Docket Number EPA-HQ-OPP-2016-0077 and EPA-HQ-OPP-2016-0139

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Bromethalin and Cholecalciferol

Proposed Interim Registration Review Decision
Case Numbers 2765 and 7600

November 2022

Approved by: _____

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Proposed Interim Registration Review Decision (PID) for bromethalin (PC Code 112802; Case 2765) and cholecalciferol (PC Codes 202901; Case 7600). In a registration review decision under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), the Agency determines whether a pesticide continues to meet FIFRA's registration standard.[1] Where appropriate, the Agency may issue an interim registration review decision before completing a registration review.[2] Among other things, the interim registration review decision may determine that new risk mitigation measures are necessary, lay out interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review.[3] For more information on bromethalin see EPA public docket EPA-HQ-OPP-2016-0077; for more information on cholecalciferol, see EPA's public docket EPA-HQ-OPP-2016-0139 at www.regulations.gov.

FIFRA[4] mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. In 2006, the Agency began implementing the registration review program. EPA will review each registered pesticide every 15 years. Through the registration review program, the Agency intends to verify that all registered pesticides continue to meet the registration standard as the ability to assess and reduce risk evolves and as policies and practices change. By periodically re-evaluating pesticides as science, public policy, and pesticide-use practices change, the Agency ensures that the public can continue to use products in the marketplace that do not present unreasonable adverse effects. For more information on the registration review program, see http://www.epa.gov/pesticide-reevaluation.

The Agency is issuing a PID for bromethalin and cholecalciferol[5] so that it can (1) move forward with aspects of the registration review that are complete and (2) propose interim risk mitigation (see Appendices A and B). EPA is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service to improve the consultation process for national threatened and endangered (listed) species for pesticides under the Endangered Species Act (ESA).[6] The Agency has not yet fully evaluated bromethalin and cholecalciferol's risks to federally listed species. However, EPA expects to complete its listed-species assessment by November 2024 and subsequently, initiate any necessary consultation with the Services. Additionally, before completing registration review, EPA will complete endocrine screening for bromethalin and cholecalciferol under the Federal Food, Drug, and Cosmetic Act (FFDCA).[7] For more

[1] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57.
[2] 40 C.F.R. §§ 155.56, 155.58.
[3] 40 C.F.R. § 155.56.
[4] As amended by the Food Quality Protection Act (FQPA) of 1996, Pub. L. No. 104-170, 110 Stat. 1489.
[5] Along with bromethalin and cholecalciferol, the Agency is also issuing the PIDs for other rodenticides (chlorophacinone, diphacinone, warfarin, brodifacoum, bromadiolone, difenacoum, difethialone, strychnine, and zinc phosphide).
[6] Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.
[7] Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), 21 U.S.C. § 346a(p).

information on the listed-species assessment and the endocrine screening for the bromethalin and cholecalciferol registration review, see Appendices F and G.

Bromethalin is a single-dose poison that blocks nerve transmissions and was developed in the 1980s. Bell Laboratories Inc., HACCO Inc., and Woodstream Corporation are the three technical registrants for bromethalin. Cholecalciferol is a sterol also known as Vitamin D_3 and has been used as a rodenticide since the 1980s; there are no technical registrants for this rodenticide, but there are end use registrations.

EPA completed the Rodenticide Cluster RED in 1998, which included bromethalin, a neurotoxic rodenticide, and certain anticoagulant rodenticides. In 2008, EPA issued its Risk Mitigation Decision (RMD) for Ten Rodenticides, hereafter referred to as the 2008 RMD[8], which constituted the Agency's final action in response to the remand order in *West Harlem Environmental Action and Natural Resources Defense Council v. U.S. Environmental Protection Agency*, 380 F.Supp.2d 289 (S.D.N.Y.2005). Although neither are anticoagulants, both bromethalin and cholecalciferol were included in the 2008 RMD. The 2008 RMD included additional restrictions in the form of label mitigation to reduce the potential for non-target organism exposure, including children and non-target wildlife. In 2012, the Agency revised the 2008 RMD, that allowed for greater flexibility for professional use commensal rodenticide products.

There are EPA-registered bromethalin products intended for commercial use (sold in packages $\geq$ 4 lbs bait) on rats, mice, wood rats, voles, and moles inside of and within 100 feet (ft) of structures with some products allowing burrow baiting and/or use in sewers. There are also EPA-registered bromethalin products intended for residential use (sold in packages $\leq$ 1 lb of bait) on rats and mice inside of and within 50 ft of structures and also registered for use in burrows to control moles.

There are EPA-registered cholecalciferol products intended for commercial use (sold in packages $\geq$ 4 lbs bait) on rats and mice inside of and within 100 ft of structures with some products allowing burrow baiting. There are also EPA-registered cholecalciferol products intended for residential use (sold in packages $\leq$ 1 lb of bait) on rats and mice inside of and within 50 ft of structures.

Endangered Species Assessment(s) for Rodenticides

The anticoagulant rodenticides brodifacoum, bromadiolone, and warfarin and its sodium salt, as well as the non-anticoagulant rodenticide zinc phosphide are rodenticide active ingredients mentioned in a stipulated partial settlement agreement in the case of Center for Biological Diversity (CBD) v. United States Environmental Protection Agency, No. 3:11 cv 0293 JCS (N.D. Cal). Among other provisions, this agreement sets a November 2024 deadline for EPA to complete nationwide ESA section 7(a)(2) effects determinations for brodifacoum, bromadiolone, warfarin and its sodium salt, and zinc phosphide and as appropriate, initiate any consultation(s) with the Services that EPA may determine to be necessary as a result of those effects determinations. In addition to those four active ingredients, EPA also intends to make effects determinations, and consult as appropriate, on the additional anticoagulant rodenticide active

[8] Available from www.regulations.gov @EPA-HQ-OPP-2006-0955-0764

ingredients chlorophacinone, difenacoum, difethialone, diphacinone and its sodium salt, and the non-anticoagulant rodenticides bromethalin, cholecalciferol, and strychnine by November 2024. Prior to completing its effects determinations, the Agency plans to issue a draft biological evaluation (BE) for these 11 rodenticide active ingredients for a 60-day public comment period by the end of November 2023.

Therefore, as noted above, EPA intends to conduct a grouped assessment of potential effects of 11 rodenticide active ingredients on listed species and their designated critical habitats. In addition to effects determinations, EPA intends to predict whether any of the currently registered rodenticide uses are likely to jeopardize listed species or adversely modify their designated critical habitats. For those species or designated critical habitats where EPA predicts that jeopardy or adverse modification is likely, EPA intends to identify and incorporate mitigations before concluding registration review. EPA expects to mitigate to an extent necessary to reduce exposure, through avoidance and minimization, such that EPA can predict that there is no likelihood of jeopardy and adverse modification.

In support of this PID, EPA has completed a partial ESA assessment by making draft effects determinations for three pilot species and one designated critical habitat with predictions on the likelihood of jeopardy to the three pilot species and adverse modification to the designated critical habitat. EPA has also proposed mitigations for these three species and critical habitat. EPA intends to discuss the draft effects determinations in this pilot assessment and the proposed mitigations with FWS. After considering both input from FWS and public comments, EPA may revise the analyses and mitigations, if appropriate. EPA is using this group of three species and one critical habitat as a pilot to establish an approach for assessing potential effects and identifying mitigations to avoid and minimize exposure such that jeopardy or adverse modification is not likely for listed species or designated critical habitats. EPA also intends to apply approaches used for these three species and one critical habitat in the final analyses to all listed species and designated critical habitats that may be exposed to rodenticides.

This document is organized in five sections:

- *Introduction* (summarizing the registration review milestones and responding to public comments on the draft risk assessments);
- *Use* (discussing how and where bromethalin and cholecalciferol are used);
- *Scientific Assessments* (summarizing EPA's risk and benefits assessments, updating or revising previous risk assessments, and discussing risk characterization);
- *Proposed Interim Registration Review Decision* (presenting EPA's proposed decision, regulatory rationale, and any mitigation measures to address risks of concern); and
- *Next Steps and Timeline* (discussing how and when EPA intends to complete registration review).

A. Summary of Bromethalin and Cholecalciferol Registration Review

On July 15, 2016, the Agency formally initiated registration review for bromethalin and cholecalciferol with the opening of registration review dockets for the two cases.[9] The following summary highlights the docket openings and other significant milestones that have occurred thus far during the registration review of bromethalin and cholecalciferol:

[9] 40 C.F.R. § 155.50

- July 2016 – EPA posted the *Bromethalin Preliminary Work Plan* (PWP) (June 28, 2016), *Cholecalciferol Preliminary Work Plan* (PWP) (June 29, 2016), *Bromethalin Human Health Scoping Document in Support of Registration Review* (May 16, 2016), *Cholecalciferol Human Health Scoping Document in Support of Registration Review* (May 15, 2016), *Problem Formulation for the Environmental Fate, Ecological Risk, and Drinking Water Assessments to be Conducted in Support of the Registration Review for Bromethalin* (June 27, 2016), and *Addendum: Registration Review: Preliminary Problem Formulation for Environmental Fate, Ecological Risk, Endangered Species, and Human Health Drinking Water Exposure Assessments for Cholecalciferol* (June 29, 2016) to the respective public dockets for a 60-day public comment period.

- December 2016 – EPA posted the *Bromethalin Final Work Plan* (FWP) (December 19, 2016) and *Cholecalciferol Final Work Plan* (FWP) (December 19, 2016) to the public docket. The Agency received two comments on the bromethalin PWP and three comments on the cholecalciferol PWP. The comments did not result in changes to scheduling, the planned data requirements, or planned risk assessments.

- February 2019 – EPA issued generic data call-ins (GDCIs) for bromethalin and for cholecalciferol to obtain data needed to conduct the registration review risk assessments (GDCI-112802-1717 and GDCI-202901-1621, respectively). The Agency has waived the ecological effects data requirements (SS-1311: honeybee adult acute oral toxicity and 850.2300: avian reproduction) and guideline 870.7485 (Metabolism and Pharmacokinetics) for bromethalin. EPA has waived data requirements for guideline 850.2300 (Avian Reproduction), 870.3700 (Prenatal Developmental Toxicity), and 870.7485 (Metabolism and Pharmacokinetics) for cholecalciferol. Both GDCIs are considered fulfilled.

- May 2020 – EPA posted the 2020 HH DRAs (*Bromethalin: Draft Human Health Risk Assessment for Registration Review* (March 20, 2020), and *Cholecalciferol: Draft Human Health Risk Assessment for Registration Review* (March 24, 2020) and the 2020 Eco DRAs (*Bromethalin: Draft Ecological Risk Assessment for Registration Review* (March 31, 2020), and *Cholecalciferol: Draft Ecological Risk Assessment for Registration Review* (March 31, 2020) for a 60-day public comment period. For bromethalin the Agency received two comments from two commenters and for cholecalciferol the Agency received eight comments from seven commenters posted to the respective dockets. An additional comment was posted to the bromadiolone docket (EPA-HQ-OPP-2015-0768-0046) that mentions bromethalin and cholecalciferol. The Agency has summarized and responded to these comments in Section I.B., below. The comments did not change the risk assessments or registration review timeline for bromethalin and cholecalciferol.

- November 2022– EPA completed this PID for bromethalin and cholecalciferol and it is available in the public docket for a 75-day public comment period. Along with the PID, EPA plans to post the following documents to the public docket:
    - *Rodenticides: Draft Effects Determinations and Evaluation of Proposed Mitigations Intended to Avoid Jeopardizing Three Federally Listed Endangered*

and Threatened Species and Avoid Adversely Modifying One Designated Critical Habitat (September 28, 2022)
- *Rodenticides: Revised Tier 1 Update Review of Human Incidents* (October 11, 2022)
- *Use and Benefits Assessment for 11 Rodenticides and Impacts of Potential Risk Mitigation* (October 27, 2022)
- *Response to Public Comments on Draft Ecological Risk Assessment for 7 Anticoagulant Rodenticides* (April 5, 2021)

B. Summary of Public Comments on the Draft Risk Assessments and Agency Responses

During the 60-day public comment period for the bromethalin and cholecalciferol draft risk assessments (May 4, 2020 to July 6, 2020), the Agency received seven unique public comments. All seven comments were submitted to the cholecalciferol docket. Two comments (Center for Biological Diversity (CBD) and United States Department of Agriculture (USDA)/Office of Pest Management Policy (OPMP)) were also submitted to the bromethalin docket. Comments were submitted by four anonymous public commenters, USDA/OPMP, CBD, and Responsible Industry for a Sound Environment (RISE). The Agency has summarized and responded to all substantive comments and comments of a broader regulatory nature below. The Agency thanks all commenters for commenting and has considered all comments in developing this PID.

Comments Submitted by Anonymous Public Commenters (Docket IDs: EPA-HQ-OPP-2016-0139-0020, -0021, -0022, & -0023)

Comment: All four comments pertain to environmental impacts of anticoagulant rodenticides, not bromethalin or cholecalciferol, and the primary and secondary poisoning of wildlife.

EPA Response: EPA appreciates this feedback and input from the public and has relayed these comments to the anticoagulant rodenticide team.

Comments Submitted by Center for Biological Diversity (CBD) (Docket IDs: EPA-HQ-OPP-2016-0077-0020 and EPA-HQ-OPP-2016-0139-0026, -0027)

Comment: CBD's comments focus on the EPA's duty under the Endangered Species Act (ESA) to consult with the Services on the registration review of bromethalin and cholecalciferol. CBD's comments mention various aspects of the risk assessment process (*e.g.*, use of the best available data), including necessary data and studies (*e.g.*, those necessary to develop listed-species risk assessments) and evaluation of effects on listed species and their designated critical habitat. CBD also expressed concern about the rigor of EPA's preliminary determinations for this registration review regarding the effects of bromethalin/cholecalciferol on listed species and their designated critical habitat. CBD also expressed concern about the effects of bromethalin and cholecalciferol on pollinators and other beneficial insects, possible endocrine disruption effects on human health and environmental safety, and any additive, cumulative and synergistic effects from the use of bromethalin and cholecalciferol. CBD also expressed concern over misuse and illegal uses of rodenticides.

EPA Response: Through registration review of bromethalin and cholecalciferol, EPA intends to identify mitigation to avoid likely jeopardy to listed species and adverse modification of their critical habitats. EPA intends to complete a draft biological evaluation (BE) in November 2023. This BE will also include draft predictions of likely jeopardy and adverse modification. EPA will also identify mitigation intended to avoid and minimize exposures such that the uses of the rodenticides will not likely jeopardize listed species or adversely modify their critical habitats. EPA has completed a draft analysis with pilot species that will be used to inform analyses and mitigations for other listed species that will be incorporated into the BE. EPA intends to complete a final BE for all of the rodenticides in November 2024.

EPA is currently developing a policy on how to consider synergy claims made by registrants in their patents and patent applications. For more information on this policy, see the interim process posted for public comment on September 9, 2019, to EPA's public docket (EPA-HQ-OPP-2017-0433).

Additionally, EPA considered the potential for non-target exposure in the development of risk mitigation measures as part of the bromethalin and cholecalciferol's registration review. For more information, see Section IV.A. Proposed Risk Mitigation and Regulatory Rationale.

Comments Submitted by Responsible Industry for a Sustainable Environment (RISE) (Docket ID: EPA-HQ-OPP-2016-0139-0024)

Comment: RISE commented that certain exposure data calculations appear to be errors resulting from copying or transposing data from various sources as they are off by several orders of magnitude. Revising these calculations will provide a more accurate exposure picture. RISE recommended the 2004 Erickson data as one source for refining and revising the calculations.

