Zinc Phosphide

Proposed Interim Registration Review Decision
Case Number 0026

November 2022

Approved by: _____

Mary Elissa Reaves, Ph.D.
Director
Pesticide Re-evaluation Division

Date: 11-14-2022

Table of Contents

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Proposed Interim Registration Review Decision (PID) for Zinc Phosphide (PC Code 088601, case 0026). 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 zinc phosphide, see EPA's public docket (EPA-HQ-OPP-2016-0140) 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 is to 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 zinc phosphide[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 (the Services) 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 zinc phosphide'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 zinc phosphide under the Federal Food, Drug, and Cosmetic Act (FFDCA).[7] For more information on the listed-species assessment and the endocrine screening for the zinc phosphide registration review, see Appendices F and G.

[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 zinc phosphide, the Agency is also issuing the PIDs for other rodenticides (warfarin, chlorophacinone, diphacinone, brodifacoum, difenacoum, bromadiolone, difethialone, bromethalin, cholecalciferol and strychnine).
[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).

Products containing zinc phosphide were first registered in 1947 (with the United States Department of Agriculture). EPA issued a registration standard in 1982. EPA completed the Reregistration Eligibility Decision (RED) for zinc phosphide in July 1998. In 2008, EPA issued its Risk Mitigation Decision (RMD) for Ten Rodenticides, hereafter referred to as the 2008 RMD, 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). 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 to allow greater flexibility for professional use commensal rodenticide products. Between technical formulations, end use products, and FIFRA Section 18 labels, there are 100 active registrations for zinc phosphide. Zinc phosphide technical registrants include Bell Laboratories, Inc. and Neogen Corporation. Zinc phosphide is available as a restricted use pesticide (RUP) for the control of various species of mice, rats, voles, ground squirrels, pocket gophers, prairie dogs, marmots, nutria, muskrats, and woodchucks. There are also consumer sized products for underground gopher uses, which must be sold in packaging ≤ 1 lb. of bait. Zinc phosphide may be applied above and/or belowground on numerous agricultural and non-agricultural areas. For further information on use, see Section II.

Endangered Species Assessment(s) for Rodenticides
The non-anticoagulant rodenticide active ingredient zinc phosphide, as well as the anticoagulant rodenticide active ingredients brodifacoum, bromadiolone, and 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 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 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 to 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 into five sections:

- *Introduction* (summarizing the registration review milestones and responding to public comments);
- *Use* (discussing how and where zinc phosphide is 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 Zinc Phosphide Registration Review

On July 15, 2016, the Agency formally initiated registration review for zinc phosphide with the opening of the registration review docket for the case.[8] The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of zinc phosphide:

- July 2016 – EPA posted the *Zinc Phosphide Preliminary Work Plan* (PWP) (June 27, 2016), *Zinc Phosphide: Human Health Assessment Scoping Document in Support of Registration Review* (April 20, 2016), and *Zinc Phosphide: Preliminary Problem Formulation for Environmental Fate, Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments in Support of Registration Review* (June 22, 2016) to the public docket for a 60-day public comment period.

- December 2016 – EPA posted the *Zinc Phosphide Final Work Plan* (FWP) (December 19, 2016) to the public docket. The Agency received three comments on the PWP. In the FWP, EPA noted that the comments on the PWP did not change the planned data requirements.

[8] 40 C.F.R. § 155.50

- February 2019 – EPA issued a generic data call-in (GDCI) for zinc phosphide to obtain data needed to conduct the registration review risk assessments (GDCI-088601-1623). The Agency has waived three of the ecological effects data requirements, received one study, and waived all human health data requirements for zinc phosphide. Accordingly, all data requirements have been waived or are satisfied for the purpose of registration review.

