol PID

Current Status

- Irgarol (aka Cybutryne) is a triazine compound but is not a part of the triazine cumulative.
- Currently, 17 products are registered including one technical.
- Irgarol is registered for use as marine and/or freshwater antifoulant paint for commercial vessels and pleasure boats, and as a materials preservative in paints and building materials.
- Irgarol was first registered in the U.S. in 1960.
- Publication Target: September 2020

Key Points

- The International Maritime Organization (IMO) has proposed a ban on irgarol use as antifoulant paint because of its potential to cause coral bleaching. EPA (OITA, OW and OPP) has no objection to the proposed ban.
    - The recommended IMO timeline for the ban on use of irgarol is: no new applications of irgarol as of 10/2021 and no existing irgarol-containing coatings after 10/2026 unless sealed.
    - All registrants have been informed of the proposed AFP use cancellation by EPA to align with the IMO timeline and generally agree with cancellation of the AFP saltwater uses. Registrants are currently providing feedback on the proposed freshwater AFP use cancellation but are also in general agreement. EPA will continue communicating with registrants regarding cancellation of the antifoulant use.
    - No public comments were submitted to the docket for the DRA.
    - In antifouling paints, irgarol is often combined with copper, or copper compounds such as cuprous oxide or copper thiocyanate.
    - In material preservative products, irgarol is often combined with carbendazim (MBC), chlorothalonil, and/or DCOIT (3(2H)-Isothiazolone, 4,5-dichloro-2-octyl-).

DRA Human Health Conclusions

- Low toxicity to humans
- No dietary routes of exposure
- Risk (antifouling use) – dermal and inhalation risks identified for Do-It-Yourself painters; inhalation risks identified for occupational workers
- Risk (paint preservative) – some occupational risks for inhalation and dermal routes of exposure

DRA Ecological Risk Conclusions

- Moderately to highly toxic to aquatic animals; especially toxic to aquatic plants
    - Often combined with copper compounds – the copper controls aquatic animals
    - Irgarol itself is an s-triazine – moderately to highly toxic to aquatic animals; especially toxic to aquatic plants
- The ecological risk assessment evaluated an estuarine/marine marina exposure scenario for the antifoulant paint use of irgarol

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- Risk to aquatic animals is below levels of concern; Risk concerns exist for algae and aquatic plants (and, thus, potential risks for coral).
- The potential risks to corals were qualitatively assessed in the DRA
    - Corals are dependent upon algae for nutrients, and because irgarol is persistent in aquatic environments and toxic to algae (EC50 = 0.1 μg ai/L), there is a potential for irgarol to adversely impact coral (by affecting the symbiotic algae found in coral)

Proposed Mitigation in PID

- Residential inhalation
    - Preserved paint (DIY) use via airless sprayer – lower the application rate
- Residential dermal
    - Anti-foulant Paint (AFP) use
- Currently discussing with registrants to propose cancellation of the AFP use
- Brush and roller – lower the application rate, if the use remains
    - Preserved paint (DIY) use
- Brush and roller – lower the application rate
- Occupational handler – inhalation
    - Currently discussing with registrants to propose to cancel the AFP uses
- If the AFP uses remain – respirator will be required
    - Paint preservative use
- Airless sprayer – lower application rate
- Open-pour – respirator or closed loading
- Occupational handler - dermal
    - Materials preservative
- Open-pour powder - goggles or face shield and rubber gloves and protective clothing
- Ecological concerns
    - Deletion of AFP use or limit to freshwater only use

Communications

No rollout is proposed, and OCSPP/OPA will have a desk statement on hand for any press inquiries. All registrants have been informed of the proposed AFP use cancellation and generally agree with cancellation of the AFP saltwater uses. Registrants are providing more information on a proposed freshwater AFP use cancellation. Stakeholders will also have an additional chance to provide public comments on our proposed interim decision. OCSPP/OPA may have a desk statement on-hand for any press inquiries.

Q4 Antimicrobial PID Summaries

Dibromo-3-nitrilopropionamide (DBNPA):
Release Proposed Interim Decision. DBNPA is registered for use in water treatment, paper production, oil and gas, and as a materials preservative in residential and occupational paints, cleaners, and laundry detergent. Inhalation risks were identified for residential painters, occupational painters, occupational handlers who apply DBNPA to preserve materials, occupational handlers who apply materials preserved with DBNPA, and aggregate exposure to children due to incidental ingestion. There are no dietary concerns other than as it relates to aggregate exposure to children due to incidental ingestion. No ecological risks of concern were identified. The proposed mitigation strategy is to cancel the material preservative uses of DBNPA in paints, coatings, stains, pigment, dye, filler suspensions, polymer dispersions, emulsions, and cleaning products. However, AD is evaluating further information recently provided by the registrant, which may enable the mitigation to be changed to application rate reduction for the uses described. For material preservative uses in paper mill additives, adhesives, glues, and tackifiers, the proposed mitigation is to implement closed loading and delivery systems. To address aggregate exposure to children, the proposed mitigation is to reduce the application rate of household cleaners to 200 ppm. Anticipated stakeholder reaction: Due to respiratory risks, several uses are being proposed for removal. Ongoing and frequent stakeholder communication is anticipated.

Halohydantoins:
Release Proposed Interim Decision (PID). Halohydantoins are registered for use for microbial control in water and water systems (disinfectant in pools, spas, hot tubs; sanitizer for hard surfaces, toilet bowls; bacterial and fungal control in industrial water systems; egg washing, fruit/vegetable washing and drinking water disinfection). The human health risk assessment identified risks of concern for inhalation exposures to occupational handlers in various larger water treatment scenarios. Risks are not expected to nontarget aquatic or terrestrial organisms because the halohydantoins are expected to degrade rapidly to non-toxic degradates in the environment. AD is making a "no effects" call for Federally listed species and their designated critical habitats. To mitigate the risks to occupational handlers, AD is proposing to require that halohydantoin products be applied with closed-loading systems or incorporate other engineering controls that would greatly reduce exposure for workers in the scenarios where risks were identified. Communication with the registrants is ongoing as the mitigation plan is being finalized. Anticipated Stakeholder Reaction: Moderate stakeholder feedback is anticipated due to the risks of concern that have been identified for occupational handlers.