EPA Response: EPA obtained formulas for calculations of exposure from its past risk assessments and re-ran those calculations to ensure that the same results were found. EPA would appreciate any specific examples of calculations which may be in error as no errors were identified as part of the re-assessment.

Comment: RISE commented that it is unclear why incidents from island eradication efforts were included in the risk assessment and stated that more explanation would be helpful as well as providing as opportunity for refinement as these applications are unique and unusual. While essential for protecting species and fragile island ecosystems, they are not representative of typical labeled use patterns.

EPA Response: EPA recognizes that the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspective Service (APHIS) registrations are used in support of conservation efforts in consultation with the FWS and APHIS takes appropriate measures to safeguard protected species while using rodenticides for this purpose. Therefore, these incidents were included in EPA's analysis because they constituted an approved, controlled use of these rodenticides. They also offer a unique situation where these chemicals are used, and there is systematic monitoring afterwards to give insight into the ecological risks and secondary exposure.

Comment: RISE commented that relative to chronic toxicity to birds, they believe that the risk assessment could be further refined for most, if not all, of the rodenticides based on existing label

instructions (e.g., bait used outdoors and above ground is required to be in tamper-resistant bait stations designed to exclude non-rodent animals) and bait station design (e.g., bait stations limit the size of birds that could enter the bait stations and the amount of bait that could be consumed). RISE also commented that in the event of accidental non-target exposure, it is unrealistic that this would be a repeated occurrence.

EPA Response: The Agency has taken current mitigation measures into account in its decision-making. While bait stations are intended to limit exposure, it cannot be precluded, especially when considering secondary exposure. EPA has waived avian reproduction studies for cholecalciferol. For secondary exposure, chronic exposure is possible due to the persistence of the chemicals in target animals and the fact that the bait is likely to be present (for primary consumption) for prolonged periods of time at different locations. Chronic/sublethal effects in birds are possible given the exposures and body burdens documented in wildlife incident reports.

Comments Submitted by the United States Department of Agriculture Office of Pest Management Policy (USDA/OPMP) (Docket ID: EPA-HQ-OPP-2016-0077-0021 and EPA-HQ-OPP-2016-0139-0025)

Comment: USDA OPMP commented on the 2020 HH DRA and 2020 Eco DRA and supported EPA's streamlined approach to the risk assessments for the rodenticides. USDA OPMP stated that it is ready to provide EPA with additional information on the benefits of these rodenticides, as well as additional characterization information to help address and/or refine EPA's risk estimates, if needed.

EPA Response: EPA appreciates the additional information provided by USDA OPMP when requested regarding the importance of continued registration of various rodenticide products, their benefits, and additional characterization especially as they relate to conservation, agriculture, and public health uses. Since submission of this comment, USDA OPMP has provided EPA with additional use, usage, and benefits information for the Agency's consideration that has been incorporated into this PID. For more detailed information on the use, usage, and benefits information, see *Use and Benefits Assessment for 11 Rodenticides and Impacts of Potential Risk Mitigation* (October 27, 2022).

Comment: USDA OPMP commented that certain site-specific mitigations can further reduce exposure to wildlife. For example, elevating bait stations can eliminate access to bait for many protected mammal species, such as kangaroo rats and the Tulare grasshopper mouse, which are not associated with climbing trees.

EPA Response: EPA appreciates and welcomes OPMP's suggestions for Best Management Practices (BMPs) like the use of elevated bait stations). The California Department of Pesticide Regulation (CalDPR) has shared specifications for both a modified and elevated bait station which is referenced later in this PID as it pertains to the Agency's proposed mitigation intended to reduce potential exposures to and take for listed species.

Comment: USDA encourages EPA to continue to examine the efficacy of prior mitigations, and to consider the importance of rodenticide uses when developing any additional mitigations. USDA noted it is unclear from the data provided in the anticoagulant and non-anticoagulant rodenticide ecological risk assessments how many incident reports were associated with legal

uses, or how many were associated with residential uses compared to agricultural or commercial uses. USDA recommended additional characterization of incidents may provide insight into which use patterns are more frequently associated with incidents.

EPA Response: EPA recognizes the limitations of the incident data available but maintains its importance in an overall weight of evidence approach when taken together with the conclusions of its risk assessments. For bromethalin and cholecalciferol, incident reports demonstrate continued evidence of adverse effects on non-target organisms through primary bait consumption, both for wildlife and for pets. EPA has considered the importance of rodenticide use in developing the proposed mitigation outlined in this PID and will continue to monitor the effectiveness of the 2008 RMD mitigation measures.

II. USE

Bromethalin

Bromethalin is a neurotoxicant that, after one or more feedings, causes paralysis of the central nervous system and respiratory arrest by blocking nerve impulse transmission. A lethal dose of bromethalin can be consumed in a single day of feeding but it can take approximately 2-4 days for the target pest to die. Bait shyness (*i.e.*, a learned hesitancy by the rodent to avoid consumption of rodenticide bait due to previous non-fatal exposure) associated with bromethalin use has not been documented, indicating that bait shyness may not be a substantial concern for bromethalin.

Bromethalin is available as a general use pesticide (non-RUP) for the control of various species of mice, rats, voles, and moles. Bromethalin is permitted for use in and within 100 ft of manmade structures and in and within 100 ft of transportation vehicles. Burrow baiting and sewer use is allowed.

Bromethalin is formulated as blocks/pellets/bait packs, meal bait, and worm or grub shaped bait for mole control. Bromethalin can be used in refillable and non-refillable bait stations. Bait stations are mandatory in indoor and outdoor use sites (except within burrows) when using bromethalin where children, pets or non-target animals can access the placement location. There are no active Special Local Need (SLNs) registrations.

Cholecalciferol

Cholecalciferol, also known as vitamin D_3, stimulates the mobilization of calcium from the bone matrix into blood plasma, resulting in death from hypercalcemia. The target pest typically needs multiple days of feeding upon a cholecalciferol bait to obtain a lethal dose, with the animal then typically dying in in 3-4 days. Sub-lethal poisoning and recovery, as well as bait shyness has been observed for cholecalciferol.

Cholecalciferol is available as a general use pesticide (non-RUP) for the control of various species of mice, rats, and voles. Cholecalciferol is permitted for use in and within 100 ft of manmade structures and in and within 100 ft of transportation vehicles. Burrow baiting is allowed.

Cholecalciferol is formulated as blocks, pellets, and bait packs and can be used in refillable and non-refillable bait stations. Cholecalciferol is also registered for use as an outdoor manual

application on the Midway Atoll by FWS to protect listed species (EPA Reg # 12455-117). All other outdoor applications are required to be in a bait station. Bait stations are mandatory in indoor and outdoor uses (except within burrows) when using cholecalciferol where children, pets or non-target animals can access the placement location. There are no active SLNs. There are no active SLNs.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

The Agency has summarized the 2020 HH DRAs for bromethalin and cholecalciferol below. The Agency used the most current science policies and risk assessment methodologies to prepare these risk assessments in support of the registration review of bromethalin and cholecalciferol. For additional details on the 2020 HH DRAs, see *Bromethalin: Draft Human Health Risk Assessment for Registration Review* (March 20, 2020) and *Cholecalciferol: Draft Human Health Risk Assessment for Registration Review* (March 24, 2020) in EPA's public docket (EPA-HQ-OPP-2016-0077 and EPA-HQ-OPP-2016-0139, respectively).

1. Risk Summary and Characterization

Based on the available hazard and toxicity profile for bromethalin and cholecalciferol, the Agency concluded that potential exposure may result in adverse effects and potential risks of concern. As these conclusions are consistent with the Agency's conclusions from the 2008 RMD, a quantitative risk assessment was not necessary, and a qualitative risk assessment was conducted for the purpose of registration review.

Dietary (Food + Water) Risks

Because bromethalin and cholecalciferol only have non-food uses, exposure from residues in food is not anticipated. Exposure to bromethalin and cholecalciferol residues in drinking water is not anticipated from currently registered uses. Therefore, a dietary exposure assessment from food and drinking water was not conducted.

Residential Handler and Residential Post-Application Risks

Residential handler and post-application exposures to adults or children for loose formulations (not in ready-to-use (RTU) bait stations or other formulation or packaging which prevents exposure) are not anticipated given the restrictions from the 2008 RMD for rodenticides.[10] The RMD required consumer (≤1 pound) cholecalciferol and bromethalin end-use products used in residential settings to be individually wrapped soft bait and/or larger bait block forms and applied in bait stations, so residential handler exposure is expected to be negligible. Except for the FWS use on the Midway Atoll, all cholecalciferol products require bait-station use for outdoor, above-ground use and tamper-resistant stations must be used if children, pets, or non-target wildlife could potentially access the bait. Based on the use profile and packaging

[10] Available at www.regulations.gov. Document number EPA-HQ-OPP-2006-0955-0820. The 2008 Risk Mitigation Decision required all residential consumer use products be in securable bait form, in a tamper resistant bait station, within 50 ft of a building, and ≤1 lb of bait.

requirements for cholecalciferol, residential handler or post-application (adults or children) exposures are not anticipated and therefore, quantitative assessments were not conducted.

Most, but not all, bromethalin and cholecalciferol products specify that gloves are to be worn when handling bait or disposing of carcasses.

Non-Occupational Spray Drift Risks

Non-occupational exposure from spray drift or volatilization is not anticipated for the current/registered uses of bromethalin and cholecalciferol based on the formulations of the active ingredients.

Aggregate Risks

In an aggregate assessment, EPA considers the combined pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. The Agency sums the exposures from these sources and compares the aggregate risk to quantitative estimates of hazard. EPA considers the route and duration of exposure when assessing aggregate risks. For bromethalin and cholecalciferol exposure is not expected for food, water and residential sources as previously discussed, so aggregate exposure is not expected.

Cumulative Risks

EPA has not made a common mechanism of toxicity to humans finding for bromethalin, cholecalciferol, and any other substance. These rodenticides do not appear to produce toxic metabolites produced by other substances. Therefore, EPA has premised this PID and the underlying risk assessments on the determination that these rodenticides do not have a common mechanism of toxicity with other substances.

Occupational Handler Risks

Bromethalin and cholecalciferol rodenticide products with limited potential for dermal and inhalation exposures include blocks/pellets/bait packs, meal bait, and worm or grub shaped bait for mole control which prevents human exposure. Bromethalin and cholecalciferol rodenticides that may result in the potential for dermal or inhalation exposures include "loose" formulations, not in RTU bait stations or other formulations or packaging which prevents exposure. These formulations include blocks/pellets/bait packs, and meal bait. The Agency anticipates these formulations generate particulates and therefore the potential for dermal and inhalation exposure as these products are applied, distributed, used to fill/refill bait stations, or otherwise contacted by the applicator. A quantitative occupational handler assessment was not conducted as the risk management approach for registration review is to limit/reduce human exposure (dermal and inhalation) to the extent possible to limit/reduce potential risk.

Occupational Post-Application Risks

Occupational post-application dermal or inhalation exposures are not anticipated because the formulations are expected to be of low volatility and no significant contact with foliar or surface residues are expected for workers in areas previously treated with rodenticides.

2. Human Incidents and Epidemiology

EPA reviewed bromethalin and cholecalciferol incidents reported to both the Incident Data System (IDS) and the National Institute for Occupational Safety and Health (NIOSH) Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides. Additionally, EPA reviewed aggregate data reported in the American Association of Poison Control Centers (AAPCC) Annual Report, and California Pesticide Illness Surveillance Program (PISP) for occupational incidents. The rodenticides in the report included the anticoagulant rodenticides as well as the non-anticoagulant rodenticides. The rodenticides were previously reviewed in 2015. At that time, the 2008 RMD had only recently been fully implemented so insufficient information was available to determine if the RMD impacted the frequency or severity of incidents for the rodenticides.

IDS and AAPCC data suggest that the overall total frequency of rodenticide human incidents reported appears to be decreasing over time, suggesting that the 2008 RMD may have contributed to an overall decrease in exposure incidents involving the rodenticide products. In IDS, the total number of rodenticide incidents decreased slightly from 198 incidents in 2009 to 146 incidents reported in 2018 (26% decline). However, during the same time periods of comparison in IDS and AAPCC (2008-2018 and 2004-2017, respectively), the annual frequency of exposure incidents involving non-anticoagulant incident reports increased over time. The number of non-anticoagulant incidents reported to IDS (2008 to 2018) increased 60% and the number of incidents reported to the AAPCC (2004 to 2017) increased by 41%. The Agency does not have access to more detailed data to examine the reason for this trend, but the observed increase may be the result of non-anticoagulants having replaced the SGARs for residential consumer use.

AAPCC data were also reviewed for reduction in reported rodenticide incidents in children under the age of six years old. A comparison of child rodenticide exposures from 2011 to 2017 identified a 46% decline in child rodenticide incident reports.

As of EPA's latest search on July 12, 2019, the main IDS showed 37 incidents were reported for bromethalin from January 1, 2015 to July 12, 2019. Thirty-one of these incidents were of moderate severity, two were classified as major severity, and two incidents resulted in death, both of which were suicides. In the aggregate IDS, 195 minor severity incidents were reported from January 1, 2015 to July 12, 2019 for bromethalin. EPA evaluated NIOSH SENSOR-Pesticides, California PISP, and IDS for occupational incidents. Overall, there was a low frequency of occupational incidents reported in SENSOR-Pesticides, State SENSOR Pesticide Data, California PISP, and Main IDS for rodenticides including the non-anticoagulant rodenticides. From 2011 to 2015, only one reported case involved bromethalin.

For cholecalciferol, the July 12, 2019 search of the main IDS showed one incident reported involving cholecalciferol from January 1, 2015 to July 12, 2019 that resulted in death. Upon further review, this incident was most likely not due to cholecalciferol exposure. In the aggregate IDS, eight minor severity incidents were reported from January 1, 2015 to July 12, 2019 for cholecalciferol. The Agency intends to continue monitoring human incidents for bromethalin and cholecalciferol and will conduct additional analyses, if necessary.

3. Tolerances

No tolerances are established or needed because the use sites and the use patterns for bromethalin and cholecalciferol are not expected to result in residues on food, feed, and forage.

4. Human Health Data Needs

Given the hazard profile and known toxicity of bromethalin and cholecalciferol, no additional hazard or exposure data is currently identified for bromethalin or cholecalciferol.

B. Ecological Risks

The 2020 bromethalin and cholecalciferol ecological DRAs are summarized below. The Agency used the most current science policies and risk assessment methodologies to prepare risk assessments in support of the registration review of bromethalin and cholecalciferol.[11] For additional details on the 2020 Eco DRAs, see the *Bromethalin Draft Ecological Risk Assessment* in EPA's public docket EPA-HQ-OPP-2016-0077 and the *Cholecalciferol Draft Ecological Risk Assessment* in EPA's public docket EPA-HQ-OPP-2016-0139.

The Agency has not yet fully evaluated bromethalin and cholecalciferol's risks to listed species. However, EPA will complete its listed-species assessment and any necessary consultation with the Services before completing the registration review for bromethalin and cholecalciferol. See Appendix F for more details. As such, Section III.B focuses on risks to non-listed species. EPA is currently working with its federal partners and other stakeholders to improve the consultation process for listed species and their designated critical habitats. As a pilot, EPA has completed draft effects determinations and predicted the likelihood of jeopardy for three listed species and adverse modification for one designated critical habitat. EPA has proposed mitigations for these three species and one critical habitat. A summary of the pilot is included in Section III.C, below. EPA considers these assessments and associated mitigations to be pilots for other listed species that may be similarly exposed and affected by rodenticides. In November 2023, EPA intends to issue draft effects determinations for the 11 rodenticides for all listed species and their designated critical habitats. The Agency has committed to finalizing effects determinations for the rodenticides by November 2024.