- October 2020 – EPA posted *Zinc Phosphide: Draft Human Health Risk Assessment for Registration Review of Zinc Phosphide*. (September 21, 2020; 2020 Human Health Risk Assessment (HHRA)) and *Zinc Phosphide: Draft Ecological Risk Assessment for the Registration Review* (June 24, 2020; 2020 Ecological Risk Assessment (ERA)) for a 60-day public comment period. The Agency received four comments from four commenters. 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 zinc phosphide.

- October 2022 – EPA completed the PID for zinc phosphide and made it 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:

    - *Use and Benefits Assessment for 11 Rodenticides and Impacts of Potential Risk Mitigation* (October 27, 2022)
    - *Zinc Phosphide: Response to Comments on the Draft Human Health Risk Assessment for Registration Review* (November 15, 2022)
    - *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)*

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

During the 60-day public-comment period for the zinc phosphide draft risk assessments (October 19, 2020 to December 18, 2020), the Agency received four public comments. Comments were submitted by the United States Department of Agriculture Office of Pest Management Policy (USDA OPMP), the United States Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS), Center for Biological Diversity (CBD), and Western IPM Center and Oregon Department of Agriculture together. The Agency has summarized and responded to all substantive comments and comments of a broader regulatory nature below. For more detailed EPA responses on the 2020 HH DRA see *Zinc Phosphide: Response to Comments on the Draft Human Health Risk Assessment for Registration Review* (November 15, 2022). The Agency thanks all commenters for participating and has considered all comments in developing this PID.

Comments Submitted by USDA OPMP (Docket ID: EPA-HQ-OPP-2016-0140-0021)

Comment: USDA OPMP agrees with the risk findings in the ecological risk assessment as well as the qualitative approach used in the human health risk assessment. USDA OPMP urges the Agency to create consistency across all labels for protection of non-target species while maintaining accessibility of zinc phosphide. They emphasized that zinc phosphide is an essential management tool across U.S. agriculture, including various specialty crops, grain and forage crops, and orchards, as well as in non-agricultural areas. USDA OPMP is willing to discuss zinc phosphide use and usage data with EPA if necessary.

EPA Response: EPA thanks USDA OPMP for its comments and has considered them in the development of the risk management decisions proposed in this PID. 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 responses on the use, usage, and benefits information, see *Use and Benefits Assessment for 11 Rodenticides and Impacts of Potential Risk Mitigation* (October 27, 2022), which will be posted to zinc phosphide's public docket along with this PID.

Comments Submitted by USDA APHIS (Docket ID: EPA-HQ-OPP- EPA-HQ-OPP-2016-0140-0022)

Comment: USDA APHIS states that zinc phosphide is a crucial wildlife damage management tool used to protect human health and safety at airports and lessen harm to agriculture and private property. There were six issues raised from USDA APHIS. USDA APHIS asked for revisions of wording in the DRA. They also requested that EPA exempt zinc phosphide concentrate (EPA Reg No 56228-6) from the 2008 Revised Risk Mitigation Decision for Ten Rodenticides because it is primarily a "field use" product and was not listed with the other concentrate products in the RMD. APHIS specified they approve of maintaining the established tolerances for grapes, grass, potato, sugarcane, timothy, and wheat in 40 CFR 180.284(a), stated that a tolerance for sugar beets in California has been established, and requested that EPA recognize the IR-4 residue data for sugar beets. Lastly, they noted a discrepancy in a table in the DRA where use directions or limitations from one of their registrations (56228-14) is missing. As a registrant, USDA APHIS supports the reregistration of zinc phosphide.

EPA Response: EPA thanks USDA APHIS for its comments. The Agency has determined the suggested edits do not change the overall risk conclusions, so the Agency is not issuing an updated risk assessment at this time. In this PID, EPA is proposing to make all zinc phosphide products RUP and zinc phosphide concentrate (EPA Reg No 56228-6) will still be subject to the 2008 RMD and should include restrictions from the 2008 RMD on the label. EPA appreciates the note on tolerances. The Agency has no objection to maintaining U.S. tolerance for grapes, grass, potato, sugarcane, timothy, and wheat in 40 CFR 180.284(a) as there were no residues above the limit of quantification (LOQ) (<0.05 or <0.1 ppm) in these commodities. The Agency also has no objections including California for the regional use of zinc phosphide on sugar beet. See IV.E below for more explanation of the tolerances, which states that residue data for sugar beets supports registered uses in CA.