Ortho-Phenylphenol (O-PP) and salts:
Release Proposed Interim Decision. O-PP (PC Code 064103) and its sodium and potassium salts (PC Codes 064104 and 064108, respectively) are registered for use in antimicrobial and conventional pesticide applications. As an antimicrobial, O-PP and salts are used as disinfectants, sanitizers, bacteriocides/bacteriostats, deodorizers, algaecides, fungicide/fungistats, molluscicides, tuberculocides, and virucides in a broad variety of settings. Conventional products are only formulated with sodium or potassium. O-PP and registered uses include the post-harvest fungicidal treatment of citrus and pears. Additionally, there are also conventional insecticide products that contain O-PP salts as antimicrobial agents.

- Antimicrobial risks and mitigation: The risk assessment identified risks for residential handlers (paints), residential post-application (foggers, carpets, textiles); and occupational handlers

(preparing preserved textiles, preparing preserved paints, applying preserved paints, foggers, air deodorizers, sapstain control). Additionally, based on an aggregate risk assessment, risks were exceeded for combined exposures to plastic toys, textiles, carpets, and floor cleaners when combined with average dietary exposure. Aside from aggregate risk, there were no dietary risks of concern identified for O-PP and salts. Anticipated mitigation measures include reducing maximum application rates for many uses, additional PPE, requiring closed loading of materials preservatives, clarifying label language to preclude risk (e.g., only for use in carpet backing, rather than carpet fibers), and removing paints from O-PP only labels (no vapor risk from salts). For ecological exposures, the use of O-PP and salts in cooling towers were found to be moderately toxic to freshwater and marine/estuarine fish and aquatic plants; and sapstain control was found to be highly toxic to bees. It is anticipated that mitigation for ecological risks will not be needed as the exposure is assumed to be low because O-PP and salts will dilute to nontoxic levels once cooling tower water enters streams and sapstain is not a common use of O-PP or its salts. Anticipated stakeholder reaction: One substantive comment was received from manufacturers of O-PP, which included proposed mitigation of risks that were incorporated into this PID as well as feedback on the risk assessment. This feedback currently is under review and could possibly lower the risks of concern. Ongoing stakeholder engagement is anticipated.

- Conventional risks and mitigation: The risk assessment identified potential risks for occupational handlers and occupational post-application inhalation exposures following post-harvest application to citrus and pears. Mitigation planning is ongoing within the registration review team. Measures currently being discussed include application rate reductions and additional PPE (PF10 respirators), but consideration of additional measures may be needed based on the risk concerns previously described. Anticipated stakeholder reaction: Ongoing stakeholder engagement is anticipated.

Organic Esters of Phosphoric Acid (OEPA):

AD is using the RED from 2008 in lieu of conducting a new DRA for OEPA. Although there has been some acknowledgement from the registrants about outstanding GDCI data (30 studies called-in), no data has been submitted. Therefore, the RED includes the best available science. There are no new uses that weren't already assessed for the RED. The proposed approach is a combined DRA/PID where the risk conclusions from the RED will be cited in a memo and released at the same time with the PID. The PID will propose the same or similar risk mitigation that was included in the RED but never incorporated to the labels. The registrant has already agreed to remove some of the uses including treated carpet cleaners, textiles and mattress covers that triggered risk concerns in the RED, which will also address some of the data called in for the reg review GDCI. Registrants have indicated that the paint use is important for them to keep.

- **Key details:** OEPA consists of a mixture of three chemicals: Phosphoric acid, mono(2-ethylhexyl) ester (PC Code 111286), phosphoric acid, bis(2-ethylhexyl) ester, compound with 2,2'-(coco alkylimino)bis (ethanol) (PC Code 129079), and phosphoric acid, mono(2-ethylhexyl) ester, compounds with diethanolamine N-coco alkyl derivatives (PC Code 129080). OEPA is registered for use as a preservative for a wide variety of materials.
- **RED Human health risk assessment conclusions:** Based on the use patterns of OEPA assessed in the RED, which have not changed, no dietary exposure is expected. Furthermore, since these uses occur in an indoor environment, it is not expected that OEPA will impact any source of

drinking water. There are dermal and inhalation risks of concern for residential and occupational handlers using OEPA-preserved paint (brush and airless sprayer), which registrants have indicated is an important use. Therefore, AD is considering whether an updated ORE assessment would be needed to move forward with the paint use. There are also post-application residential risks of concern from OEPA-treated mattresses, textile/clothing and carpet/floor shampoos. There are aggregate risks from post-application exposure to treated materials.

- **RED Ecological risk assessment conclusions:** The Agency anticipates some of the registered uses of OEPA may result in environmental exposures; and, an endangered species effect determination has not been made.
- **Risk mitigation:** The PID will include the risk mitigation measures from the RED, such as prohibiting the product from being incorporated into toys, reducing the rates for various uses, including carpet and textile use, closed loading systems and PPE requirements. The mitigation for the paint use might be different from the RED which was to reduce the max rate from 5% to 0.25%. Registrants have indicated they'd like to keep that use at a rate of 2%.
- **Anticipated stakeholder reaction:** Overall stakeholder reaction is anticipated to be low. If we choose to propose to lower the paint use rate below what registrants have indicated as desired, they will likely comment on the PID and request EPA to redo the risk assessment.

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Q4 BPPD PID Fact Sheets

None.

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Q4 BPPD PID Summaries

1-Methylcyclopropene:
Release Proposed Interim Decision. 1-Methylcyclopropene (1-MCP) is considered a plant growth regulator that acts as an ethylene inhibitor by blocking the attachment of ethylene to tissue of plants and, therefore, prolonging the life of food and nonfood commodities. 1-MCP is applied to a wide array of agricultural and non-agricultural commodities to counteract the ripening effects of ethylene. No human health or ecological risks were identified. No mitigation or labeling changes are needed for the registration review of 1-MCP. Anticipated stakeholder reaction: Minimal stakeholder reaction is anticipated.