1. Risk Summary and Characterization

Terrestrial Risks

Mammals

Bromethalin

Bromethalin causes toxic effects to the central nervous system of mammals as shown in acute and subchronic feeding studies. Based on available ecotoxicity data, bromethalin is classified as very highly toxic to mammals on an acute exposure basis. In assessing rodenticide risk, unlike most other pesticides, the rodenticide bait is the food item of concern. Thus, the amount of active

[11] The 2020 Eco DRA is a FIFRA assessment and focuses on potential risks to species not listed under the Endangered Species Act (ESA).

ingredient in the formulated bait is used as an estimated environmental concentration (EEC) in the risk assessment. As such, there are two pathways of exposure: primary consumption (in which the animal consumes the bait directly) and secondary consumption (in which the animal consumes animals which have consumed the bait directly).

This information is used to estimate the amount of bait that mammals of various sizes need to consume to obtain a dose expected to be lethal to 50% of the individuals in the population (*i.e.,* LD_{50} dose). Estimates of food-ingestion rates (grams of dry matter per day) are determined from established allometric equations. The concentration of bromethalin in the bait is also used to estimate initial dietary exposure (mg a.i./kg in bait), which in turn is used to calculate mammalian dietary-based risk quotients (RQs).

Exposure to terrestrial mammals through bait consumption is calculated as mg a.i./kg-bw, where kg-bw is the kilograms body weight of the consuming individual for three standard weight classes. Exposure (food dry weight consumption) estimates were derived using allometric equations as these best approximate those individuals with high potential for consuming grain and they would give the most conservative exposure estimates. Food dry weight was assumed to be equivalent to food wet weights as the expected water content of the bait would be minimal.

The RQs are generated by dividing these exposure estimates (mg ai/kg-bw) for a given weight class of mammal by the most conservative toxicity endpoint (LD_{50}) adjusted for the default body weights.

Single day primary exposure of rodents results in RQs that range from 2.4 to 13, all of which exceed the acute risk level of concern (LOC) of 0.5. At this time, no chronic toxicity studies conducted using the rat are available for risk assessment. Without these data, there is uncertainty as to the potential effects of long-term, low-dose exposure that can cause reproduction or other sublethal effects.

Risk from secondary exposure has been qualitatively assessed in previous evaluations. These previous assessments concluded that secondary exposure, which is exposure from animals eating the animals that consumed bromethalin bait, is considered possible but has not been documented. Bromethalin partitions into fatty (adipose) tissue, and animals that eat carcasses of poisoned rodents would ingest residues in this tissue as well as possible bait material remaining in the gut.

In one study, four domestic dogs were provided a diet for 14 days of ground meat consisting of rats fed bait containing 0.005% bromethalin for one day. None of the four dogs died and no signs of toxicity were observed, thus indicating that 0.005% bromethalin bait does not pose a secondary hazard to dogs. Bromethalin bait is registered at concentrations up to 0.01% for rodent control and 0.025% for mole control. Therefore, this study does not provide enough information to claim that secondary hazard to predators and scavengers from ingestion of bromethalin at higher treatment rates is not possible.

A metabolism study testing rats indicated that bromethalin is transformed into the toxic metabolite desmethylbromethalin, and the residues of bromethalin and desmethylbromethalin are moderately persistent in the body of the rat (half-life of 5.6 days). Although the study of dogs fed a diet of rats poisoned with bromethalin did not result in apparent toxicity to the dogs, the

metabolism study suggests the potential for secondary poisoning if a predator consumes a small mammal within a few days after the latter has fed on a bromethalin bait.

Unlike anticoagulant rodenticides, the toxicity of bromethalin is fairly fast-acting. In rats, at doses intended to be lethal, signs of toxicity occur within 2-12 hours. With repeated sublethal doses, signs of toxicity occur within 12-24 hours. In a comparative pen study, rats fed a bromethalin bait (0.01%) stopped feeding after four days and died within 1-6 days, whereas rats fed bromadiolone or brodifacoum bait (0.005%) continued to survive and feed for 10 days. In dogs, clinical signs of toxicity occur in 6.5 to 8 hours, with death occurring in 15 to 63 hours. In cats, clinical signs of toxicity occur within 1-2 days and death occurs in 48-97 hours.

Cholecalciferol

Cholecalciferol ingestion results in hypercalcemia of blood plasma, metastatic calcification of soft tissues, and ultimately death. The compound is classified as highly toxic to mammals on an acute exposure basis.

Cholecalciferol risk to mammals was evaluated assuming mammals can access cholecalciferol bait despite the requirement that all above-ground uses be inside tamper-proof bait stations. Acute dose-based RQs for mammals range from 1.34 to 24, all of which exceed the acute risk LOC of 0.5. There are no chronic toxicity data for mammals; therefore, there is uncertainty as to the potential effect on mammals from long-term, low-dose exposure.

For mammals, the amount of bait that a mammal would have to consume to reach the LD_{50} of 11.8 mg a.i./kg-bw was calculated. This analysis indicated that compared to the daily food intake for various sized mammals, a relatively small amount of bait (*i.e.,* 0.12 g for small mammals) is needed to reach a lethal dose. The amount of bait needed to reach the LD_{50} is much less than the daily food intake, ranging from <1% for small mammals to about 74% of the daily food intake for larger mammals, indicating that it is much easier for small non-target mammals to consume a lethal dose.

There are limited data to assess potential risk to predators or scavengers that may consume mammalian prey containing cholecalciferol residues (secondary exposure). In one study, rodent carcass location data using radio-tracked rats during a poisoning operation indicated that most poisoned rodents die below ground. Uncertainties in the risk assessment include the ability for non-target wildlife to access the bait that is contained in tamper-resistant bait stations or pellets placed in underground burrows and the extent to which poisoned animals remain below ground. Based on available evidence that most rodents poisoned with cholecalciferol die below ground, secondary exposure while uncertain, is expected to be low.

Birds, Reptiles, and Terrestrial-Phase Amphibians

Bromethalin

Based on available ecotoxicity data, bromethalin is classified as very highly toxic to birds on an acute exposure basis. As discussed above for mammals, in assessing rodenticide risk, unlike most pesticides, the rodenticide bait is the food item of concern. As such, there are two pathways

for exposure: primary (in which the animal consumes the bait directly) and secondary (in which the animal consumes animals which have consumed the bait directly).

RQs were calculated for birds using the process as described above for mammals. Single day primary exposure of passerine birds results in RQs that range from 2.4 to 20, all of which exceed the LOC of 0.5. At this time, data are unavailable to quantify chronic risks as chronic toxicity studies have not been submitted. Without these data, there is uncertainty as to the potential effects of long-term, low-dose exposure that can cause reproduction or other sublethal effects. However, given the high avian acute toxicity of bromethalin, long-term low-dose exposure of non-target birds is unlikely to be widespread and chronic data is considered to be of low value at this time.

Secondary exposure is considered possible and three bromethalin incidents involving owls and hawks present evidence that secondary exposures can occur. The fast action of bromethalin compared to anticoagulant rodenticides limits the potential time for a secondary consumer to find living animals which have consumed bromethalin; however, there is potential for scavengers to feed upon animals that have died from exposure to bromethalin.

Cholecalciferol

Cholecalciferol is classified as practically non-toxic to birds (which serve as surrogates for reptiles and terrestrial-phase amphibians) on an acute oral exposure basis. Primary exposure through cholecalciferol bait consumption was calculated using two methods. For the first method, cholecalciferol exposure was calculated as mg a.i./kg-bw, where the kg-bw is the weight of the consuming individual for three standard weight classes. For the second method of exposure calculation, for birds, the amount of bait a bird would have to consume to reach the LD_{50} value was calculated.

To calculate the acute RQ for birds, it was assumed that the non-definitive LD_{50} of >2,000 mg a.i./kg-bw was a definitive value (LD_{50} = 2,000 mg a.i./kg-bw). Even though this approach results in a conservative estimate of acute risk to birds, the resulting RQ values (*i.e.*, <0.03 to <0.16) did not exceed the acute risk LOC of 0.5.

Although a definitive acute toxicity value is not available for birds, if it assumed that the LD_{50} is 2,000 mg a.i./kg-bw, the amount of bait that a bird would have to consume to reach that dose level can be calculated. The amount of bait (g) to be consumed to reach the LD_{50} exceeds the daily food intake by 6- to 29-fold, indicating that it is unlikely that a bird would consume enough bait to result in potentially lethal effects.

There are limited data to assess potential risk to predators or scavengers that may consume animals containing cholecalciferol residues (secondary exposure). However, the registrant submitted published literature which contains information on the potential risk to birds exposed to insects that may feed on cholecalciferol bait. A study that examined invertebrate feeding on untreated baits used for vertebrate control in New Zealand under a worst-case scenario (*i.e.*, aerial application of cereal baits applied to a forest floor) concluded that only a few of the invertebrate species likely to be present were found on baits and the total number of invertebrates

found on baits was low compared to the number likely to be present[12]. Therefore, the potential risk to insectivorous birds exposed to contaminated insects is low.

In another study, as mentioned above, rodent carcass location data using radio-tracked rats during a poisoning operation indicated that most poisoned rodents die below ground. However, even if some poisoned carcasses with cholecalciferol were available to predatory or scavenging birds, there would be low risk from secondary poisoning as no mortality or adverse effects were observed during a study where a predator and scavengers (one Red-tailed Hawk [*Buteo jamaicensis*] and two Turkey Vultures [*Cathartes aura*]) were fed one large or two small cholecalciferol-exposed rats for 10 days. It was determined that cholecalciferol is a lower risk to birds from secondary poisoning when compared with other more acutely toxic rodenticides[13]. Given that most rodent carcasses poisoned with rodenticides die below ground and avian predators and scavengers tested are not very sensitive to cholecalciferol exposure, the risk to birds from secondary poisoning with cholecalciferol is expected to be low. Uncertainties include the ability for non-target wildlife to access the bait that is contained in tamper-resistant bait stations or pellets placed in underground burrows. However, based on the available scientific literature and use patterns, the potential for secondary exposure from cholecalciferol is expected to be low.

Terrestrial Invertebrates

Due to a lack of expected exposure given the registered use patterns, bromethalin toxicity data on honey bees (*Apis mellifera*), which serve as surrogates for both *Apis* and non-*Apis* bees, have not been submitted and have not been requested by EPA. Exposure of soil-dwelling terrestrial invertebrates to bromethalin cannot be precluded from some outdoor uses of bromethalin, particularly in animal burrows. Insects may be attracted to and feed on baits and/or transport bait outside of bait stations where they, as well as the bait particles, may subsequently be fed upon by insectivorous wildlife. However, exposure is not expected to be widespread given the registered use patterns.

Cholecalciferol, based on scientific literature, is classified as practically non-toxic to honey bees on an acute oral exposure basis. No additional data are available for acute contact or chronic oral toxicity for adult bees or acute/chronic toxicity to larval bees. Risk to terrestrial invertebrates was not calculated due to the low likelihood of exposure given the use of cholecalciferol in bait stations or placement in rodent burrows where bees would not likely be attracted to the product. Furthermore, label instructions stipulate that unconsumed bait be collected, and the likelihood that bees would nest in an active rodent burrow is considered low. Potential risks to terrestrial invertebrates (*e.g.,* carrion beetles) through ingestion of residues in rodents killed by the compound is uncertain but expected to be low.

Terrestrial Plants

According to Title 40 Part 158 of the Code of Federal Regulations, terrestrial plant toxicity data are not required for contained pesticide treatments such as bait stations. Based on the use

[12] Spurr E. B. and K. W. Drew. 1999. Invertebrates feeding on baits used for vertebrate pest control in New Zealand. New Zealand Journal of Ecology, 23(2):167-173.
[13] Howald, G.R., P. Mineau, J.E. Elliot, and K. M. Cheng. 1999. Brodifacoum poisoning of avian scavengers during rat control on a seabird colony. Ecotoxicology, 8:431-447.

patterns, as modified by the 2008 RMD, meaningful exposure of terrestrial plants to bromethalin and cholecalciferol is not expected. Since exposure of terrestrial plants is expected to be low, risk is expected to be low.

Aquatic Risks

Due to the current use patterns, which requires the use of bait stations or application directly within animal burrows, exposure of aquatic organisms to bromethalin and cholecalciferol products is not expected.

2. Ecological Incidents

EPA reviewed bromethalin and cholecalciferol incidents reported to IDS. As of EPA's latest search in February of 2020, bromethalin showed 53 wildlife incidents reported from 1996 to 2020. Fifty-two (93%) of the incidents were reported between 2010 and 2018, subsequent to the 2009 implementation of the 2008 RMD with more restricted use and bait station requirements, indicating that wildlife incidents have continued since 2010. However, there is an apparent decline in the number of reported incidents after 2016, which may be a result of the increased prevalence of EPA-registered rodenticide products which are consistent with the mitigation specified in the 2008 RMD. The apparent increase in the number of incidents in 2015 and 2016 may be due to several factors, including: increased bromethalin use, more systematic reporting, and the development of a method for analyzing desmethylbromethalin in tissues.

As expected for rodenticides, reported incidents for bromethalin impacted primarily mammals. Few incidents were reported among the bird and reptile taxa. Bromethalin incidents are often identified by finding bromethalin metabolite (desmethylbromethalin) in liver tissue and/or evidence from carcass necropsy. These analyses are expensive, which limits the extent of analyses and incident reporting. California accounts for a majority (67%) of reported incidents for bromethalin; New York accounts for the second most incidents (25%); and, the two states combined account for approximately 92% of reported incidents.

For cholecalciferol, a February 2020 search of the IDS database from January 1997 to September 2019 found one wildlife incident involving a striped skunk whose liver tested positive for cholecalciferol (>2.6 mg/kg).

In addition to wildlife incidents, over 6,000 bromethalin and 282 cholecalciferol domestic animal (pet) incidents have been reported during the same time periods. The majority of these incidents (85% for bromethalin) are minor to moderate in severity but serve to suggest that effects to non-target species can occur from bromethalin and cholecalciferol exposure. The majority of pet incidents (63% for bromethalin) were reported between 2010 and 2018. There is a decline in the number of reported incidents after 2016, when existing stocks of products that have since been amended consistent with the RMD would be out of circulation.