Comments Submitted by Center for Biological Diversity (Docket ID: EPA-HQ-OPP-2016-0140-0024)

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 zinc phosphide. 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 expressed concern about the rigor of EPA's preliminary determinations for this registration review regarding the effects of zinc phosphide on listed species and their designated critical habitat. CBD also expressed concern about the effects of zinc phosphide 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 zinc phosphide.

EPA Response: Through registration review of zinc phosphide, EPA intends to identify mitigations to avoid likely jeopardy and adverse modification of listed species and their critical habitats. EPA intends to complete a draft BE in November 2023. This BE will also include draft predictions of likely jeopardy and adverse modification. EPA will also identify mitigations that are 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 zinc phosphide 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 zinc phosphide's registration review. For more information, see Section IV.A. Proposed Risk Mitigation and Regulatory Rationale.

Comments Submitted by Western IPM Center and Oregon Department of Agriculture (Docket ID: EPA-HQ-OPP-2016-0140-0023)

Comment: Oregon State University and Oregon Department of Agriculture commented on behalf of themselves and the Western IPM Center to discuss the use of zinc phosphide in the Pacific Northwest, specifically for key agricultural uses in Oregon. Many crops in Oregon can be lost due to uncontrolled vole populations. The commenter stated that there are no viable alternatives to zinc phosphide to control voles in commercial agricultural production in Oregon. They also stated that the current section 3 labels provide protection and that there are also additional restrictions on all of Oregon's FIFRA Section 24(c) Special Local Need (SLN) labels to protect nontarget mammals and migrating birds. The commenter mentioned that there have been 27 compliance cases involving zinc phosphide since 2014 and none of them were related to adverse impacts to endangered species or migratory birds. There was also an incident in 2014

involving streaked horned larks, and upon investigation there was phosphine in the pooled gizzard contents from four larks. However, it was noted that FWS expressed caution about these results due to the small size of the sample and the uncertain exposure pathway.

EPA Response: The Agency appreciates the detailed information provided by the commenter. The Agency considers use and alternatives information in its assessment of benefits of a pesticide. Along with the Agency's ecological risk assessment, incident information is used in its weight-of-evidence approach to mitigating risk. For the non-anticoagulant rodenticides, which include zinc phosphide, incident information indicates non-target incidents continue to occur. Please refer to section III.B.2. For details regarding the Agency's conclusions regarding ecological risk and proposed mitigation, please see section III.B and section IV.A.

II. USE

Zinc phosphide is an acute poison that may kill a target rodent following a single feeding within several hours. Zinc phosphide's toxicity is a consequence of the phosphine gas produced when phosphide comes into contact with water and stomach acids.

Zinc phosphide is formulated as pellets, a tracking powder and as a dust or granules for coating grains, peanuts, meat, fruits or vegetables as a bait. Zinc phosphide is registered for use as a RUP and non-RUP rodenticide. Allowable application methods vary by site and pest but include broadcasting by hand, aircraft, and ground equipment; spot treatments; hand-application of tracking powder; and burrow baiting (including the use of a burrow builder). Indoor use of tracking powder is restricted to areas away from human and pet traffic. Zinc phosphide is registered for use as a RUP and non-RUP rodenticide.

Non-RUP uses of zinc phosphide may be applied aboveground to control mice, rats, and voles in and within 100 feet of man-made structures including residential, agricultural, industrial, commercial, public buildings, and similar man-made structures (including in and within 100 feet of transport vehicles). For non-RUP products, bait stations are mandatory for outdoor above ground use, and in all areas accessible to children, pets, and other non-target species. It may also be applied belowground within residential lawns and within 100 feet of buildings to control pocket gophers and moles. In Oregon, zinc phosphide pellets may be applied belowground in grape vineyards for control of voles and mice. Based on residue data from field trials conducted in support of the subject tolerances, EPA concluded that acute and chronic dietary exposure associated with the uses of zinc phosphide is unlikely.