Beauveria bassiana:
Release Proposed Interim Decision. *Beauveria bassiana* are fungi registered for insecticidal use on a wide range of insects. It is registered for use on a variety of food crops, ornamentals, turf, in poultry and livestock manure, and is also registered for use on bedbug treatment sites that include offices, indoor dwellings, modes of transport, building structures and furniture. *Beauveria bassiana* are also found in nature on insects worldwide. Pesticide products containing *Beauveria bassiana* are registered for use in residential and agricultural settings. No human health or ecological risks were identified when used in accordance with label directions. Anticipated stakeholder reaction: Minimal stakeholder reaction is anticipated.

Kaolin:
Release Proposed Interim Decision. Kaolin is a naturally occuring clay that is registered for use as an insecticide, fungicide, and as a plant growth regulator. It is registered for use on a variety of food crops, ornamentals and turf to control insects and powdery mildew, and to protect against heat stress and sun damage. It is registered for both agricultural and residential uses as well as being used extensively in cosmetics, healthcare products, and as a food additive. No human health or ecological risks were identified. No mitigation or labeling changes are needed for the registration review of Kaolin. Anticipated stakeholder reaction: Minimal stakeholder reaction is anticipated.

Methoprene, Kinoprene, and Hydroprene:
Release Combined Final Work Plan and Proposed Interim Decision. Methoprene, kinoprene, and hydroprene are synthetic analogs to naturally-occurring insect juvenile hormones. Pesticide products containing methoprene, kinoprene, or hydroprene are registered for use as larvicides or insect growth regulators that inhibit the growth process of molting insects, thereby inhibiting their ability to mature to adulthood and reproduce. No human health or ecological risks were identified. No mitigation or labeling changes are needed for the registration review of methoprene, kinoprene, and hydroprene. Anticipated stakeholder reaction: Minimal stakeholder reaction is anticipated.

Paecilomyces species:
Release Proposed Interim Decision. The active ingredients included in the *Paecilomyces* species case include *Isaria fumosorosea* Apopka Strain 97, *Purpureocilium lilacinum* Strain 251, and *Isaria fumosorosea* strain FE 9901. *Paecilomyces* species are naturally occurring microorganisms and are used to reduce/control various insects (i.e. aphids, whiteflies, locust), mites, and plant parasitic nematodes. Products containing *Paecilomyces* species are registered for use on food and nonfood agricultural crops, turf, and ornamentals. No human health or ecological risks were identified. No mitigation or labeling changes are needed for the registration review of *Paecilomyces* species. The Agency is making a "no

effect" determination under ESA. Anticipated stakeholder reaction: Minimal stakeholder reaction is anticipated.

Streptomyces lydicus strain WYEC 108:
Release Proposed Interim Decision. *Streptomyces lydicus* strain WYEC 108 is a naturally occurring soil microorganism. It is registered for use to reduce/control various root and foliar plant diseases generally caused by fungi and molds (e.g., *Alternaria*, *Botrytis*, *Erysiphe*, *Sclerotinia*, *Phytophthora*), and in a few cases, by bacteria (e.g., *Erwinia, Xanthomonas*), or nematodes (*Belonolaimus longicaudatus*, *Tylenchulus semipenetrans*). Products containing *Streptomyces lydicus* strain WYEC 108 are registered for use on food and nonfood agricultural crops, in greenhouses, turf, ornamentals, and in residential settings. No human health or ecological risks were identified. The Agency is making a "no effect" determination under ESA. Additionally, no mitigation or labeling changes are needed for the registration review of *Streptomyces lydicus* strain WYEC 108. Anticipated stakeholder reaction: Minimal stakeholder reaction is anticipated.

Q4 Interim Decisions

Q4 Conventional ID Fact Sheets

Gonadotropin Releasing Hormone (GnRH) Registration Review Final Decision

Current Status

- The Registration Review Final Decision for the Gonadotropin Releasing Hormone (GnRH) will be completed in September 2020 and issued for public comment later in FY 2021 (fall 2020).
- GnRH is a non-lethal, immunocontraceptive vaccine used to manage populations of female white-tailed deer, wild or feral female horses, and female burros on federal, state, tribal, public, and private lands.
- Administered by injection only (dart, jab-stick, or by hand) and only by wildlife management program personnel or trained research scientists and veterinarians.
- There are three existing registered products with GnRH – one for deer and two for horses and burros.
- Alternatives to GnRH include use of another immunocontraceptive vaccine (porcine zona pellucida) and by removal or slaughter. There is no information on the extent of use of GnRH.

Key Points

- Limited GnRH exposure potential to humans and non-target organisms primarily due to:
    - administration by injection only,
    - rapid metabolism by mammals (half-lives less than an hour) which reduces secondary exposure;
    - GnRH is a protein that quickly denatures in both the environment and in the digestive tract of birds or mammals; and
    - GnRH is not effective by oral administration.
- GnRH is not registered for any food/feed uses, therefore no U.S. tolerances are established.
- EPA identified limited potential risks to workers by accidental self-injection.
- EPA made a "no effect" determination under the Endangered Species Act (ESA) for all listed species.
- EPA concluded that no data or new assessment was needed for the registration review of GnRH.
- An exemption order for EDSP has been prepared for signature by OSCPP IO, which is anticipated to be signed by the OCSPP AA mid-August 2020.

Proposed Mitigation in PID and ID Changes

- EPA did not propose or require any further data or mitigation measures.
- PRD plans to move forward with completing the Final Decision in September 2020 for all uses once the EDSP Exemption Order is finalized and signed by the OCSPP AA.

Communications— There was no stakeholder reaction to the combined GnRH FWP/DRA/PID. The agency anticipates minimal reaction to the GnRH Final Decision.