Collectively, these incidents suggest that effects to non-target animals are occurring from exposure to bromethalin and cholecalciferol. The number of actual incidents may be higher than what is reported to the Agency. Incidents may go unreported since side effects may not be immediately apparent or readily attributed to the use of a chemical. Although incident reporting is required under FIFRA Section 6(a)(2), the absence of reports in IDS does not indicate that the

chemical has no effects on wildlife; rather, it is possible that incidents are unnoticed and unreported. Most animal carcasses are never found by humans, scavengers quickly remove and consume carcasses, carcasses or incapacitated animals discovered by humans are not always reported to proper authorities, and carcasses discovered and reported are not typically analyzed for rodenticides. Animals that are impaired due to rodenticide poisoning may be incapacitated and therefore more likely to die of other causes (*e.g.,* motor vehicle accidents, window strikes, predation) and therefore not reported as rodenticide wildlife incidents, even if rodenticide poisoning was a contributing factor. See the 2020 Eco DRA for a detailed analysis of ecological incidents. The Agency intends to monitor ecological incidents for the anticoagulant rodenticides and will conduct additional analyses if necessary

3. Ecological and Environmental Fate Data Needs

The ecological database for bromethalin and cholecalciferol is considered complete for the purposes of registration review. In response to the GDCI issued in support of registration review for bromethalin, waiver requests for studies on avian reproduction toxicity (850.2300), mammalian metabolism and pharmacokinetics (870.7485) and honey bee adult oral toxicity (SS-1311) were submitted. All of the waivers were granted. In response to the GDCI issued in support of registration review for cholecalciferol, waiver requests for studies on avian sub-acute dietary toxicity (850.2200), avian reproduction toxicity (850.2300), mammalian metabolism and pharmacokinetics (870.7485) and prenatal developmental toxicity (870.3700) were submitted. All of these studies were waived. In 2017, a data gap was identified for acute oral toxicity to adult bees; however, a study has been identified in the peer-reviewed scientific literature which addresses the data gap.

C. ESA Pilot

In April 2022, EPA released a comprehensive, long-term approach to meeting its ESA obligations for pesticides, which is outlined in *Balancing Wildlife Protections and Responsible Pesticide Use* (referred to hereafter as ESA workplan).[14] Given EPA's large ESA workload for registration review, the Agency identified a set of pilot chemicals, including the rodenticides, as a starting point to focus its early mitigation efforts. EPA believes that working through several pilot chemicals and pilot listed species will help registrants, users, and other stakeholders to better understand how the Agency predicts the likelihood of jeopardy (J) to listed species and adverse modification (AM) to designated critical habitat (collectively "J/AM"), identifies listed species and critical habitats that are likely in need of early mitigation, and predicts whether the proposed mitigation will reduce or eliminate the likelihood of J/AM. EPA's predictions on the likelihood of J/AM will also help to inform the consultation process with the Services, which have authority over these species. The Services will make the final J/AM determinations for the pilot listed species, and for any other listed species and critical habitats that are likely to be adversely affected by the registered uses of bromethalin and cholecalciferol.

Using its authorities under FIFRA, and in advance of completion of consultation with the Services, EPA is proposing mitigation for three pilot listed species for bromethalin and cholecalciferol. The proposed mitigations are intended to reduce (through avoidance and

[14] *Balancing Wildlife Protection and Responsible Pesticide Use: How EPA Will Meet its Endangered Species Act Obligations* (2022). Available at https://www.epa.gov/endangered-species/epas-workplan-and-progress-toward-better-protections-endangered-species#workplan

minimization) potential exposures, effects, and take[15] such that EPA can predict that there is not a likelihood of jeopardy for the pilot species or adverse modification of the designated critical habitat. EPA selected these species for the pilot because the FIFRA taxa-level risk assessment (Section III.B) concluded that bromethalin poses risks to mammals and birds that are primary consumers and cholecalciferol poses risks to mammals that are primary consumers. There is the potential for risk to secondary consumers from bromethalin and cholecalciferol, but it is expected to be low. The species and critical habitat selected for the pilot represent examples of the listed species that may be exposed to rodenticides through different routes of exposure (*i.e.,* primary and secondary consumption of rodenticides). For the pilot, EPA evaluated three listed species:

- Stephens' kangaroo rat (*Dipodomys stephensi*)[16];
- Attwater's prairie-chicken (*Tympanuchus cupido attwateri*)[17]; and the
- California condor (*Gymnogyps californianus*)[18].

Below is a summary of some of the pilot listed species' characteristics. Maps of the three species' ranges and the designated critical habitat can be found in Appendix E. Additional information on the J/AM analysis can be found in *Rodenticides: Draft Effects Determinations and Evaluation of Proposed Mitigations Intended to Avoid Jeopardizing Three Federally Listed Endangered and Threatened Species and Avoid Adversely Modifying One Designated Critical Habitat* (September 28, 2022).

1. Stephens' kangaroo rat *(Dipodomys stephensi)*

The Stephens' kangaroo rat (SKR, *Dipodomys stephensi*) was federally listed as endangered in 1998 but was recently reclassified as threatened due to a reduction of threats since listing and the implementation of conservation actions; it is a small rodent that lives in warm, dry desert and grassland habitats in Southern California. For a map of the SKR range, see Appendix E, Figure 1. SKR eat seeds from forbs and native and non-native grasses, and because adults are seed-eaters, it is assumed that they may be primary consumers of rodenticide bait, especially treated grain. SKR are also taxonomically like commensal rodents that are the targets of rodenticides; the design and application method of rodenticides makes them inherently attractive to kangaroo rats, which may mistake the treated bait for a dietary item. SKR was chosen as a pilot species because it represents a mammal that is a primary consumer. SKR does not have a designated critical habitat.

[15] Take as defined by the Endangered Species Act means, "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in any such conduct." Incidental take is an unintentional, but not unexpected, taking.

[16] Entity ID 39

[17] Entity ID 83

[18] Entity ID 66

2. Attwater's prairie-chicken *(Tympanuchus cupido attwateri)*

The Attwater's prairie-chicken (APC, *Tympanuchus cupido attwateri*) has been federally listed as endangered since 1967; it is a grouse unique to the Texas Coastal prairies. For a map of the APC range, see Appendix E, Figure 2. Adult APCs primarily consume foliage, insects, and seeds and grains, including corn, peanuts, and rice. Since the APC consume seeds and grains, they may also be primary consumers of rodenticide bait, especially baits that are formulated as grains. APC was chosen as a pilot because it represents a bird that is a primary consumer. The APC does not have a designated critical habitat.

3. California condor *(Gymnogyps californianus)*

The California condor (CC, *Gymnogyps californianus*) has been federally listed as endangered across its entire range since 1967 and reached near extinction in the 1980s; the CC is one of the rarest species of birds in the world. For a map of the CC range, see Appendix E, Figure 3. As of 2020, it was estimated that 504 individuals were left in the wild. CCs are obligate scavengers that primarily feed on large mammalian carcasses; however, medium- to small-sized carrion and squirrels are also consumed. The CC was chosen as a pilot species because it represents a bird that is a secondary consumer. The CC does have a designated critical habitat. For a map of the critical habitat of the CC, see Appendix E, Figure 4.

Because these species are all under the authority of FWS, EPA adapted the approach used by the FWS in their recent Malathion Biological Opinion[19] to predict whether there was a likelihood that the current registered uses of the rodenticides could jeopardize these species or adversely modify the designated critical habitat. For those rodenticides and species or critical habitat that EPA predicted a likelihood of J/AM, EPA has proposed mitigations.

The approach to predict the likelihood of J/AM involves:

- evaluation of the species' vulnerability (metric determined by FWS);
- evaluation of the magnitude of effects by comparing exposure estimates to toxicity endpoints for uses of bromethalin and cholecalciferol;
- determination of the extent of overlap of the species' range (and the critical habitat) with use areas determined by use data layers (UDLs).

Each of these factors was assigned one of the three categories: high, medium, or low. For each species and critical habitat, these three factors were weighed to predict the likelihood of J/AM.

EPA completed draft effects determinations for the three pilot species and one designated critical habitat for all currently registered uses of 11 rodenticide active ingredients. The Agency will consider public comments and feedback from FWS, and registrants, and determine whether changes are needed to this assessment. Table 1 below summarizes the draft individual effects determinations and predictions of J/AM. These draft determinations and predictions are based on currently registered uses of the rodenticides.

[19] FWS. 2022. *Biological and Conference Opinion on the Registration of Malathion Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act*. February 28, 2022. Ecological Services Program. U.S. Fish and Wildlife Service. Available at https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions

Table 1. Summary of draft individual level effects determinations and predictions of jeopardy and adverse modification by pilot species and rodenticide.

Rodenticide	Stephens' kangaroo rat		Attwater's prairie-chicken		California condor	
	Effects Determination	Jeopardy prediction	Effects Determination	Jeopardy prediction	Effects Determination	Jeopardy and adverse modification prediction[2]
Brodifacoum	LAA	Likely	NE	NA	NE	NA
Bromadiolone	LAA	Likely	NE	NA	NE	NA
Bromethalin	LAA	Likely	NE	NA	NLAA	NA
Cholecalciferol	LAA	Not Likely	NE	NA	NE	NA
Chlorophacinone	LAA	Likely	LAA	Not Likely	LAA	Likely
Difenacoum	LAA	Likely	NE	NA	NE	NA
Difethialone	LAA	Likely	NE	NA	NE	NA
Diphacinone[1]	LAA	Likely	NLAA	NA	LAA	Likely
Strychnine	LAA	Likely	NE	NA	LAA	Likely
Warfarin[1]	LAA	Likely	NE	NA	LAA	Likely
Zinc phosphide	LAA	Likely	LAA	Likely	LAA	Likely

NE=no effect
NLAA=not likely to adversely affect
NA=not applicable
LAA=likely to adversely affect
[1] includes the sodium salt
[2] adverse modification prediction applies to critical habitat

The analyses led to initial predictions of the likelihood of jeopardy for the Stephens' kangaroo rat for bromethalin. The initial prediction of the likelihood of jeopardy for the Stephens' kangaroo rat for cholecalciferol was not likely, although the effects determination was Likely to Adversely Affect (LAA) for both chemicals for the Stephens' kangaroo rat. For the Attwater's prairie-chicken and the California condor for bromethalin and cholecalciferol the initial prediction of the likelihood of jeopardy was not applicable (NA). The effects determinations were no effect (NE) for both chemicals for the Attwater's prairie-chicken and for the California condor for cholecalciferol. The effects determination for the California condor was Not Likely to Adversely Affect (NLAA) for bromethalin. Only one of the species (*i.e.*, the California condor) has a final designated critical habitat and EPA predicts not applicable (NA) of adverse modification of designated critical habitat for the California condor for both bromethalin and cholecalciferol. EPA is proposing mitigation measures that are intended to reduce (through avoidance and minimization) potential exposures and effects such that EPA predicts that there would not be a likelihood of jeopardy for the pilot listed species. Additionally, with these proposed mitigation measures, EPA predicts that there would not be a likelihood of adverse modification for the designated critical habitat for the California condor. In addition, these mitigations are also expected to reduce the potential for "take" (e.g., kill or harm) of individuals. As noted above, FWS will make the final determinations on jeopardy for each of the species and adverse modification for the designated critical habitat, and will evaluate the adequacy of EPA's proposed mitigation measures in addressing the Agency's initial prediction of J/AM. For more on the proposed mitigations see Section IV.B, Proposed Risk Mitigation and Regulatory Rationale for ESA pilot.

The assessments for three species and associated mitigations are considered pilots for other listed species that may be similarly exposed and affected by rodenticides. In November 2023, EPA intends to draft effects determinations for these 11 rodenticides for all listed species and critical habitats. Any feedback received on the draft effects determinations for the three pilot species and one designated critical habitat received during the public comment period on the PID will be taken into consideration for the November 2023 draft effects determinations.

D. Benefits Assessment

Bromethalin and cholecalciferol are important for controlling rats, mice, voles, and moles (bromethalin only) in and around structures and vessels. The purpose of controlling these pests is to protect people, animals, structures, and the environment from the risks posed. Rodents pose a substantial threat to human health and the environment by consuming food and feed, vectoring disease and ectoparasites to people and animals, damaging structures and equipment, and disrupting ecosystem balance and biodiversity.

Extension and government recommendations for rodent control stress the importance of integrated pest management (IPM), which involves using the most appropriate means of control for the specifics of the pest problem. IPM is a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks. Most sectors concurrently use multiple means of rodent control, each best suited to particular pest problems. Chemical rodenticides, including bromethalin and cholecalciferol, are most important for controlling rodents when non-chemical methods of control (*e.g.*, sanitation, exclusion, and mechanical traps) are insufficient, such as in highly rodent-attractive settings like sewers and food-handling establishments.

Bromethalin and cholecalciferol have several benefits relative to other rodenticides. Bromethalin and cholecalciferol have acute modes of action, and they kill rodents after fewer feedings, and more quickly than what is typical of first-generation anticoagulant rodenticides (FGARs). For these reasons, bromethalin and cholecalciferol baits can be desirable in some cases because mortality occurs relatively quickly, and without needing the target pests to feed on bait for several consecutive nights. Bromethalin and cholecalciferol are not subject to the same genetic resistance concerns as the anticoagulant rodenticides, meaning that these rodenticides can be used for effective rodent control where rodenticide resistance may be a concern. For more information on the benefits of bromethalin and cholecalciferol, please see *Benefits of 11 Rodenticides and Impacts of Potential Mitigation* (October 27, 2022), available in the public docket.

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed Risk Mitigation and Regulatory Rationale

The Agency is proposing additional risk mitigation measures to reduce the potential for human health exposures (i.e., children and occupational handlers) and ecological exposures to non-target wildlife, including federally protected, federally listed, and non-listed species, while minimizing the impacts on users to the greatest extent possible.

While the 2008 RMD reduced the potential for human health exposure for residential/consumer users, non-target human health and ecological exposure incidents continue to occur. The Agency is proposing that additional human health mitigation measures are necessary to further reduce the potential for human health exposures, including exposures to children. Proposed mitigation measures to further reduce human exposures are also expected to address potential risks to pets. Similar to what EPA is proposing for the other rodenticides, EPA is likewise proposing to classify specific bromethalin and cholecalciferol products as RUPs and to prohibit refillable bait stations for consumer-sized products. These additional proposed restrictions are expected to minimize misuse and protect human health by reducing the availability of bait to which humans, including children, could be exposed. Additionally, the 2020 HH DRA identified the potential for dermal and inhalation exposures to occupational handlers using products that are loose formulations, including granules, grain meals, waxy/paraffinized and non-paraffinized pellets. The Agency is proposing that additional PPE is necessary for occupational handlers using products that are loose formulations to reduce the potential for dermal and inhalation exposure.

EPA identified the potential for risk for primary consumers of bait (mammals and birds) and secondary consumers (*e.g.*, birds of prey and predatory mammals), supported by risk estimation and incident reports showing that primary and possibly secondary exposure to non-target organisms, including listed species, have continued to occur. Building upon the mitigation measures implemented as a result of the 1998 Rodenticide Cluster RED, 2008 RMD, and the 2012 Rozol Prairie Dog Bait and Kaput-D Prairie Dog Bait BiOps, the Agency is proposing that additional ecological mitigation measures are necessary as part of registration review to further reduce non-target exposures. EPA is proposing to add post-application follow-up statements for the search, collection, and disposal of target species carcasses, the cleanup of bait moved from its original placement location, and the reporting of dead/dying non-target organisms.

EPA is also proposing to classify specific bromethalin and cholecalciferol non-consumer products as RUPs to reduce pet exposure incidents as well as non-target wildlife exposures.

Although the Agency is not making a complete endangered species finding at this time, the proposed label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of bromethalin and cholecalciferol. Additionally, the Agency is committed to identifying and incorporating early mitigation for vulnerable listed species. These mitigations will be discussed in Section IV.B. Proposed Risk Mitigation and Regulatory Rationale for ESA Pilot, below. In this PID, EPA is proposing additional mitigation measures to be included in draft bulletins for the three pilot listed species—Stephens' kangaroo rat, Attwater's prairie-chicken, and the California condor—and the one critical habitat. EPA intends to publish these early-ESA species mitigation measures in Bulletins Live! Two (BLT)[20], and is proposing to add a link to BLT to all product labels, except those registered exclusively for use by general consumers (i.e., residential homeowners). The Agency anticipates completing the draft BEs for all 11 rodenticide active ingredients in 2023 and the final BEs in 2024.