Zinc phosphide is also available as a RUP for the control of various species of mice, rats, voles, ground squirrels, pocket gophers, prairie dogs, marmots, nutria, muskrats, woodchucks. Rodents may be both public health pests and agricultural pests. Zinc phosphide may be applied above and/or belowground, dependent on use site, as an RUP, on numerous agricultural areas: rangeland, pasture, agricultural crops (grape vineyards, potatoes, sugarbeets, sugarcane, bushberries, caneberries, cucurbits, beans (dry), artichokes), grain crops (alfalfa, barley, oats, triticale, wheat, reduced and no-till corn), fruit and nut tree orchards (including avocados, and macadamia nuts), conifer/Christmas tree and hardwood plantations, poplar/cottonwood, timothy and alfalfa hay mixtures, timothy and alfalfa grown for seed, and surrounding crop borders. RUP

nonagricultural use sites of zinc phosphide which may be applied above and/or belowground, dependent on use site, include rights of ways and highway medians, in and around agricultural, commercial, residential and industrial buildings and transport vehicles, nonbearing nursery stock, ornamentals, golf courses, parks, airport grasses and runways, lawns, areas beside canals, ditch banks and other borders on turf farms, reforestation seeding areas, and forest areas (including wind breaks). Zinc phosphide, RUP and formulated as a tracking powder, may also be used aboveground indoors and outdoors on the Wake Atoll for control of Polynesian rats.

There are a number of RUP and non-RUP special local needs registrations for zinc phosphide across various states including registrations for additional application methods (such as aerial broadcasting), specifying additional agricultural and non-agricultural use sites (such as within hop fields in Oregon) and/or additional rodent target pests on use sites (for example, to control prairie dogs on potatoes, barley, and sugar beets, as well as other crops, in Kansas).

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

The Agency has summarized the 2020 HHRA below. The Agency used the most current science policies and risk assessment methodologies to prepare this risk assessment in support of the registration review of zinc phosphide. Based on the available hazard and toxicity profile for zinc phosphide reviewed during the scoping phase of registration review, the Agency concluded that any 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, consistent with the other rodenticides. For additional details on the 2020 HHRA, see *Zinc Phosphide: Draft Human Health Risk Assessment for Registration Review of Zinc Phosphide* in EPA's public docket (EPA-HQ-OPP-2016-0140).

1. Risk Summary and Characterization

Dietary (Food + Water) Risks

Acute or chronic dietary exposure associated with zinc phosphide is considered unlikely as stated in the 1998 RED. Residue data from field trials was collected and phosphine residues were below the LOQs (<0.05 or <0.1 ppm). The residue data provides evidence that phosphine residues from zinc phosphide are not present on human food items. Residues of zinc phosphide on livestock feedstuffs ingested by livestock would be quickly converted to phosphine and then metabolized to naturally occurring phosphorus compounds. Therefore, there would also not be residues of phosphine expected in livestock commodities.

The characteristics of phosphine gas were also evaluated due to zinc phosphide's conversion to phosphine gas. Residue data for phosphine gas used as a fumigant show that with proper aeration or processing following treatment, residues of phosphine become nondetectable on fumigated commodities, even at a maximum label rate of 2,500 ppm phosphine for use on fresh fruits and vegetables. No residues were detected in or on any commodity after aeration following a holding period of 24 hours. Furthermore, any phosphine gas below the limit of detection (LOD) would

likely dissipate with food preparation and cooking. Therefore, the Agency concluded that the registered uses of phosphine as a quarantine fumigant of imported/exported fruits and vegetables should be classified as a non-food use and there are no risks of concern. Given conclusions on phosphine gas, dietary exposures to phosphine generated from the use of zinc phosphide are not expected based on the physical/chemical properties of phosphine, its use pattern, and non-detectable residues in food commodities at harvest.