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MCPA Registration Review Interim Decision

Current Status

- MCPA is a selective, post-emergence, systemic phenoxy herbicide used to control perennial and broadleaf weeds in a variety of agricultural, residential, and non-agricultural sites.
- After the PID comment period, the human health DRA/ORE were revised, and the mitigation was updated consistent with the risks identified in the revised DRA/ORE. PRD plans to move forward with completing the ID in September 2020 for all uses except clover and then amend the ID once the data supporting the clover use is submitted and reviewed by OPP.
- Publication target (flexible): October, carryover from Q3

Key Points

- OPP published DRAs in November 2018 and identified outstanding residue chemistry data to support the direct use of MCPA to clover (forage and hay) and alfalfa (forage and hay). The MCPA Task Force Three (MCPA TF3) indicated they would not be supporting the data to retain these uses. The IR-4 project commented that they will be conducting field trials to support the direct use to clover (forage and hay) with an anticipated submission to EPA in July 2020.
- The MCPA TF3 provided comments of various substance on the MCPA DRAs and supporting documents that resulted in revisions to the human health DRA/ORE.
- The PID was published in December 2019 with mitigation consistent with the risks identified in the revised DRA/ORE.

Proposed Mitigation in PID and ID Changes

- The MCPA mitigation in the PID included: the prohibition of application methods for specific use sites, additional PPE, extended REIs, mandatory and advisory spray drift requirements, updated environmental hazards statements, resistance management, and various label cleanup measures. In addition, the proposed deletion of direct use of MCPA on alfalfa and clover without the supporting field trials.
- During the PID comment period, the MCPA TF3 identified errors in the revised DRA/ORE, resulting in an additional version of the revised DRA/ORE. Updated mitigation required in the ID includes the prohibition of backpack sprayers for rights-of-way, additional PPE, a 24-hour REI, mandatory and advisory spray drift requirements, updated environmental hazards statements, resistance management, and various label cleanup measures.
- The IR-4 Project commented on the PID regarding the preliminary data from the field trials, indicating that residues will be below the existing tolerances (<0.5 parts per million) for MCPA clover forage and clover hay. IR-4 has been in contact with PRD/RD and noted that the data are currently in the quality assurance audit phase and the final report is anticipated to be submitted in July 2020.

Communications

- PRD has met with MCPA TF3 and the registrants have agreed to the mitigation.
- The IR-4 project anticipates submitting data to EPA through an R298 action, which is to amend an established tolerance; domestic or import; submission of corresponding labels (13-month timeframe). At this time, the data has not yet been submitted.

Methyl Bromide Registration Review Interim Decision

Current Status

- Methyl bromide is a broad-spectrum fumigant chemical that can be used as an acaricide, antimicrobial, fungicide, herbicide, insecticide, nematicide, and vertebrate control agent for soil fumigation uses and for fumigation of imported and domestic commodities. There are no residential uses. Under the Clean Air Act and the Montreal Protocol, methyl bromide has been phased out and only quarantine and critical uses are allowed.
- Methyl Bromide is a restricted use pesticide and may only be applied by certified applicators or under the supervision of a certified applicator. An Amended Reregistration Eligibility Decision (RED) was completed for methyl bromide in May 2009.
- Publication target: September 2020

Key Points

- OPP performed extensive risk assessment and implemented significant risk mitigation during the reregistration of methyl bromide in 2009.
- Current methyl bromide labels require occupational handlers to wear various levels of personal protective equipment (PPE), perform active monitoring during the application, record site-specific monitoring plans and specify application parameters such as commodity aeration, work time restrictions, tarping, restricted entry periods, and buffer zones.
- The risk conclusions reached in the registration review draft human health and ecological risk assessments did not significantly alter the risk benefit determination outlined in the 2009 amended RED.
- Comments received on the draft risk assessment mostly focused on support for the use and benefits of methyl bromide. The Methyl Bromide Industry Panel (MBIP) comment disagrees that guideline 875.2500 (Inhalation Exposure Study) remains a data gap.

Proposed Mitigation in PID and ID Changes

- The methyl bromide PID outlines labeling updates, including amendments to PPE language, clarification of directions for use in shadehouses, strengthening existing fumigant management plan (FMP) requirements for commodity applications, and removing expired Critical Use Exemptions (CUE) uses from all existing labels.
- Based on stakeholder comments, the ID will retain the CUE uses on labels and clarify CUE label statements.

Communications

- The Methyl Bromide Industry Panel, USDA and growers who commented disagree with the removal of all CUE uses from labels. Comments submitted during the PID expressed overall concerns over the removal of these uses from labels, despite these exemptions no longer being in effect. These stakeholders should be satisfied that these CUE uses will not be removed.

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Pyrethroids Registration Review FY20 Q4 IDs (bifenthrin, cyfluthrins, cyphenothrin, deltamethrin, d-phenothrin, esfenvalerate, fenpropathrin, imiprothrin, permethrin, prallethrin, tau-fluvalinate, tefluthrin, tetramethrin)

Current Status/Key Points

- Pyrethroids are a class of insecticides which includes a total of 24 chemicals.
- They are broad-spectrum and target a wide range of pests in both agricultural and non-agricultural settings. Agricultural uses include rice, alfalfa, sunflowers, soybeans, wheat, tree nuts, vegetables, and other crops. Non-agricultural uses include public health mosquito abatement programs, indoor and outdoor residential/commercial and industrial spaces and structures, pets, clothing, and medical and veterinary products.
- The Registration Review Interim Decisions (IDs) for 13 pyrethroids will be completed in September 2020: bifenthrin, cyfluthrins, cyphenothrin, deltamethrin, d-phenothrin, esfenvalerate, fenpropathrin, imiprothrin, permethrin, prallethrin, tau-fluvalinate, tefluthrin, and tetramethrin.
- Ten pyrethroids pose no human health risks of concern. Three pyrethroids IDs being released finalize mitigation proposed in the May 2020 PIDs to reduce potential residential post application and occupational handler risks.
- Nine pyrethroids are labeled for agricultural uses which pose potential risks to pollinators (except tefluthrin), and, therefore, the IDs finalize pollinator labeling as proposed in the February and May 2020 PIDs. The OCSPP IO was briefed on and approved these proposed measures on 1/22/20. Pollinator labeling includes updated environmental hazards, and information on incident reporting, managed pollinator protection plans, and pollinator best management practices. Additional tier I pollinator data will be required for cases without a complete dataset.
- The agency is working on responding to comments and updating risk mitigation as necessary based on the comments.