Finally, in this PID, EPA is also proposing to update the Terms and Conditions for Registration for all rodenticide registrations, requiring registrants to develop, implement, and maintain rodenticide stewardship plans that include the development of education and outreach materials

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

intended for product users. EPA is proposing that the terms and conditions require these materials to be made available on registrant's websites. The Agency is proposing that industry stewardship will highlight the importance of best management practices for bromethalin and cholecalciferol use to end-users as part of an IPM approach and will contribute to the reduction of potential non-target exposures.

The impacts of the mitigation measures are described for each measure below. For more information on the anticipated impacts of EPA's proposed mitigations for bromethalin and cholecalciferol, see Section III.D and *Use and Benefits of 11 Rodenticides and Impacts of Potential Risk Mitigation* (October 27, 2022), available in the public docket.

1. Restricted Use Pesticide Classification

The 2008 RMD required packaging size requirements to distinguish products that are intended for use by general consumers and products that are intended for use by commercial and professional pest control operators. To minimize children's exposure to bromethalin and cholecalciferol products, EPA required that all rodenticide products marketed to consumers only be sold with at least one tamper-resistant bait station in the package, with loose bait forms being prohibited. Bromethalin and cholecalciferol products sold in packages $\geq$ 4 lbs. of bait are intended for commercial/professional use by pest control operators.

Despite these packaging size requirements, non-target incidents (including children, domestic pets, and non-target wildlife, including listed species) have continued to occur.

Consistent with the Agency's intent for certain bromethalin and cholecalciferol products only be made available for commercial/professional use, the Agency is proposing all bromethalin and cholecalciferol products packaged in quantities $\geq$ 4 lbs. of bait be classified as RUP.

Currently, there are bromethalin and cholecalciferol products classified as RUP due to hazard to non-target organisms (as specified in 40 CFR 152.170(c)). EPA proposes that the remaining bromethalin and cholecalciferol products packaged in quantities greater than or equal to four lbs of bait have characteristics that meet the criteria for restricted use due to hazard to non-target organisms and other evidence (as specified in 40 CFR 152.170(d)).

Criteria for Hazard to Non-Target Species

In accordance with 40 CFR 152.170(c)(iv), EPA may consider restricted use classification for products intended for outdoor use where "under conditions of label use or widespread and commonly recognized practice, the pesticide may cause discernible adverse effects on non-target organisms, such as significant mortality or effects on the physiology, growth, population levels or reproduction rates of such organisms, resulting from direct or indirect exposure to the pesticide, its metabolites or its degradation products." Incident reports demonstrate continued evidence of discernable adverse effects on non-target organisms through primary and possibly secondary consumption involving bromethalin and cholecalciferol. Risk concerns are further supported by ecological risk estimates calculated for bromethalin exceeding the Agency's level of concern for acute exposures for birds and mammals and for cholecalciferol exceeding the Agency's levels of concern for acute exposure to mammals. According to incident reports and

RQ exceedances, bromethalin and cholecalciferol may cause adverse effect on non-target organisms through primary and possibly secondary consumption.

Other Evidence

In accordance with 40 CFR 152.170(d), "the Agency may also consider evidence such as field studies, use history, accident data, monitoring data, or other pertinent evidence in deciding whether the product or use may pose a serious hazard to man or the environment that can reasonably be mitigated by restricted use classification." Incidents reported to IDS are evidence that humans, pets, and wildlife are being exposed to bromethalin and cholecalciferol, resulting in poisonings via primary and secondary exposure. For more detailed information regarding bromethalin and cholecalciferol incidents, see Sections III.A.2 and III.B.2.

For both criteria described above, RUP classification would ensure the retail purchase and use of these products are by persons that are trained and certified to apply pesticides, which is expected to decrease the likelihood of misapplication, including overapplication, and therefore reduce the potential for exposure to non-target organisms.

In summary, bromethalin and cholecalciferol products packaged in quantities $\geq$ 4 lbs. of bait meet the standard for restricted use because:

1) use of these products poses a serious hazard that may be mitigated by restricting their use;
2) current labeling is not adequate to mitigate these risks;
3) restriction of these products would decrease the risk of adverse effects; and
4) even if directions for use are followed, use may result in discernible adverse effects on non-target organisms through primary and possibly secondary exposure.

Therefore, EPA is proposing to classify all bromethalin and cholecalciferol products packaged in quantities $\geq$ 4 lbs. as restricted use. By doing so, the retail sale and use of the bromethalin and cholecalciferol products mentioned above would be restricted to certified applicators or persons under their direct supervision and only for those categories covered by the Certified Applicator's certification.

For bromethalin and cholecalciferol labels that are already RUP, the Agency is proposing that these labels are updated to be consistent with Chapter 6 of the Label Review Manual[21] which covers Restricted Use Classification and labeling.

The Agency anticipates that limiting individuals who are not certified applicators to rodenticide products containing one pound or less of bromethalin or cholecalciferol bait in non-refillable, tamper-resistant bait stations (and those specifically registered for use in mole tunnels[22]) could increase the cost of rodent control for residential consumers and for equine and aquaculture operations, which report frequently using consumer products and not possessing applicator

[21] https://www.epa.gov/sites/default/files/2017-10/documents/chap-06-jan-2012.pdf

[22] The Agency is also proposing to allow consumer access to the first-generation anticoagulant rodenticides in similar non-refillable, tamper-resistant bait stations containing less than one pound of bait, while making all other rodenticide products RUP. More information on these mitigations can be found in the dockets for the other rodenticides. For the purpose of assessing mitigations, the Agency considers the total impact of the mitigations proposed in this PID and in the other rodenticides PIDs.

certification. The Agency anticipates residential consumers could replace restricted bromethalin and cholecalciferol products with products that are not restricted for most residential needs; however, this mitigation may increase the cost of control due to the requirement that consumer products only contain non-refillable bait stations.

In addition, when taking into account currently proposed mitigation for other rodenticides undergoing registration review, non-certified individuals would not have any chemical options for below ground rodent control except for bromethalin baits formulated as poison mole worms. Non-certified individuals needing a greater level of control, such as residential consumers who need restricted use rodenticides to control severe rodent infestations or rodents in wall voids, and equine operations who need to control burrowing pests like ground squirrels or pocket gophers, may need to hire certified applicators, at increased costs. If, as a result of this mitigation, equine or aquaculture operators have to obtain certification in order to continue using rodenticides effectively, they could face increased operational costs, including the time, and training associated with obtaining and maintaining applicator certification. Certified applicators or those who contract them may experience increased costs per application due to the recordkeeping required by RUPs.

By limiting the options available to users who are not certified applicators, an increased use of FGARs, bromethalin, and cholecalciferol,**Error! Bookmark not defined.** relative to other rodenticides, is likely to result. The magnitude of these impacts may be further increased when considering the Agency's proposals of also designating the non-anticoagulant rodenticides zinc phosphide and strychnine as RUPs.

The Agency intends to work with co-regulators at the state level and other stakeholders on understanding their needs for implementation and outreach. EPA seeks comment from stakeholders on the potential impacts of the proposed RUP classification.

2. Personal Protective Equipment (PPE)

Loose formulations have the capability to generate particulates and therefore the potential for dermal and inhalation exposures as these products are applied, distributed, used to fill/refill bait stations, or otherwise contacted. EPA has determined that additional PPE for occupational handlers is necessary to minimize dermal and inhalation exposure from loose formulations to the greatest extent possible.

New Respirator and Gloves Requirement for Bromethalin and Cholecalciferol Handlers

The Agency proposes adding respirator and gloves statements to mitigate potential dermal and inhalation exposure risks to occupational handlers for loose formulations of rodenticide products, which are not covered by the agricultural Worker Protection Standard (WPS). The Agency proposes that an APF10 (half-mask elastomeric) respirator is needed and proposes adding any associated fit test, training, and medical evaluation requirements[23] for products that are meal

[23] Pursuant to 40 C.F.R. pt. 170, EPA requires fit testing (29 C.F.R. § 1910.134), training (29 C.F.R. § 1910.134(k)(1)(i)-(vi)), and medical evaluations (29 C.F.R. § 1910.134)—conducted in accordance with the cited OSHA regulations—for all handlers that are required to wear respirators and whose work falls within the scope of the WPS. Label Review Manual at Ch. 10, App. A, https://www.epa.gov/pesticide-registration/label-review-manual.

baits, grain meals, and waxy/paraffinized or non-paraffinized pellets that are not contained in tamper-resistant bait stations.

The Agency anticipates these formulations have the capability to generate particulates and therefore the potential for dermal and inhalation exposures as these products are applied, distributed, used to fill/refill bait stations, or otherwise contacted. EPA is proposing that additional PPE for occupational handlers is necessary to minimize dermal and inhalation exposure to the greatest extent possible.

Requiring a respirator and any associated fit testing, training, and medical evaluation may impose a cost on handlers or employers. If a bromethalin or cholecalciferol handler currently does not have a respirator, additional costs will be incurred by the handler or the handler's employer, including the cost of the respirator and any required respirator fit test, training, and medical exam.[24]

EPA's 2020 HH DRA assumes National Institute for Occupational Safety and Health (NIOSH) protection factors[25] in estimating the inhalation risks and the risk reduction associated with different respirators. If the respirator does not fit properly, EPA's proposed PPE for bromethalin and cholecalciferol may not reduce risks as detailed above and may result in unreasonable adverse effects for the pesticide handler.[26]

The Agency also proposes requiring gloves for anticoagulant rodenticide handlers. The new glove statement should be consistent with Chapter 10 of the Label Review Manual.[27]

Requiring respirators and gloves for handlers would have little impact on the efficacy or feasibility of rodent control; however, the Agency expects that this mitigation could increase the cost of control for organizations who employ certified applicators and consumers who hire certified applicators, if those certified applicators do not currently own and utilize respirators. Organizations who employ certified applicators could be responsible for these costs for their employees, and pest control companies could attempt to pass any increased costs resulting from these mitigations along to customers.

The Agency will consider updates to this requirement should data be submitted that impacts EPA's conclusions regarding the potential for dermal and inhalation exposures.

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[24] Respirator costs are extremely variable, depending upon the protection level desired, disposability, comfort, and the kinds of vapors and particulates filtered. For example, the average cost of a particulate filtering facepiece respirator is lower than the average cost of an elastomeric half mask respirator. Based on available information, EPA has determined that the cost of the respirators (whether disposable or reusable) is relatively minor in comparison to WPS requirements. In 2015, EPA estimated that the annual cost of the WPS requirements (respirator fit test, training and medical exam) was approximately $180 per worker. For more details, see EPA's Economic Analysis of the Agricultural Worker Protection Standard Revisions, at 205 (2015), available in the public docket EPA-HQ-OPP-2011-0184-2522. Costs may be different if an anticoagulant rodenticide handler typically uses other chemicals requiring a respirator in the production system or as part of the business (*e.g.*, eliminated cost of additional fit testing, increased cost of purchasing filters for the respirator on a more frequent basis).

[25] NIOSH protection factors assume that respirators are used according to OSHA's standards.

[26] Proper fit and use of respirators is essential to accomplish the protections respirators are intended to provide. Respirator fit tests are currently required by the Occupational Safety and Health Administration (OSHA) for other occupational settings to ensure proper protection. 29 C.F.R. § 1910.134.

[27] https://www.epa.gov/sites/default/files/2016-02/documents/chap-10-feb-2016.pdf

Updated Respirator and Gloves Requirement for Bromethalin and Cholecalciferol Handlers

In addition to the proposed new PPE requirements, the Agency proposes updating the gloves statements currently on bromethalin and cholecalciferol labels[28], consistent with Chapter 10 of the Label Review Manual.[29] In particular, EPA proposes removing any references to specific categories in EPA's chemical-resistance category selection chart and specifying the appropriate type(s) of glove. The proposed clarification does not fundamentally change the PPE that workers currently must use.

The Agency proposes updating the respirator statement currently on bromethalin and cholecalciferol rodenticide labels.[27] The respirator statement should state that a APF10 (half-mask elastomeric) respirator is needed, along with any associated fit test, training, and medical evaluation requirements[30] for products that are meal bait, grain meals, and waxy/paraffinized or non-paraffinized pellets that are not contained in tamper-resistant bait stations. The proposed clarification does not fundamentally change the PPE that workers currently must use.

3. Application Method Prohibitions for Consumer Size Products

The 2008 RMD required consumer size bromethalin and cholecalciferol products to be sold with a ready-to-use (disposable or refillable) bait station, except for products that are labeled solely for use outdoors, below-ground for control of moles. As noted in the Agency's 2011 Tier I incident report, rodenticides were found to be involved in numerous incidents, including incidents involving children less than 6 years old, and nearly all of those incidents were the result of label directions to keep bait away from children, pets, and non-target wildlife not being followed. Based on the Agency's most recent incident reviews, non-target primary exposures including those to children, domestic pets, and non-target wildlife (including listed species), have continued to occur despite these restrictions. Data from IDS indicate that the total number of rodenticide (anticoagulant and non-anticoagulant) incidents decreased only slightly, from 198 incidents in 2009 to 146 incidents in 2018. Incident data indicate that while the mitigation from the RMD may be contributing to decreases among some rodenticides and populations, overall, there continues to be incidents resulting from users not following label directions.

In particular, the Agency continues to be concerned with the potential risk from improperly stored bait from refillable bait stations and the potential for misuse of bait refills to contribute to these incidents and is proposing that prohibiting refillable, consumer bait station products will reduce the potential for these non-target primary exposures from occurring. Therefore, EPA proposes the following language for consumer size rodenticide products containing bromethalin, except for below-ground mole control, and cholecalciferol:

- Applications must be made in a ready-to-use non-refillable bait stations.

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[28] For specific label language, see Appendix B.

[29] Label Review Manual, https://www.epa.gov/pesticide-registration/label-review-manual.

[30] Pursuant to 40 C.F.R. pt. 170, EPA requires fit testing (29 C.F.R. § 1910.134), training (29 C.F.R. § 1910.134(k)(1)(i)-(vi)), and medical evaluations (29 C.F.R. § 1910.134)—conducted in accordance with the cited OSHA regulations—for all handlers that are required to wear respirators and whose work falls within the scope of the WPS. Label Review Manual at Ch. 10, App. A, https://www.epa.gov/pesticide-registration/label-review-manual.

The gummy, non-meal, non-paraffinized rodenticide formulation (EPA Reg. 149-19) for mole control underground is not affected by this proposed mitigation.