A Drinking Water Assessment (DWA) was not conducted for any registered uses of zinc phosphide because the Agency concluded that zinc phosphide exposure through drinking water is expected to be minimal. This is because the compound is essentially insoluble in water (i.e., it tends to degrade in water rather than dissolve). Therefore, it is not expected to easily move off-site since it should not be dissolved in runoff and registered formulations should not produce substantial spray drift.

Residential Handler and Post-Application Risks

Zinc phosphide end-use products with potential dermal and inhalation exposures include "loose" formulations not in RTU bait stations including pellets, tracking powder, and dust or granules for coating grains, peanuts, meat, fruits or vegetables as a bait. Zinc phosphide is also registered for use in belowground burrows, as tracking powder indoors or in structural voids around buildings, in bait stations in and around homes, in golf courses and parks, in agricultural fields and orchards, and non-crop areas including rights-of-way and pasture lands. These formulations could generate particulates with the potential for inhalation and/or dermal exposure when applied, distributed, used to fill or refill bait stations, or contacted in another manner.

There is potential for residential handler exposure while applying pellets/bait belowground to pocket gopher or mole burrows in home lawns. However, phosphine gas exposure is expected to be limited due to the lack of conditions necessary for liberation of phosphine gas, such as aqueous solutions or high moisture content and non-neutral pH soils. Bait stations, tracking powder, and granule bait used above ground in and around homes are all restricted use pesticides and therefore residential handler exposure is not anticipated.

Residential post-application exposures are not expected from underground applications in burrows because zinc phosphide does not react quickly enough, even when wet, to produce lethal concentrations (to burrowing rodents) of phosphine gas inside a confined space such as a burrow. Because of this, it is not expected to produce sufficient concentrations of phosphine gas in the surrounding application site either. Indoor use patterns would not likely have the necessary conditions (i.e., aqueous solutions, high moisture content soils with non-neutral pHs) to liberate phosphine gas.

Dermal and incidental oral post-application exposures to tracking powders and above ground bait uses in and around homes are not expected due to mitigation measures currently in place requiring that above ground bait uses require tamper-resistant bait stations and applications of both bait stations and tracking powders are prohibited from being used in locations accessible to children and/or pets. As described in the response to comments, EPA registration number 56228-

6 currently allows for aboveground use without a bait station, but this registration is subject to the 2008 RMD, and this will be addressed in Appendix B.

There may be potential for residential post-application dermal and inhalation exposures for directed spot non-broadcast uses (i.e., bait placed at burrow openings) of zinc phosphide on golf courses and parks. There may also be potential for dermal, inhalation, and incidental oral (children only) exposures from broadcasts uses of zinc phosphide in golf courses and parks, which would be contrary to the Agency's human health risk management goals for zinc phosphide articulated in the RMD.

Bystander Risks

Non-occupational/bystander exposure resulting from off-site transport (i.e., spray drift) is unlikely due to how the chemical is formulated and used, except for the granular broadcast applications of zinc phosphide on agricultural fields, rangeland, and commercial orchards. Drift is not a concern when applying solid materials (e.g., by aerial equipment).

The only bystander inhalation exposure pathway of concern for zinc phosphide results from the release of phosphine gas from the solid formulation of zinc phosphide. As noted, this occurs when the solid formulation encounters aqueous solutions and soils with high moisture content and a non-neutral pH. Volatilization is an exposure pathway for zinc phosphide through its release of phosphine gas, but the amount of phosphine produced from the use of zinc phosphide is expected to be minimal in comparison to the direct use of phosphine. For the underground use of phosphine in rodent burrows the Agency concluded that based on the limited use pattern, label directions, underground placement, and the air monitoring data, residential post-application exposures from outdoor underground applications are not expected to exceed the regulatory limits.

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.