Human Health Risks and Mitigation

- A separate human health risk assessment was conducted for each chemical. EPA proposed chemical specific human health mitigation in PIDs for each chemical between November 2019 and May 2020.
- The data and modeling generated by the Council for the Advancement of Pyrethroids Human Health Risk Assessment (CAPHRA), a group composed of registrants across a number of pyrethroid chemicals, in conjunction with available literature, was the basis of a decision to reduce the FQPA Safety Factor from 3x to 1x, resulting in changes to human health risk estimates for a number of pyrethroids.
    - EPA completed updated amendments to the human health risk assessments that reflect this change. These updated assessments were published between November 2019 and May 2020.
- The 1st pyrethroid white paper detailing EPA's scientific rationale for the safety factor reduction was released in August 2019. EPA received 14 public comments relating to this white paper and other human health issues. EPA will finalize its response to comments with the IDs in September.
- The 2nd pyrethroid white paper explaining the insufficiency of the current PBPK model to estimate uncertainty factors for individual pyrethroid risk assessments was provided to CAPHRA in December 2019 and published in February 2020. Comments were not accepted on this paper.
- Three IDs maintain mitigation that was proposed in their PIDs. Bifenthrin use requires mitigation to address potential residential post application risk. Bifenthrin, cyfluthrins, and prallethrin uses require mitigation to address potential occupational handler risks.

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Ecological Risks and Mitigation

- Risk to pollinators: There are potential acute risks of concern identified for bees from agricultural uses of pyrethroids. Bee mortality incidents confirm these findings.
- Risks to aquatic invertebrates and fish: There are potential risks to aquatic organisms because pyrethroids bind tightly to soil and aquatic organisms can be exposed from runoff and erosion.
- The agency issued a combined ecological risk assessment and a single Ecological Risk Mitigation Proposal to address risk to aquatic invertebrates and fish, because this class of chemicals exhibits a common insecticidal mode of action and shows similar ecological effects. Ecological mitigation focused on addressing runoff and spray drift concerns.

STAKEHOLDER RESPONSE

- Comments on the PIDs and the Ecological Risk Mitigation Proposal were received from registrants, state and regional agencies, university extensions, non-governmental organizations, crop and trade organizations, the U.S. Department of Agriculture, grower groups, and Pest Control Operators (PCOs). These comments did not result in changes to the human health aspects of the PIDs. Comments on the ecological risk mitigation will result in minor adjustments to the proposed runoff and/or spray drift labeling. The pyrethroid registrants requested EPA update the quantitative risk numbers in the ecological risk assessment based on information provided to EPA. While EPA is not updating the quantitative risk numbers EPA had previously considered the information and data provided by various sources qualitatively in the risk assessment and was extensively cited and relied on in EPA's risk management decision.

COMMUNICATIONS

- An OPP update, press release, and web updates are proposed for release of the pyrethroids IDs.

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Triazines (Atrazine, Simazine, & Propazine) IDs

Current Status:

- The triazines are a group of three chlorinated herbicides including atrazine, simazine and propazine.
- The triazines are used to control a variety of grasses and broadleaf weeds.
- OCSPP/OPP intends to complete the Interim Decisions (IDs) for atrazine, simazine, and propazine in September 2020.

Key Points:

- The triazines are among the most widely used herbicides in the United States and are of significant importance to corn, sorghum, and sugarcane growers.
- Atrazine only: In the PID, the agency proposed ending the requirement for the Atrazine Monitoring Program (AMP), which measures atrazine levels in surface drinking water, based on the conclusions of the atrazine draft risk assessment. The agency did not receive significant comment illustrating the continued need for monitoring through this program and therefore intends to proceed with discontinuing this requirement.
- Atrazine only: During the PID comment period, the agency received comments from grower groups in support of the concentration equivalent level of concern (CE-LOC) for aquatic plant communities of 15 μg/L as a 60-day average and comments against the CE-LOC from NGOs and individual citizens. The public comments did not result in changes to the agency's selection of the CE-LOC.

Proposed Mitigation in PID and ID Changes:

- The PIDs proposed additional Personal Protective Equipment (PPE) for workers, application rate reductions, spray drift control measures to minimize off-field drift, herbicide resistance management language, and a non-target organism advisory statement.
- Atrazine only: Based on a comment from the technical registrant, Syngenta Crop Protection LLC, some proposed changes to the tolerance expression are no longer required.
- Simazine only: Based on comments received during the public comment period, the agency reconsidered its proposed cancellation of simazine's residential turf uses. Instead, the agency will now require a rate reduction coupled with a requirement for irrigation immediately after application.

Communications:

- OCSPP/OPP has a triazine desk statement and Q&A's on-hand for any press inquiries.

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Q4 Conventional ID Summaries

Boscalid:
Release Interim Decision. Boscalid is a fungicide registered for use on row and orchard crops, as a seed treatment, and in residential areas. Potential worker risks of concern were identified for some occupational handler and post-application scenarios. Potential ecological risks of concern were identified for fish, aquatic invertebrates, birds, and mammals. To mitigate risks of concern, EPA is requiring mandatory spray drift management language, the use of gloves for certain handler scenarios, an increased REI for certain post-application activities in grapes, directions for the user to clean up spilled treated seed, and updates to surface and ground water advisories. Anticipated stakeholder reaction: Minimal stakeholder feedback is expected.