4. Endangered Species and Bulletins Live! Two Label Language

To avoid confusion with necessary protections for listed species in Bulletins Live! Two, EPA is proposing to remove any existing language on labels that contains generic references to listed species and/or species-specific use limitations. In addition, EPA is proposing that the following statement be added to all bromethalin and cholecalciferol labels, excluding those registered solely for use by the general consumer (*i.e.*, homeowners or residential consumers). This language will allow users to access the early-ESA mitigation measures (proposed in Section IV.B and Appendices D and E) and to confirm whether their application site is within the geographic regions where these risk-reduction measures are required. Addition of this statement to labels will help streamline implementation of any additional risk mitigation measures that may be identified during the ESA consultation process:

> ***"ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS:***
> *It is a Federal offense to use any pesticide in a manner that results in an unauthorized "take" (e.g., kill or otherwise harm) of an endangered species and certain threatened species, under the Endangered Species Act section 9. When using this product, you must follow the measures, including any timing restrictions, contained in the Endangered Species Protection Bulletin for the area where you are applying the product. Before using this product, you must obtain a Bulletin at any time within six months of the day of application. To obtain Bulletins, consult http://www.epa.gov/espp. For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov."*

EPA uses BLT only when mitigation applies in a particular geographic region where listed species are present and, in some cases, only during certain times of the year. A physical label cannot feasibly accommodate all these lengthy mitigation instructions. Similarly, BLT simplifies compliance by offering an easy way for users to identify where and when they are subject to the mitigation. Otherwise, users would need to use existing information from a variety of sources beyond the label to evaluate whether the location of their treatment area overlaps with an area for which EPA has identified geographically specific mitigation. Then they would need to read through hundreds of pages of a label to determine which restrictions apply to their treatment area.

Although the BLT system has been in place for many years, there may be applicators who are unfamiliar with this system. Using the online tool to determine if mitigation is required for a particular treatment area may be a new step that many users will need to take prior to an application. However, the Agency anticipates that over time and with wider implementation, BLT will become a familiar tool that is integrated into a user's planning process for pesticide applications. In February 2022, EPA released an improved version of BLT[31], which allows users to more easily find the information they need for a particular pesticide product. The Agency has

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

also developed a tutorial[32] that explains how to use the online system. In addition, the general label language referring users to BLT provides a phone number and email address for those needing technical assistance.

Appendix E provides guidance for bromethalin and cholecalciferol users to learn if they are adjacent to or within borders of a species' range or designated critical habitat.

5. Post-Application Follow-Up: Carcass Search, Collection, and Disposal Statements

To reduce the potential for non-target exposures, the Agency is proposing additional post-application follow-up statements for bromethalin and cholecalciferol labels to address carcass search, collection, and disposal. Carcass searches and subsequent disposal ensures that dead and dying organisms that have consumed rodenticide products are inaccessible to predators and scavengers, therefore reducing the potential for secondary poisoning of non-target organisms. The 2012 Rozol Prairie Dog Bait and Kaput-D Prairie Dog Bait Biological Opinions required carcass search, collection, and disposal requirements to minimize potential exposure risks to listed and non-target species and EPA is proposing that these statements are applicable to other rodenticide products, including bromethalin and cholecalciferol.

EPA is proposing to add the following advisory carcass search, collection, and disposal language to bromethalin and cholecalciferol rodenticide products classified as RUPs and registered for use in structural use sites and consumer sized bromethalin and cholecalciferol products to instruct users on the proper method to collect and dispose of carcasses if they are found at or near the application site:

> *"While wearing gloves, collect and properly dispose of visible carcasses of target pests or non-target animals. Place carcasses in leakproof plastic bags or other suitable containers and dispose of in the trash or dispose of according to the Pesticide Disposal instructions."*

6. Post-Application Follow-Up: Spilled and/or Kicked Out Bait Statement

The Agency is proposing that additional post-application follow-up statements addressing spilled bait and/or bait kicked out of burrow systems are necessary for bromethalin products registered for use in burrows. Rodent activities can move bait outside of burrow systems to areas where non-target organisms could access the bait. To reduce the potential for non-target exposures, EPA proposes adding the following mandatory post-application follow-up statements to bromethalin products registered for non-structural use sites:

> *"While wearing gloves, dispose of leftover and any visible bait that has been moved from its placement location according to the Pesticide Disposal Instructions."*

The Agency anticipates that requiring additional post-application follow-up measures for bromethalin could increase labor costs for the use of bromethalin products registered for use in non-structural use sites. This mitigation measure is expected to increase the costs of rodent control in these sites by increasing the amount of time and labor spent on site returns. Affected

[32] https://www.epa.gov/endangered-species/bulletins-live-two-blt-tutorial

individuals would have to either accept these costs or else use alternative methods of rodent control (e.g., mechanical trapping, fumigation). Alternative methods of rodent control may be insufficient; for example, in addition to the labor costs associated with setting and maintaining traps, traps could also pose a danger to equipment or non-target organisms. Hiring additional labor or contracting pest control services in order to adhere to the label could be expensive or infeasible for affected individuals.

7. Post-Application Follow-Up: Reporting Statements

EPA is proposing to add the following mandatory reporting requirements to bromethalin and cholecalciferol products classified as RUPs that are registered for use in non-structural use-sites:

> *"All dead or dying non-target animals must be reported according to EPA's Pesticide Incident Reporting website at https://www.epa.gov/pesticide-incidents as soon as possible."*

EPA is proposing to add the following advisory reporting information to consumer sized bromethalin and cholecalciferol products:

> *"All dead or dying non-target animals should be reported according to EPA's Pesticide Incident Reporting website at https://www.epa.gov/pesticide-incidents as soon as possible."*

8. Label Updates: Optional Graphics

The Agency reviews graphics on pesticide labeling on a case-by-case basis. Where products bear graphics that depict use of the product, the graphics may only depict use as described on the label, including application method, quantity of bait, and target species. Graphics depicting a non-labeled use pattern or non-labeled target species could suggest use outside of labeled parameters and result in misapplication, therefore increasing the potential for non-target organism exposure. Registrants should review all optional graphics on their bromethalin and cholecalciferol products and update them if needed when the Agency requests amended labels in conjunction with this registration review.

9. Label Updates: Organic Compatibility Claims

The Agency proposes that any cholecalciferol products that claim to be compatible with organic production also pair that claim with the following caveat:

> *"While this product is compatible with organic production, it is toxic to pets and other non-target organisms."*

As an alternative, the organic claim can be deleted.

B. Proposed Risk Mitigation and Regulatory Rationale for ESA Pilot

Rodenticides pose a general risk of mortality to non-target mammals and birds that may consume bait. Many rodenticides also pose a secondary poisoning risk to animals that prey upon or

scavenge primary consumers (e.g., birds of prey, carnivorous mammals). EPA is proposing mitigation measures intended to address the Agency's initial prediction of a likelihood of jeopardy to three listed species: Stephens' kangaroo rat, Attwater's prairie chicken, and California condor. One of those species, the California condor, also has a designated critical habitat. The proposed mitigation measures are also intended to address the Agency's initial prediction of adverse modification of the designated critical habitat of the California condor.

These three species were chosen to pilot early rodenticide proposed mitigation for listed species because they represent examples of the listed species that may be affected by rodenticides through different routes of exposure (i.e., primary and secondary consumption). The assessments for the three species and one critical habitat and associated mitigation measures are considered pilots for other listed species that may be similarly exposed and affected by rodenticides. EPA intends to apply approaches used for these three species in the final analyses to all listed species that may be exposed to rodenticides via primary or secondary exposure. EPA identified 91 listed species[33] of mammals, birds, reptiles, and amphibians that may be exposed to rodenticides through primary or secondary consumption. For bromethalin and cholecalciferol, the Agency intends to make the determinations for all listed species available in a draft BE that will be available for public comment in November 2023 and finalized in November 2024.

EPA intends to publish the proposed mitigation language for the pilot species, once it is finalized, in BLT,[34] thus the geographic-specific use restrictions would not appear on container labels. In addition, to avoid confusion with necessary protections for listed species in BLT, EPA is proposing to remove any existing language on labels that contains generic references to listed species and/or species-specific use limitations. The label language described in Section IV.A includes a label requirement to reference BLT and to use the product consistent with the appropriate bulletin(s), thus making them enforceable. These mitigation measures are spatially explicit and are therefore only applicable to applicators within the specified geographic areas. Species-specific mitigation measures and descriptions of how these mitigation measures will avoid jeopardy and adverse modification are described below. For more information on the Agency's draft effects determinations, predictions of jeopardy or adverse modification and evaluation of the proposed mitigation measures for these three pilot species, see *Rodenticides: Draft Effects Determinations and Evaluation of Proposed Mitigations Intended to Avoid Jeopardizing Three Federally Listed Endangered and Threatened Species and Avoid Adversely Modifying One Designated Critical Habitat* (September 28, 2022) (below, "the Agency's pilot ESA assessment").

EPA qualitatively assessed the potential impacts of these mitigation measures and recognizes there could be impacts on users in the spatial areas where mitigation measures and use restrictions are proposed. For more information on the anticipated impacts of EPA's proposed mitigations for the rodenticides, see *Use and Benefits of 11 Rodenticides and Impacts of Potential Mitigation* (October 27, 2022), available in the public docket.

[33] When EPA conducts a full biological evaluation for the rodenticides, the number of species may be revised based on changes to listing status or available information on species-specific diet or life history.
[34] https://www.epa.gov/endangered-species/bulletins-live-two-view-bulletins

1. Proposed Mitigation for the Stephens' Kangaroo Rat

The Agency's pilot ESA assessment led to draft predictions of jeopardy for the Stephens' kangaroo rat for bromethalin. Cholecalciferol was found to be not likely to jeopardize the Stephens' kangaroo rat. To address the initial predictions of the likelihood of jeopardy for the Stephens' kangaroo rat, EPA is proposing to prohibit broadcast applications and below-ground in-burrow applications of bromethalin products within the species' range. Additionally, the Agency is proposing to require bromethalin be applied using bait stations designed to exclude the Stephens' kangaroo rat. Appendix D of the pilot ESA assessment includes a discussion of two bait station designs available for control of the California ground squirrel, which is a pest that occurs within the range of the Stephens' kangaroo rat. For other target pests (e.g., voles), different designs may be needed to allow the target pest access, but limit access by the Stephens' kangaroo rat. EPA is interested in public comments on bait station designs for allowing access of other target pests. Because EPA intends to expand this pilot to other listed species of mammals that are primary consumers, the Agency is also interested in public comments on bait station designs for exclusion of other listed species. Bait stations shall be designed with an opening that prevents access to non-target species (opening not to exceed 3"). Additionally, bait stations shall be secured (e.g., staked) in an upright position (or elevated) and designed to prevent spillage by rodents feeding.

Prohibiting burrow-bait applications in areas with specific listed species may force users seeking rangeland and other large area control of prairie dogs, pocket gophers, and moles to switch to burrow bait stations, fumigation, or mechanical control, likely at increased cost.

Requiring that users only apply rodenticides in specifically designed bait stations designed to exclude specific listed species could prevent users from using chemical rodenticides for controlling pests with biological similarities to the listed species; these users would need to switch to mechanical, fumigation, or biological control options and may be unable to achieve the same level of control as with rodenticides.

2. Proposed Mitigation for the Attwater's Prairie-Chicken

The Agency's pilot ESA assessment led to a draft effects determination of no effect and therefore EPA did not need to make a jeopardy prediction for exposure of the Attwater's prairie-chicken to bromethalin and cholecalciferol.

3. Proposed Mitigation for the California Condor

The Agency's pilot ESA assessment led to a draft effects determination of not likely to adversely affect (NLAA) bromethalin and a draft effects determination of no effect for cholecalciferol and therefore EPA did not need to make a jeopardy prediction for exposure of the California Condor to bromethalin and cholecalciferol.

C. Proposed Updates to the Terms and Conditions of Registration

While the Agency is proposing that all bromethalin and cholecalciferol products packaged in quantities $\geq$ 4 lbs. of bait be classified as RUP, the variations between state programs and certification categories presents an opportunity for additional registrant stewardship to help ensure users have the necessary support to use their products in a safe and efficacious manner to

achieve the desired level of rodent prevention and control. Registrants have already reached out to the Agency with suggestions for a stewardship plan, and the Agency has considered those suggestions in the development of this PID. The Agency proposes the following updated terms and conditions for the rodenticide registrations:

Education and Outreach Stewardship Plan

Registrants must develop, implement, and maintain a rodenticide stewardship plan that includes the development of education and outreach materials intended for product users that are made available on registrants' websites. The purpose of these plans is to educate the user on proper rodenticide use and to address potential impacts from the use of these products to non-target organisms, including listed species. The individual plans must include the following components:

1) Rodenticide registrants must develop educational materials that describe the importance of protecting non-target organisms and best management practices to reduce potential rodenticide exposure to non-target organisms, including listed species. Materials must also describe label provisions intended to minimize the potential for product exposure to non-target organisms, including, if applicable, carcass search, collection, and disposal, cleaning up spilled or kicked-out bait, use of BLT, and incident reporting.
2) The importance of integrated pest management practices to control a rodent infestation, including, but not exclusive to, inspection, sanitation, exclusion, mechanical control, and chemical control. Additionally, these materials should include information relating to rodent biology and rodent behavior for the target pests listed on the registrant's labels, the different types of rodenticides and how they work, and the various use sites and application methods of the rodenticides for which the registrant owns the registrations.

References to the company's website on the label, including listing a web address or a Quick Response (QR) Code, renders the website as labeling under FIFRA and therefore subject to review by the Agency.

D. Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. Throughout the registration review process, EPA has sought to include all communities and persons, including minority, low-income, and indigenous populations who may be disproportionately overburdened by the exposure to bromethalin and cholecalciferol.

While people of all income levels may be exposed to mouse and rat infestations, these incidents are most common in housing for lower socio-economic populations. Proper rodent prevention measures, especially exclusion, can be expensive and/or time-consuming for low-income households and in multi-family dwellings. Furthermore, rodent prevention methods often rely on support from the entire community and may be more difficult in communities with a higher population density or with a lower quality of services (e.g., in areas with poor waste management services). In these instances, rodent control measures including mechanical trapping and use of rodenticides, including bromethalin and cholecalciferol, may have a higher benefit to these

populations relative to more affluent populations. Because the poorest populations may face the most frequent rodent infestations, these populations face the highest health and safety risks both from rodent infestations and from the use of chemical rodenticides including bromethalin and cholecalciferol. Therefore, these populations may be disproportionately affected by changes to the use patterns or availability of the rodenticides and may disproportionately experience impacts, including cost increases or reduction in rodent control, from the Agency's proposed mitigation measures for the rodenticides.

For further EJ considerations and distributional concerns associated with rodents, rodenticides, and the Agency's proposed mitigation measures, see *Use and Benefits Assessment for 11 Rodenticides and Impacts of Potential Risk Mitigation*, (October 27, 2022).

The Agency requests any additional information on any other groups or segments of the population who, as a result of their proximity and exposure to pesticides, unique exposure pathway (e.g., as a result of cultural practices), location relative to physical infrastructure, exposure to multiple stressors and cumulative impacts, lower capacity to participate in decision making, or other factors, may have unusually high exposure to bromethalin and cholecalciferol compared to the general population or who may otherwise be disproportionately affected by the use of bromethalin and cholecalciferol.

Additionally, the Agency requests information on those populations who may be disproportionately overburdened by the exposure to the diseases that are directly and indirectly transmitted by rodents and exposure to rodenticides. These populations may be most affected by the additional restrictions proposed for bromethalin and cholecalciferol, and the Agency requests additional information on the potential impacts of these proposed mitigation measures.

E. Tolerance Actions

No tolerances are established or needed for bromethalin or cholecalciferol because the use sites and the use patterns for bromethalin and cholecalciferol are not expected to result in residues on food, feed, and forage. Therefore, the Agency is not taking any tolerance actions.

F. Proposed Interim Registration Review Decision

The Agency is issuing this PID in accordance with 40 C.F.R. §§ 155.56 and 155.58. The Agency: (1) proposes that no additional data are required at this time; and (2) proposes that bromethalin and cholecalciferol do not meet the registration standard without changes to the affected registrations and their labeling. EPA proposes that the mitigation measures specified in Section IV.A and Appendices A and B and the updates to the terms and conditions specified in Section IV.C and Appendix C are sufficient to address risk concerns.