Since dietary exposures are not anticipated, and the Agency identified that there may be potential residential exposure, aggregate risk is equivalent to residential risk, which was evaluated qualitatively. As specified in the Residential Handler and Post-Application Exposure section, exposures from broadcasts uses of zinc phosphide in golf courses and parks are contrary to the Agency's human health risk management goals for zinc phosphide.

Cumulative Risks

In 2016, the Agency released guidance on how to screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and if necessary, followed by a risk-based screening approach. This framework supplements the existing guidance document for establishing common mechanism groups

(CMGs) and conducting cumulative risk assessments (CRAs). The Agency utilized this framework for the fumigant phosphine, the fumigant metal phosphides (i.e., aluminum phosphide and magnesium phosphide) and the rodenticide zinc phosphide, which all share phosphine as the primary toxic degradate and toxic moiety. Since the metal phosphides are considered different forms of phosphine, it was determined that phosphine and the metal phosphides do not form a candidate CMG and no further cumulative evaluation is necessary.

Occupational Handler Risks and Occupational Post-Application Risks

The Agency anticipates loose formulations of zinc phosphide could generate particulates and therefore there is potential for occupational inhalation and/or dermal exposure when handled/applied by mixers/loaders, applied by hand, handheld equipment or by ground/aerial equipment, distributed, used to fill/refill bait stations, or otherwise contacted. However, exposure to phosphine gas is not expected for occupational handlers due to the lack of conditions necessary to liberate phosphine gas.

Occupational post-application dermal exposure is not anticipated because contact with foliar or other surface residues are not expected for workers in areas previously treated with zinc phosphide. Likewise, occupational post-application inhalation exposure of phosphine gas is expected to be minimal because of the timing of zinc phosphide's use in agricultural settings (i.e., dormant orchards/crops; not to be applied to actively growing crops), as well as the field conditions required to liberate phosphine gas occurring on a limited basis.

Occupational workers are not expected to be present following the application in non-agricultural settings, except for workers performing golf course maintenance. Phosphine is slowly produced through hydrolysis of zinc phosphide in the ambient terrestrial environment and occurs only slowly under circumneutral pHs. Additionally, zinc phosphide does not react fast enough, even when wet, to produce lethal concentrations (to burrowing rodents) of phosphine gas inside a burrow. Therefore, it is assumed to not produce sufficient concentrations of phosphine gas in the unconfined terrestrial areas in which it is applied. Some zinc phosphide labels require applications on warm, clear days, not to be applied to bare soil, and not applied to snow covered ground to further limit the conditions for phosphine gas release. Although occupational risks are not anticipated, reduction in exposure continues to be a risk management goal.

2. Human Incidents and Epidemiology

EPA completed a Tier I updated analysis of exposure incidents for the anticoagulant and non-anticoagulant rodenticides including zinc phosphide, to identify potential patterns in the frequency and severity of the health effects attributed to commensal rodenticide exposure. The Agency evaluated its Incident Data System (IDS) and aggregate data reported in the American Association of Poison Control Centers (AAPCC) Annual Report for rodenticide incident trends over time, as a result of the 2008 RMD. EPA also evaluated the NIOSH Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides, California Pesticide Illness Surveillance Program (PISP), and IDS for occupational incidents. Rodenticides were previously reviewed in 2015, at which 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 incident for the rodenticides.

IDS contained a total of 24 incidents reported between January 2015 and July 2019 that were attributed to a product containing zinc phosphide. Nine incidents were reported in the Main-IDS, eight of which involved the single a.i. zinc phosphide (only). These eight incidents were either of moderate (seven incidents) or major severity (one incident). A total of 15 incidents were reported in the aggregate-IDS and were all of minor severity.

Trends were evaluated in the IDS and AAPCC for the non-anticoagulants as a group. The number of non-anticoagulant incidents reported to IDS (2009 to 2018) increased 60%, and the number of non-anticoagulant incidents reported to AAPCC (2004 to 2017) increased by 41%. EPA 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 second-generation anticoagulants (SGARs) for residential consumer use.