Cyproconazole:
Release Interim Decision. Cyproconazole is a broad-spectrum fungicide currently registered for use on field and seed corn, peanuts, soybeans, wheat, and triticale. It is no longer registered as a wood preservative (former AD use). There were no human health risks of concern for cyproconazole. Potential chronic risk concerns were identified for birds, reptiles, terrestrial-phase amphibians, and terrestrial invertebrates. Required mitigation includes reducing potential ecological risks by advisory spray drift language and fungicide resistance management. Anticipated stakeholder reaction: Minimal stakeholder feedback is expected.

Ethoxyquin:
Release Interim Decision. Ethoxyquin is a post-harvest antioxidant used to control browning (scald) in pears. The ethoxyquin human health risk assessment did not identify human health risks of concern. Given the chemical's limited use pattern (indoors only) and environmental fate, the agency determined *de minimis* ecological risk, and issued a "no effects" determination. The agency expects to publish the ID a quarter early, in September 2020. Anticipated stakeholder reaction: Minimal stakeholder feedback is expected.

Etoxazole:
Release Interim Decision. Etoxazole is an acaricide/ovicide in the diphenyloxazoline class. The agency identified potential risks of concern to certain occupational handlers, and to pollinators and aquatic invertebrates. To mitigate the potential concerns for occupational handlers, the agency is requiring respiratory protection for some uses and formulations. To address potential risks of concern to pollinators and aquatic invertebrates, the agency is requiring that product labels include updated spray drift management language. Anticipated stakeholder reaction: Minimal stakeholder feedback is expected.

Fluazifop-P-butyl:
Release Interim Decision. Fluazifop-P-butyl (fluazifop) is a post-emergent herbicide used to control grass weeds, with products registered for use on a variety of agricultural crops, lawns/turf, ornamentals/landscaping, non-bearing trees, and non-crop areas. Potential risks of concern were identified to occupational handlers engaged in mixing and loading liquid formulations for aerial applications and in mixing, loading, and applying liquid formulations by mechanically pressurized handguns. To mitigate the mixer/loader risks, the agency will increase PPE requirements for mixing/loading liquids for aerial applications. To mitigate the mixer/loader/applicator risks, the agency will require dilution of the spray solution by requiring a minimum spray volume of 55 gallons per acre for mechanically pressurized handgun applications. Potential risks of concern were also identified to terrestrial mammals, birds,

invertebrates (honey bees), and plants. To mitigate these potential ecological risks, the agency will require enforceable spray drift language on all fluazifop labels. Anticipated stakeholder reaction: Minimal stakeholder feedback is expected.

Mecoprop (MCPP-p):
Release Interim Decision. Mecoprop is a selective postemergence herbicide registered for use to control broadleaf weeds in non-agricultural use sites, including drainage ditch banks, golf courses, lawns, rights-of-way, roadsides, and sod farms. There are no human health risks of concern for mecoprop. Potential risks of concern were identified for mammals (chronic), birds (acute and chronic), terrestrial invertebrates (chronic for larvae), and aquatic and terrestrial plants. Required mitigation focuses on reducing ecological risks by issuing mandatory and advisory spray drift management and herbicide resistance management. The 48-hour restricted entry interval will be updated based on acute toxicity. Anticipated stakeholder reaction: Minimal stakeholder feedback is expected.

Pinoxaden:
Release Interim Decision. Pinoxaden is a selective and systemic herbicide registered for use to control annual grass weeds and broad leaf weeds in wheat and barley, and for use on turf including golf courses, sod farms, sports fields, and residential and commercial turf areas. There are no human health risks of concern. For ecological risk, potential exceedances of the level of concern were identified for monocot terrestrial plants, and for larval bees from chronic exposure; however, risk to bees is not expected as currently labeled crops are not attractive to bees. Required mitigation to reduce ecological risk includes mandatory spray drift language, a non-target organism advisory statement, herbicide resistance management language, and a requirement that all products labeled for use on wheat and barley specify the maximum annual application rate. Anticipated stakeholder reaction: Minimal stakeholder feedback is expected.

Pyraclostrobin:
Release Interim Decision. Pyraclostrobin is a broad-spectrum strobilurin fungicide that inhibits mitochondrial activity in fungi and exhibits some local systemicity in terrestrial plants. It is used to control a wide range of fungal diseases such as damping-off, blight, downy mildew, powdery mildew and snow mold in both agricultural and non-agricultural use sites, including residential sites. Only one product is labeled for homeowner use. The agency has determined that there are occupational and occupational post-application risks of concern. Ecological risks of concern were identified for mammals, terrestrial invertebrates, freshwater fish and invertebrates, aquatic-phase amphibians, and freshwater diatoms. The Proposed Interim Decision was published in May 2020 with mitigation including (1) PPE for occupational handlers-in-field uses, (2) engineering control requirement, (3) modify restricted-entry intervals, (4) spray drift management, (5) environmental hazard statements, and (6) fungicide resistance management. Comments opposed the long REIs in grapes; USDA and grower groups question the way EPA describes and assess certain activities. Common issue across multiple fungicides and insecticides used in grapes. Anticipated stakeholder reaction: The stakeholder reaction to the pyraclostrobin Proposed Interim Decision was minimal and it is anticipated that there will be some stakeholder reaction from within the grape-growing industry in response to the pyraclostrobin Interim Decision.

Pyraflufen-ethyl:
Release Interim Decision. Pyraflufen-ethyl is a contact herbicide, registered for the control of certain broadleaf weeds in many agricultural and non-agricultural use sites. It is used as a defoliant in cotton and a desiccant in potatoes to facilitate the harvesting of these crops. There are no human health risks of concern for pyraflufen-ethyl. Potential ecological risks of concern were identified for fish and terrestrial

and aquatic plants. The Proposed Interim Decision was published in May 2020 with the following mitigation: (1) update gloves statement, (2) mandatory and advisory spray drift language, (3) herbicide resistance management language, and (4) non-target organism advisory. Anticipated stakeholder reaction: The stakeholder reaction to the pyraflufen-ethyl Proposed Interim Decision was minimal and it is anticipated that there will be minimal reactions to the pyraflufen-ethyl Interim Decision.