The Agency conducted detailed draft HHRA and Eco DRAs. In these risk assessments, EPA identified the potential for occupational handler and non-target organism exposures from the continued registration of bromethalin and cholecalciferol without additional mitigation measures. The Agency identified the potential for dermal and inhalation exposures to occupational handlers from using bromethalin and cholecalciferol products that are in loose formulations. Additionally, EPA has identified potential risk for non-target exposures to children, domestic pets, and non-

target wildlife, including listed species, from bromethalin and cholecalciferol. EPA proposes that additional human health and ecological risk mitigation measures are necessary to reduce the potential for non-target exposures to occur, and therefore is proposing the following mitigation measures: RUP classification for all bromethalin and cholecalciferol products packaged in sizes $\geq$ 4 lb of bait, the prohibition of refillable bait stations for consumer sized ($\leq$ 1 lb) bromethalin and cholecalciferol products, additional PPE for occupational handlers, and the addition of post-application follow-up statements for the search, collection, and disposal of carcasses, the cleanup of bait moved from its original placement location, and the reporting of dead/dying non-target organisms.

EPA also conducted an assessment of the benefits of the use of bromethalin and cholecalciferol and determined that continuing to register bromethalin and cholecalciferol provides benefits for controlling a variety of vertebrate pests in a variety of use sites, thereby protecting people, animals, structures, and the environment from the risks that rodents pose. Rodents pose a substantial threat to human health and the environment by consuming food and feed, vectoring disease and ectoparasites to people and animals, damaging structures and equipment, and disrupting ecosystem balance and biodiversity.

During registration review, EPA considers whether a pesticide registration "continues to satisfy the FIFRA standard for registration."[35] Here, EPA proposes that bromethalin and cholecalciferol do not meet the FIFRA registration standard without the changes to the affected registrations and their labeling described in Section IV.A, Appendices A, B, and C, and the terms and conditions specified in Section IV.C and Appendix C. EPA is proposing that the addition of these mitigation measures to bromethalin and cholecalciferol labels is necessary in order to meet the risk-benefit standard.

No tolerances are established or needed for bromethalin or cholecalciferol because the use sites and the use patterns for bromethalin and cholecalciferol are not expected to result in residues on food, feed, and forage. Therefore, the Agency is not taking any tolerance actions.

In this PID, the Agency is not making any human health or environmental safety findings associated with the Endocrine Disruptor Screening Program (EDSP) screening of bromethalin and cholecalciferol. Similarly, the Agency is not making a complete endangered species finding, though the proposed mitigation is expected to reduce the extent of environmental exposure and may reduce exposure to listed species whose range or critical habitat co-occur with the use of bromethalin and cholecalciferol. As noted in Section IV.B., using its authorities under FIFRA, EPA is also proposing mitigation for the Stephens' kangaroo rat for which the Agency predicts that the currently registered uses of bromethalin has a likelihood of jeopardizing the species.

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[35] 40 C.F.R. § 155.40(a); 7 U.S.C. § 136a(c)(5); *see also* 7 U.S.C. §§ 136(bb) (defining "unreasonable adverse effects on the environment" as encompassing both "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" [FIFRA's risk-benefit standard] **and** "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FFDCA safety standard]"). In a PID, EPA sets out a proposed interim decision that includes EPA's "proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings." 40 C.F.R. §§ 155.56, 155.58(b)(1).

These mitigations are proposed in advance of completion of consultation with the Services. The Agency expects to complete a listed-species assessment by November 2024 and subsequently, initiate any necessary Endangered Species Act (ESA) Section 7 consultation with the Services. Additionally, EPA expects to make an EDSP determination before issuing a final registration review decision for bromethalin and cholecalciferol. For more information, see Appendices F and G.

G. Data Requirements

EPA does not anticipate calling-in additional data for bromethalin and cholecalciferol's registration review at this time.

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of the bromethalin and cholecalciferol PID and open a 75-day comment period.

Appendix A: Summary of Proposed Actions for Bromethalin and Cholecalciferol

Active ingredients: bromethalin and cholecalciferol Registration Review Case #s: 2765 and 7600 PC Codes: 112802 and 202901 Chemical Type: Rodenticide Chemical Family: Non-Anticoagulant Mode of Action: Neurotoxin and Hypercalcemia					
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
Infants, children, pets	Dietary	Accidental ingestion and incidental oral	Acute	Acute toxicity	RUP classification for all products sold in packages ≥ 4 lbs. Prohibition of refillable bait stations for consumer products Mandatory bait spill/kick out statements
Occupational Handlers	Air and dermal contact	Inhalation Dermal absorption	Short- and intermediate-term	Inhalation and dermal toxicity	Half-mask elastomeric respirators and gloves
Mammals, birds, terrestrial-phase amphibians and reptiles	Dietary	Ingestion	Acute	Acute toxicity	RUP classification for all products sold in packages ≥ 4 lbs. Advisory carcass search and disposal statements Mandatory or advisory reporting statements Mandatory bait spill/kick out statements
ESA Pilot Species					
Stephens' kangaroo rat (*Dipodomys stephensi*)	Dietary	Ingestion	Acute	Acute toxicity	Prohibit broadcast and in-burrow applications within the species' range for bromethalin Require specially modified bait stations designed to exclude the Stephens' kangaroo rat be used with the species' range

Appendix B: Proposed Labeling Changes for Bromethalin and Cholecalciferol Products

Description	Proposed Label Language for Bromethalin and Cholecalciferol Products	Placement on Label
	End Use Products	
Restricted Use Pesticide Statement for products packaged in quantities ≥ 4 lbs.	"Restricted Use Pesticide" (same minimum type size as signal word) "Due to Hazard to Non-target Organisms." "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."	At the top of the front panel. All of the text must be in a box. See Chapter 6 of the Label Review Manual for labelling requirements for RUPs[36]
Restricted Use Pesticide Statement for products packaged in quantities ≥ 4 lbs.	"Restricted Use Pesticide"	Directions for Use
Requirement for Gloves for products that are meal baits, grain meals, and waxy/paraffinized or non-paraffinized pellets	For products that are meal baits, grain meals, and waxy/paraffinized or non-paraffinized pellets: Add gloves statement consistent with Chapter 10 of the Label Review Manual.	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Updated Gloves Statement for products that currently require gloves	Update the gloves statement to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA's chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.	In the Personal Protective Equipment (PPE) within the Precautionary Statements
New Respirator Language for products that are meal baits, grain meals, and waxy/paraffinized or non-paraffinized pellets	For products that are granules, grain meals, and waxy/paraffinized or non-paraffinized pellets: **"Applicators and other handlers (when filling bait stations) must also:"** [**Note to registrant**: If your end-use product only requires protection from particulates only (low volatility), use the following language:] "Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N*, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N*, R or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products oil in the products.	In the Personal Protective Equipment (PPE) within the Precautionary Statements

[36] The statement must meet the minimum type size requirements of the human hazard signal words. See Chapter 6 of the Label Review Manual for labeling requirements for RUPs.

Updated Respirator Language	[**Note to registrant**: If your end-use product only requires protection from particulates only (low volatility), use the following language:] "Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N*, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N*, R or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Respirator Fit Testing Requirements for Non-WPS Uses	**"Respirator fit testing, medical qualification, and training** Using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134), employers must verify that any handler who uses a respirator is: • Fit-tested and fit-checked, • Trained, and • Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health status or respirator style or use conditions change. Upon request by local/state/federal/tribal enforcement personnel, employers must provide documentation demonstrating how they have complied with these requirements."	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Application Method Prohibitions for products packaged in quantities ≤ 1 lb. of bait labeled for consumer/residential use EXCEPTION: gummy worms for mole control (example: EPA reg. 149-19)	"Applications must be made in a ready-to-use disposable bait station. All other methods of application are prohibited."	Restrictions Section Under Directions for Use
Endangered Species Language For all products, excluding those labeled/registered solely for use by the general consumer, such as homeowners or residential consumers	"**ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS**: It is a Federal offense to use any pesticide in a manner that results in an unauthorized "take" (e.g., kill or otherwise harm) of an endangered species and certain threatened species, under the Endangered Species Act section 9. When using this product, you must follow the measures, including any timing restrictions, contained in the Endangered Species Protection Bulletin for the area where you are applying the product. Before using this product, you must obtain a Bulletin at any time within six months of the day of application. To obtain Bulletins, consult http://www.epa.gov/espp. For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov."	Directions for Use, under the heading "ENDANGERED SPECIES PROTECTION REQUIREMENTS"

Existing Label Language referring to Endangered Species	Remove any existing language on labels that contains generic references to listed species and/or species-specific use limitations.	
Mandatory Statements Regarding Post-Application Follow-Up of Spilled and/or Kicked Out Bait for Restricted Use Products packaged in sizes ≥ 4 lbs. of bait used in fields and other non-structural use sites	"While wearing gloves, dispose of leftover bait and any visible bait that has been moved from its placement location according to the Pesticide Disposal Instructions."	Directions for Use, after directions for specific sites, under the heading "Post-Application Follow-Up"
Mandatory Reporting Requirements for Restricted Use Products packaged in sizes ≥ 4 lbs. of bait used in fields and other non-structural use sites	"**Reporting** All dead or dying non-target animals must be reported according to the guidance on EPA's Pesticide Incident Reporting website at https://www.epa.gov/pesticide-incidents soon as possible."	Directions for Use, after directions for specific sites, under the heading "Post-Application Follow-Up"
Advisory Statements Regarding Post-Application Follow-Up for Restricted Use Products packaged in sizes ≥ 4 lbs. of bait used in structural use sites and for products packaged in sizes ≤ 1 lb. of bait labeled for consumer/residential use	"**Carcass Collection and Disposal** While wearing gloves, collect and properly dispose of visible carcasses of target and non-target animals. Place carcasses in leakproof plastic bags or other suitable containers and dispose of in the trash or dispose of according to the Pesticide Disposal instructions."	Directions for Use, after directions for specific sites, under the heading "Post-Application Follow-Up"
Advisory Reporting Information for Restricted Use Products packaged in sizes ≥ 4 lbs. of bait used in structural use sites and for products packaged in sizes ≤ 1 lb. of bait labeled for consumer/residential use	"**Reporting Information** All dead or dying non-target animals should be reported according to the guidance on EPA's Pesticide Incident Reporting website at https://www.epa.gov/pesticide-incidents soon as possible."	Directions for Use, after directions for specific sites, Follow-Up

For Labels that Contain Optional Graphics	All graphics must depict use consistent with the label directions. For example, graphics that depict large piles of bait that exceed label placement amounts and omit the label-required bait station are prohibited. Graphics must depict the target pest species. Graphics depicting non-target pest species are prohibited.	Optional graphics sections, wherever they appear
For Labels That Claim Compatibility with Organic Production	"While this product is compatible with organic production, it is toxic to pets and other non-target organisms."	With claims of compatibility with organic production

Registrants must also comply with the updates to the Terms and Conditions for registration specified in Appendix C.

Appendix C: Updated Terms and Conditions of Registration

The Agency proposes the following updated terms and conditions for the rodenticide registrations:

Education and Outreach Stewardship Plan

Registrants must develop, implement, and maintain a rodenticide stewardship plan that includes the development of education and outreach materials intended for product users that are made available on registrants' websites. The purpose of these plans is to educate the user on proper rodenticide use and to address potential impacts from the use of these products to non-target organisms, including listed species. The individual plans must include the following components:

1. Rodenticide registrants must develop educational materials that describe the importance of protecting non-target organisms and best management practices to reduce potential rodenticide exposure to non-target organisms, including listed species. Materials must also describe label provisions intended to minimize the potential for product exposure to non-target organisms, including, if applicable, carcass search, collection, and disposal, cleaning up spilled or kicked-out bait, overview of BLT, and incident reporting.
2. The importance of integrated pest management practices to control a rodent infestation, including, but not exclusive to, inspection, sanitation, exclusion, mechanical control, and chemical control. Additionally, these materials should include information relating to rodent biology and rodent behavior for the target pests listed on the registrant's labels, the different types of rodenticides and how they work, and the various use sites and application methods of the rodenticides for which the registrant owns the registrations.

References to the company's website on the label, including listing a web address or a Quick Response (QR) Code, renders the website as labeling under FIFRA and therefore subject to review by the Agency.

Appendix D: Proposed Bulletins Live! Two Use Limitation Language for Bromethalin Products

Table 1: Proposed Bulletins Live! Two Language for the Stephens' Kangaroo Rat (*Dipodomys stephensi*)

Active Ingredient	Use Limitation	Pesticide Use Limitation Area (PULA)

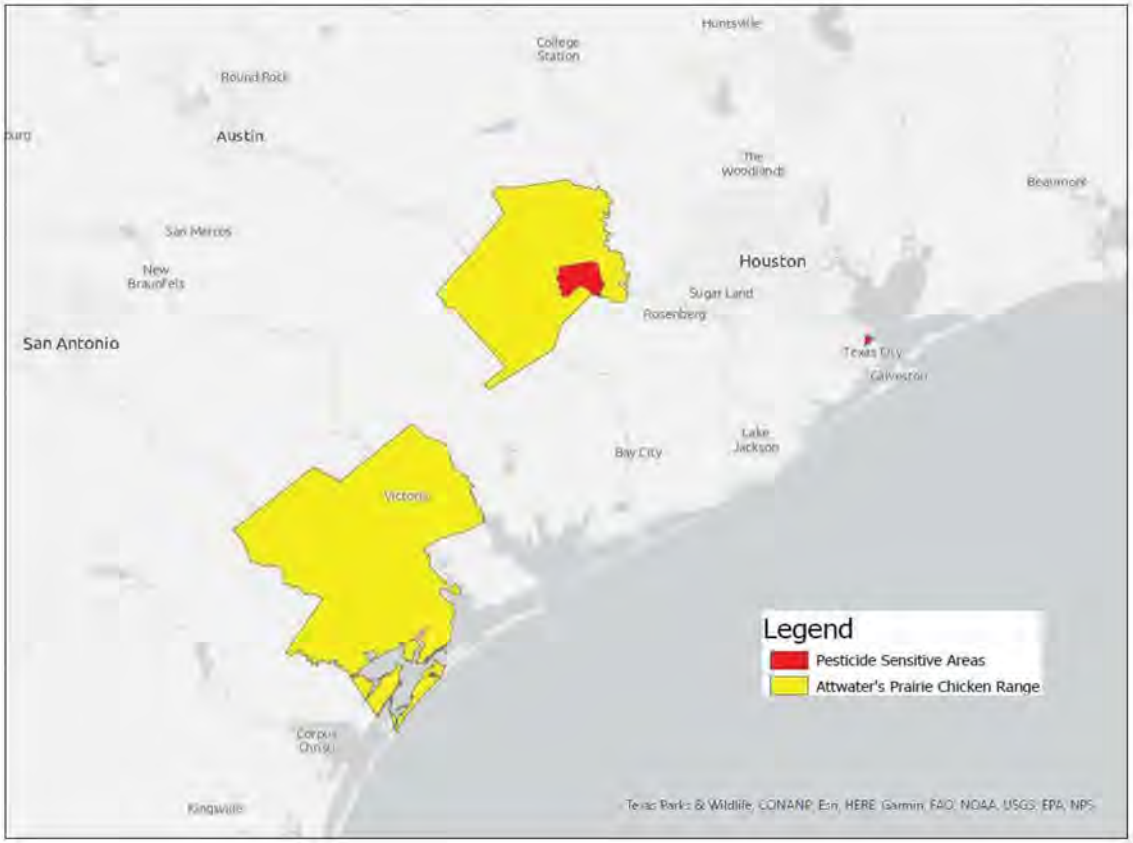
Bromethalin	• Do not apply via broadcast application. • Do not apply below ground into rodent burrows. • Modified bait stations designed to exclude listed species are required. This bulletin is relevant to a listed kangaroo rat species.	Within the FWS **range** of the Stephens' kangaroo rat (Appendix E Figure 1)