Although the number of incidents involving non-anticoagulant rodenticides increased over time, the total frequency of rodenticide incidents reported to both IDS and AAPCC appears to be decreasing over time, although incidents continue to occur. Data from IDS indicate that the total number of rodenticide (anticoagulant and non-anticoagulant) incidents slightly decreased from 198 incidents in 2009 to 146 incidents in 2018. Likewise, the total number of rodenticide incidents reported to AAPCC has been declining steadily since 2004 with 19,432 rodenticide incidents reported in 2004 and 8,494 incidents reported in 2017. 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. Overall review of IDS and AAPCC data suggest that the 2008 RMD may have contributed to an overall decrease in exposure incidents involving rodenticide products. The Agency intends to monitor human incidents for zinc phosphide and will conduct additional analyses if necessary.

Occupational incidents were evaluated separately for the rodenticides. As of EPA's latest search on July 12, 2019, SENSOR-Pesticides showed 21 occupational exposure incidents reported from 2011 to 2015, California PISP showed nine occupational exposure incidents reported from 2012 to 2016, and IDS showed two occupational exposure incidents reported from 2015 to 2019 for all rodenticide products. Two major severity cases, one in the Main-IDS and one in SENSOR-Pesticides, involved zinc phosphide. In both the SENSOR-Pesticides and PISP datasets, most occupational exposure incidents involved exposures to a zinc phosphide product (62% and 67%, respectively); primarily during the manual application of the product. Several occupational incidents reported to SENSOR-Pesticides were veterinary workers who were exposed secondarily when treating dogs that ingested zinc phosphide products. In SENSOR-Pesticides, most occupational case reports were low in severity. Of the 21 occupational cases, one case was high in severity, five cases were moderate in severity, and 15 cases were low in severity. The health effect most frequently reported among the 21 occupational rodenticide cases was nausea, followed by altered taste (metallic or chemical taste), vomiting, upper respiratory pain/irritation, and shortness of breath. Overall, there was a low frequency of occupational incidents reported in SENSOR-Pesticides, California PISP, and Main IDS; however, zinc phosphide was involved in many of the incidents reported.

3. Tolerances

Zinc phosphide is registered for uses that result in residues in or on food. Generally, a tolerance or tolerance exemption must cover the residues or the affected food is considered adulterated.[9] EPA has determined that the Agency established all of the necessary tolerances for residues resulting from zinc phosphide's legal use. The Agency has established tolerances for zinc phosphide under 40 CFR § 180.284.

Residues were below the LOQ (<0.05 or <0.1 ppm) in crops, except for the livestock feed items alfalfa forage, sugar beet tops, and timothy forage. Alfalfa forage, sugar beet tops, and timothy hay are not direct human food items; rather, they are used as animal feed. Because residues of zinc phosphide ingested by livestock would be immediately converted to phosphine and metabolized to naturally occurring phosphorus compounds, residues of zinc phosphide in livestock feed are not expected to result in residues of zinc phosphide in livestock commodities. The act of processing and washing will not allow for unreacted zinc phosphide to remain in or on food items. In addition, residues are not expected in wheat and barley grain since zinc phosphide will be applied to barley and wheat prior to the formation of seed heads.[10]

During the registration review risk assessment process EPA determined that revisions to tolerance expressions are necessary to be consistent with the 2009 guidance and revisions to tolerances are necessary to support regional registration. For more information, see Section IV.E below.

4. Human Health Data Needs

The human health database for zinc phosphide is considered complete for the purposes of registration review. EPA determined that available data were sufficient to conduct the 2020 HHRA and are sufficient to support this PID because the mode of action and toxicity profile of zinc phosphide are well understood.

B. Ecological Risks

The Agency has summarized the 2020 Eco DRA below. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of zinc phosphide.[11] For additional details on the 2020 Eco DRA, see *Zinc Phosphide: Draft Ecological Risk Assessment for Registration Review* in EPA's public docket (EPA-HQ-OPP-2016-0140).