Pymetrozine:
Release Interim Decision. Pymetrozine is a systemic insecticide registered for use on a wide variety of crops (i.e. potatoes, pecans, tomatoes, lettuce, and cole crops), ornamental plants, non-bearing fruit and nut trees in nurseries, and Christmas trees. Pymetrozine use is permitted in residential settings; however, based on label-required personal protective equipment (PPE), homeowners are not expected to apply pymetrozine. There are potential human health risks of concern, including cancer and non-cancer risk from dietary exposure through food and drinking water sources, aggregate risk resulting from the combination of dietary exposure and residential post-application contact with residues in home gardens, and occupational non-cancer risk to handlers from mixing and loading pymetrozine for aerial application to high acreage crops or chemigation on potatoes. There are potential chronic risks to mammals, birds, reptiles, terrestrial phase amphibians, and aquatic invertebrates as well as a potential risk to terrestrial invertebrates. Required mitigation includes restrictions on pymetrozine use on vulnerable soils and well setback and/or runoff management system for an outdoor ornamental/nursery production scenario, rate reductions for ornamentals grown outdoors, respirators for mixers and loaders of aerial and chemigation application equipment, advisory spray drift reduction language, insecticide resistance management, and updating maximum applications per year. Anticipated stakeholder reaction: Minimal stakeholder feedback is expected.

Thiabendazole and salts:
Release Interim Decision. Thiabenzadole is a systemic fungicide with both antimicrobial and conventional uses. Thiabendazole is registered for use on mushroom crops, for seed treatment uses, and for post-harvest or bulb-dip treatments on various agricultural crops. The salt, thiabendazole hypophosphite, is registered for use as a tree injection. Antimicrobial uses of thiabendazole include use as a preservative in adhesives, coatings, paper, textiles, and paints. Potential human health risks of concern were identified for certain occupational exposures from conventional and antimicrobial uses. For ecological risk, potential risks of concern were identified from conventional uses for seed-eating birds and mammals. A down-the-drain screening-level analysis of the antimicrobial uses shows potential risks to aquatic organisms. Occupational risks of concern from conventional uses resolve with the addition of a respirator. Occupational risks of concern from antimicrobial uses resolve with a reduction in the use rate. Data on thiabendazole content of spent mushroom compost has been provided to the agency. Anticipated stakeholder reaction: Minimal stakeholder feedback is expected.

Q4 Antimicrobial ID Fact Sheets

Chlorine Gas Interim Decision

Current Status

- Chlorine gas is registered for use as a disinfectant and sanitizer to treat water in industrial and commercial processes.
- OCSPP intends to complete the Interim Decision (ID) for the registration review of chlorine gas.

Key Points

- Chlorine gas is used as a disinfectant and sanitizer in commercial and industrial cooling towers (once-through and recirculating), municipal water supplies and treatment plants, sewage and wastewater management plants, pulp and paper mills, swimming pools, agricultural irrigation systems, and public water systems.
- Products containing chlorine gas are formulated as 99.5% liquid compressed chlorine gas.
- Chlorine gas is extremely irritating, poisonous, and explosive.
- Chlorine is formulated as a pressurized gas and distributed in large stationary containers such as tank cars, tank trucks, or 150-pound to 1-ton cylinders.
- Chlorine gas should be used only by trained, experienced personnel, under the supervision of the registrant. Chlorine gas users are also subject to state and municipal regulatory requirements.
- EPA published a Draft Risk Assessment (DRA) for chlorine gas in 2019 which found no human health or ecological risks of concern.

Proposed Mitigation in PID and ID changes

- Because of EPA's risk findings, OCSPP proposed the following mitigation:
    - Due to high acute toxicity of compressed chlorine gas, OCSPP proposes to classify chlorine gas as a restricted use pesticide (RUP) for all uses except public water systems, municipal water supplies and treatment plants, and sewage and wastewater treatment plants. RUPs are for sale and use by certified operators only. Drinking water and wastewater treatment uses are already covered by federal, state, and local certification requirements that apply only to water and wastewater treatment operators. Stakeholders commented on the PID to indicate their support for classifying chlorine gas as a RUP as proposed.
    - OCSPP also proposes to add label language for discharging chlorine-treated pool water.
- However, current labels are not in compliance with labeling elements required by FIFRA and outlined in 40 CFR § 156.10; therefore, OCSPP proposed to move key label requirements from a reference to a third-party guidance (*i.e.*, Chlorine Institute pamphlets) onto the actual pesticide labels, including incorporating label changes identified and requested back in the 1999 Reregistration Eligibility Decision (RED). This would include the following:
    - Range of application rates, including minimum and maximum;
    - Application methods and use sites;
    - Specific directions for use;
    - Protective personnel equipment (PPE);
    - Storage and disposal instructions, *e.g.*, store in a dry area, away from sources of heat, separate from other gasses, procedures in the event of a damaged or leaking tank; and
    - First aid and precautionary statements.

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- The label would cite to Chlorine Institute pamphlets for additional guidance beyond FIFRA's required label elements.
- Public comments submitted by registrants as well as industry groups indicate relevant stakeholders are in favor of the label cleanup and RUP classification proposed in the PID. Therefore, these changes will remain in the ID.

Communications

- No rollout is proposed; OCSPP/OPA will have a desk statement on hand for any press inquiries.
- Press attention: expected to be minimal.
- Stakeholder reactions: Public comments submitted by registrants (represented by the Chlorine Institute) and industry groups (American Water Works Association, American Chemistry Council, municipal water boards) indicate they are in favor of the label cleanup and RUP classification as proposed in the PID.