Appendix E: Ranges and Critical Habitats of Pilot Species for Early-ESA Mitigation

Figure 1. Stephens' kangaroo rat (*Dipodomys stephensi*) range.[37]

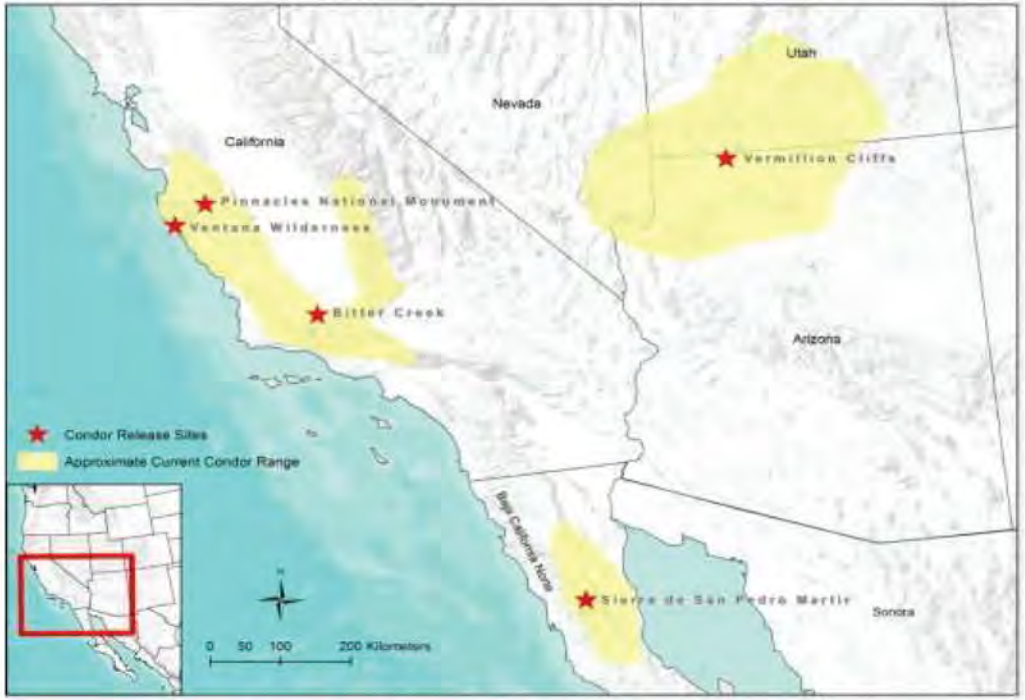
[37] U.S. Fish and Wildlife Service. 2021a. Species Report for the Stephens' kangaroo rat (*Dipodomys stephensi*). Version 1.2, August 2021. U.S. Fish and Wildlife Service, Pacific Southwest Region, Sacramento, California. xii + 121 pp.

Figure 2. Attwater's prairie-chicken (*Tympanuchus cupido attwateri*) range and Pesticide Sensitive Areas (Pesticide Sensitive Area Shapefile generated by EPA using range data from FWS Environmental Conservation Online System (ECOS; https://ecos.fws.gov/ecp/), downloaded December 2020; and Pesticide Sensitive Data from FWS.[38]



[38] U.S. Fish and Wildlife Service. 2004. Recommended Protection Measures for Pesticide Applications in Region 2 of the U.S. Fish and Wildlife Service. U.S. Fish and Wildlife Service Region 2, Environmental Contaminants Program, Austin, TX. 199 pp.

Figure 3. California condor range (*Gymnogyps californianus*) and active release sites from 2012.[39]



[39] U.S. Fish and Wildlife Service. 2013. California Condor (*Gymnogyps californianus*) 5 Year Review: Summary and Evaluation. U.S. Fish and Wildlife Service, Pacific Southwest Region. June 2013. 64 pp.

Figure 4. California condor (*Gymnogyps californianus*) critical habitat, from the Environmental Conservation Online System (ECOS; retrieved April 15, 2022).

Table 1: Links to Access Spatial Units for Pilot Species Ranges and Designated Critical Habitats

Species	Spatial Area	Link
Stephens' Kangaroo rat (*Dipodomys stephensi*)	Range	https://ecos.fws.gov/ecp/species/3495
Attwater's prairie-chicken (*Tympanuchus cupido attwateri*)	Range	https://ecos.fws.gov/ecp/species/7259
California condor (*Gymnogyps californianus*)	Range and Designated Critical Habitat	https://ecos.fws.gov/ecp/species/8193

Guidance for bromethalin and cholecalciferol users to determine if a treatment area will be subjected to the proposed mitigation for listed species.

The Agency is providing guidance for users to determine if their treatment area will be impacted by the proposed mitigation so that they are better equipped to provide comments. Bromethalin and cholecalciferol users can use links provided in third column of Table 1 to access information on each species' biology, listing status, range and designated critical habitat, if defined. As an example, if one were to click on the link for California condor, the website shown in Figure 5 below appears. Visitors to the webpage will note that there are sections titled 'Range Information' and 'Critical Habitat' at the top of the webpage (red boxes in Figure 5). By clicking on 'Range Information,' the map in that section of the webpage shows the range of the species (Figure 6 below). Note in the upper left-hand corner, there is a zoom tool that allows individuals to zoom in on the map to determine if the area(s) to be treated is located within the California condor's range and subject to the mitigation described in this PID. If visitors to the webpage click on 'Critical Habitat' shown in Figure 5, they will be directed to a map for the critical habitat (Figure 7 below). Figure 7 below also includes a zoomed in picture of a critical habitat to show the level of granularity the maps online are capable of providing.

Figure 5. The ECOS website linked in Table 1 for the California condor. Red boxes surrounding 'Range Information' and 'Critical Habitat' will direct website visitors to range and critical habitat maps featured in Figures 6 and 7 below, respectively.

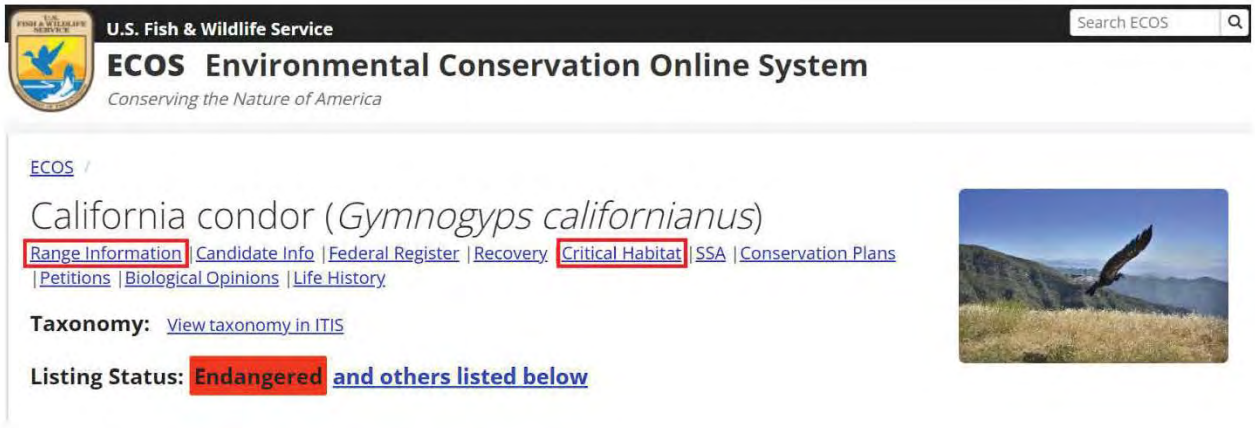


Figure 6. California condor range map.

Figure 7. An overview of the California condor designated critical habitat. Inset map shows a close-up view of one of the constituent designated habitats.

Appendix F: Background on Listed-Species Approach

This Appendix provides general background about the Agency's assessment of the effects of pesticides on listed species and designated critical habitats under the Endangered Species Act (ESA). Additional background specific to bromethalin and cholecalciferol appears at the conclusion of this Appendix.

Developing Approaches for ESA Assessments and Consultations for FIFRA Actions

In 2015, EPA, along with the Services—the Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS)—and the United States Department of Agriculture (USDA) (referred to as "the agencies") released their joint Interim Approaches[40] for assessing the effects of pesticides to listed species. The agencies jointly developed these Interim Approaches in response to the 2013 National Academy of Sciences' recommendations that discussed specific scientific and technical issues related to the development of assessments of pesticides' effects to listed species. Since that time, the agencies have been continuing to work to improve the approaches for assessing effects to listed species. After receiving input from the Services and USDA on proposed revisions to the interim method and after consideration of public comments received, EPA released an updated Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides ("Revised Method") in March 2020.[41]

The agencies also continue to work collaboratively through a FIFRA Interagency Working Group (IWG). The IWG was created under the 2018 Farm Bill to recommend improvements to the ESA section 7 consultation process for FIFRA actions and to increase opportunities for stakeholder input. This group is led by EPA and includes representatives from NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). The IWG outlines its recommendations and progress on implementing those recommendations in reports to Congress.[42]

Consultation on Chemicals in Registration Review

EPA initially conducted biological evaluations (BEs) using the interim method on three pilot chemicals representing the first nationwide pesticide consultations (final pilot BEs for chlorpyrifos, malathion, and diazinon were completed in January 2017). These initial pilot consultations were envisioned as the start of an iterative process. Later that year, NMFS issued a final biological opinion for these three pesticides. In 2019, EPA requested to reinitiate formal consultation with NMFS on malathion, chlorpyrifos and diazinon to consider new information that was not available when NMFS issued its 2017 biological opinion. EPA received a final malathion biological opinion[43] from FWS in February 2022 and a final biological opinion from NMFS on malathion, chlorpyrifos and diazinon in June 2022.[44] The Agency plans to implement

[40] https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report
[41] https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional
[42] https://www.epa.gov/endangered-species/reports-congress-improving-consultation-process-under-endangered-species-act
[43] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions
[44] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions

both biological opinions according to the 18-month timeframes specified in the biological opinions.

In 2020, EPA released draft BEs for the first two chemicals conducted using the 2020 Revised Method—carbaryl and methomyl. Subsequently, EPA has used the Revised Method to complete final BEs for carbaryl, methomyl, atrazine, simazine, glyphosate, clothianidin, imidacloprid, and thiamethoxam. EPA is currently in consultation with the Services on these active ingredients.

EPA's New Actives Policy and the 2022 Workplan
The 2018 Farm Bill established a FIFRA Interagency Working Group (IWG) to recommend improvements to the ESA section 7 consultation process for FIFRA actions and to increase opportunities for stakeholder input. This group is led by EPA and includes representatives from NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). The IWG outlines its recommendations and progress on implementing those recommendations in reports to Congress.[45] The agencies continue to work collaboratively, consistent with Congress's intent in creating the IWG.

In January 2022, EPA announced a policy[46] to evaluate potential effects of new conventional pesticide active ingredients to listed species and their designated critical habitat and initiate consultation with the Services, as appropriate, before registering these new pesticides. Before the Agency registers new uses of pesticides for use on pesticide-tolerant crops, EPA will also continue to make effects determinations. If these determinations are likely to adversely affect determinations, the Agency will not register the use unless it can predict that registering the new use will not have a likelihood of jeopardizing listed species or adversely modifying their designated critical habitats. EPA will also initiate consultation with the Services as appropriate.

In April 2022, EPA released a comprehensive, long-term approach to meeting ESA obligations, which is outlined in *Balancing Wildlife Protections and Responsible Pesticide Use.*[47] This workplan reflects the Agency's most comprehensive thinking to date on how to create a sustainable ESA-FIFRA program that focuses on meeting EPA's ESA obligations and improving protection for listed species while minimizing regulatory impacts to pesticide users and collaborating with other agencies and stakeholders on implementing the plan.

ESA Assessments or Biological Opinions Impacting Bromethalin and Cholecalciferol

The non-anticoagulant rodenticide active ingredient zinc phosphide, as well as the anticoagulant rodenticide active ingredients brodifacoum, bromadiolone, warfarin and its sodium salt, are rodenticide active ingredients mentioned in a stipulated partial settlement agreement in *Center for Biological Diversity (CBD) v. United States Environmental Protection Agency*, No. 3:11-cv-0293 (N.D. Cal). Among other provisions, this settlement agreement sets a November 2024 deadline for EPA to complete nationwide ESA section 7(a)(2) effects determinations for brodifacoum, bromadiolone, warfarin and its sodium salt, and zinc phosphide and as appropriate, initiate any consultation(s) with the Services that EPA may determine are necessary based on

[45] https://www.epa.gov/endangered-species/reports-congress-improving-consultation-process-under-endangered-species-act.
[46] https://www.epa.gov/newsreleases/epa-announces-endangered-species-act-protection-policy-new-pesticides
[47] https://www.epa.gov/endangered-species

those effects determinations. In addition to those four active ingredients, EPA also intends to make effects determinations, and consult as appropriate, on the additional rodenticide active ingredients bromethalin, chlorophacinone, cholecalciferol, difenacoum, difethialone, diphacinone and its sodium salt, and strychnine by November 2024. Prior to finalizing its effects determinations, the Agency plans to issue draft BE for these 11 rodenticide active ingredients for a 60-day public comment period by the end of November 2023.

Appendix G: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for bromethalin and cholecalciferol, the EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA §408(p), bromethalin and cholecalciferol are subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA § 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The Agency has reviewed all of the assay data received for the List 1[48] chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. A second list of chemicals identified for EDSP screening was published on June 14, 2013,[49] and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. Bromethalin and cholecalciferol are not on either list. For further information on the status of the EDSP, the policies and procedures, the lists of

[48] See https://www.regulations.gov/document/EPA-HQ-OPPT-2004-0109-0080 for the Final First List of Chemicals for Tier 1 Screening in the EDSP.
[49] See https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0477-0074 for the Final Second List of Chemicals for Tier 1 Screening in the EDSP.

chemicals, future lists, the test guidelines and the Tier 1 screening battery, visit the EPA website.[50]

EPA's EDSP is actively pursuing the application of new approach methods (NAMs) to create a more efficient and robust screening program. In October 2020, EPA underwent a reorganization and the EDSP was moved to the Office of Pesticide Programs. This reorganization provides better alignment of the EDSP with the procedures and methods used by the program offices. On July 28, 2021, the Office of Inspector General (OIG) released its new report on the EDSP and made ten recommendations. EPA is also developing a strategic planning document for EDSP which will be available for public comment in 2022. EPA expects additional documents for public release in 2021-2023 that address aspects of EDSP chemical determinations. EPA looks forward to working with stakeholders and the scientific community to accelerate the implementation of this important program into pesticide risk assessments and decision making.

In this PID, EPA is making no human health or environmental safety findings associated with the EDSP screening of bromethalin and cholecalciferol.

[50] https://www.epa.gov/endocrine-disruption