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Q4 Antimicrobial ID Summaries

Phenol and Salt:
Release Interim Registration Review Decision (ID). The phenol and salt case contains two active ingredients: phenol and the alkali metal salt of phenol - sodium phenate. Products containing phenol and sodium phenate are registered for use as hard surface disinfectants, deodorizers and cleaners and are primarily used in remediation situations such as mold/mildew cleaning and crime scene clean-up. They are also registered for use in food handling/storage premises and hospitals as well as in residential premises and to clean and deodorize washable fabrics. The DRA identified risks associated with commercial dietary exposures as well as occupational handler dermal and vapor inhalation exposures. AD is requiring the following mitigation strategies: In order to mitigate commercial dietary risks, labels will specify that phenol and salt products can only be used on floors and walls in food premises, but not food contact surfaces. Occupational handler risks will be mitigated by limiting the duration of use of phenol products by occupational handlers, as well as requiring personal protective equipment (PF10 respirators and chemical resistant gloves). There are no risks identified for aquatic or terrestrial organisms, and the Agency is a making a "no effects" determination for Federally listed species and their designated critical habitats. Anticipated Stakeholder Reaction: Minimal stakeholder reaction is anticipated. Mitigation strategies were created with input from the registrants and no comments were received in response to the proposed interim decision.

Terbuthylazine:
Release Interim Decision. Terbuthylazine is registered as a bactericide, fungicide, and algaecide to be used in recirculating cooling towers and ornamental/decorative fountains. A human health risk assessment for registered uses of terbuthylazine is not needed for registration review, as there are no exposures in food and drinking water, and there are no residential exposures. Application of currently registered products in recirculating cooling towers and ornamental/decorative is restricted to closed-system loading and delivery. Open pouring is prohibited. Terbuthylazine is highly toxic to aquatic organisms (including plants) but nontoxic to birds. Label changes are being required to reduce ecological exposures from discharges by recirculating cooling towers and ornamental/decorative fountains. Anticipated stakeholder reaction: One comment was received supporting the conclusions of the PID, and minimal stakeholder reaction is anticipated.

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Q4 BPPD ID Fact Sheets

None.

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Q4 BPPD ID Summaries

***Bacillus thuringiensis* Plant-incorporated Protectants (PIPs) in Cotton – Lepidopteran Pests:**
Release Interim Decision. In cotton, PIPs derived from the bacterium *Bacillus thuringiensis (Bt)* have been genetically engineered into cotton hybrids to provide insecticidal protection against certain major Lepidopteran insect pests, such as cotton bollworm (CBW; *Helicoverpa zea*), tobacco budworm (TBW, *Heliothis virescens*), and pink bollworm (PBW, *Pectinophora gossypiella*). The PIP active ingredients are designated by "events," which refer to specific acts of introducing the genetic material of the *Bt* trait into the cotton plant's genome. Nine *Bt* cotton PIP active ingredients have products containing them registered thus far. The individual PIP toxins have been combined with other *Bt* toxins to create "pyramided" varieties (i.e., two or more toxins targeting the same pest). *Bt* cotton pyramids are intended for commercial production by cotton growers; single PIP varieties are used for breeding purposes only. To date, a total of 17 products containing *Bt* cotton PIPs have been registered, including six pyramided products for commercial use and 11 single trait products for breeding purposes. These products are sold to growers in the form of seeds, which must be planted according to label instructions designed to enhance Insect Resistance Management (IRM). No human health or ecological risks were identified. Anticipated stakeholder reaction: Minimal stakeholder reaction is expected.

Coniothyrium species:
Release Interim Decision. *Coniothyrium minitans* strain CON/M/91-08 is a naturally occurring soil microorganism and mycoparasite of the sclerotia of Ascomycotina and Deuteromycotina (e.g., the common plant pathogens, *Sclerotinia sclerotiorum* and *Sclerotinia minor*). It is registered for use to reduce/control *Sclerotinia sclerotiorum* and *Sclerotinia minor* in agricultural soil. It is registered for use on agricultural crops, greenhouses, and nursery soil where plants are susceptible to *Sclerotinia sclerotiorum* and *Sclerotinia minor*. No human health or ecological risks were identified. No mitigation or labeling changes are needed for the registration review of *Coniothyrium* species. Anticipated stakeholder reaction: Minimal stakeholder reaction is anticipated.

Flower Oils:
Release Interim Decision. Flower oils are natural components of plants with nontoxic modes of action. They are used in a range of pesticide and nonpesticide products. The flower oils case includes the following active ingredients: oil of mustard, oil of citronella, indole, lavandin oil, oil of lemongrass, oil of eucalyptus, oil of orange, eugenol, bergamot oil, alpha-ionone, balsam fir oil, geraniol, and oil of thyme. Products containing flower oils are registered for use as insect repellants and used on all agricultural commodities. No human health or ecological risks were identified. No mitigation or labeling changes are needed for the registration review of flower oils. Anticipated stakeholder reaction: Minimal stakeholder reaction is anticipated.

Gliocladium species:
Release Interim Decision. *Gliocladium* strains (*Gliocladium virens* G-21 *and Gliocladium catenulatum* strain J1446) are naturally occuring fungi found throughout the United States. Pesticide products containing *Gliocladium* as an active ingredient are registered for use as a fungicide. Pesticide products containing *Gliocladium* prevent plants from becoming infected with root rots and various other fungal disease. No human health or ecological risks were identified. No mitigation or labeling changes are needed for the registration review of *Gliocladium* species. Anticipated stakeholder reaction: Minimal stakeholder reaction is anticipated.

Vegetable Oils:
Release Interim Decision. Vegetable oils are natural components of plants with nontoxic modes of action. They are used in a range of pesticide and nonpesticide products, such as cosmetics or commonly consumed cooking oils. The vegetable oils case contains the following active ingredients: canola oil, soybean oil, castor oil, and jojoba oil. Products containing vegetable oils are registered for use as fungicides, miticides, insecticides, and insect repellants and used on all agricultural commodities. No human health or ecological risks were identified. Anticipated stakeholder reaction: Minimal stakeholder reaction is expected.

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