The Agency has not yet fully evaluated zinc phosphide'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 zinc phosphide. 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

[9] 21 U.S.C. §§ 342, 346(a).
[10] https://www.federalregister.gov/documents/2003/09/30/03-24844/zinc-phosphide-pesticide-tolerance
[11] The 2020 Eco DRA is a FIFRA assessment and focuses on potential risks to species not listed under the Endangered Species Act (ESA).

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, including zinc phosphide, 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

Zinc phosphide is registered for use sites (e.g., orchards) where wildlife is expected to occur. Although the target of zinc phosphide is mammals, it is expected that non-target animals may be exposed through both primary exposure (direct consumption of bait) and secondary exposure (consumption of animals that have consumed bait). The below sections discuss risks to birds and mammals, as well as reptiles and terrestrial-phase amphibians, from both primary and secondary exposure.

Terrestrial Risks

Primary Exposure:

Mammals

The Agency identified risks of concern from primary consumption by mammals. To assess primary consumption, and calculate dose-based exposure for mammals, the concentration in bait is multiplied by the food consumption rate of the assessed mammal and then divided by its body weight. Standard body weights are used to assess risks to small, medium, and large mammals. Food intake rates for all mammal and rodent species are calculated for these three body weights using allometric equations. Risk quotients (RQs) are calculated by dividing estimated doses by adjusted median lethal dose (LD_{50}) values to account for differences in body weight between tested species (i.e., laboratory rat) and the assessed species. This approach assumes that baits contain an insignificant amount of water and therefore dry weight food intake rate equations are used. The food intake rate is multiplied by the concentration of zinc phosphide present in baits (i.e., 20,000 mg a.i./kg) and then divided by the weight of the assessed animal to calculate the dose-based estimated environmental concentration (EEC). Dose-based RQs range from 38 to 85, which all exceed the acute LOC of 0.5. These RQs assume that the exposed mammals consume 100% of their daily diet as a bait with zinc phosphide. If the assessed mammals even eat 1.2-2.6% of their diet as bait, they would receive a dose equivalent to the LD_{50}, i.e., where 50% of the exposed mammals died. However, if the assessed mammals eat only 0.59-1.3% of their daily diet as bait, the LOC would not be exceeded (i.e., <10% of exposed mammals would be estimated to die).

LD_{50}s are available for several test species (laboratory rat, black-tailed prairie dog, deer mouse and voles), with values ranging from 18-59 mg a.i./kg-bw. Given the proximity of these values to

the laboratory rat value used to derive RQs (i.e., 21 mg a.i./kg-bw), estimated doses also exceed toxicity values for the other tested mammal species.

Birds

There is risk of mortality to birds from consumption of baits made of zinc phosphide. Zinc phosphide baits contain 2% zinc phosphide, which is equivalent to 20,000 mg a.i./kg-bait. The avian median lethal concentration (LC_{50}) is 470 mg a.i./kg. Dietary-based RQs for birds are 43 for the consumption of baits, which exceeds the LOC of 0.5. Other subacute dietary toxicity data are available for mallard ducks (LC_{50} values of 1,285 and 2,885 mg a.i./kg-diet) and Japanese quail (LC_{50}=950 mg a.i./kg-diet). Concentrations in bait are a factor of 21x above the LC_{50} values for these species. This analysis does not consider the amount of food ingested or the animal size, which differs from the dose-based exposure estimates that are discussed next. This analysis compares the concentration in bait to the concentration in food which resulted in a 50% mortality of birds who ingested zinc phosphide.

For a dose-based analysis, the concentration in bait is multiplied by the rate of food consumption rate of the assessed bird and then divided by bird body weight. The standard body weights are used to assess risk to small, medium, and large birds. Food intake rates are calculated for these three body weights using allometric equations. RQs are calculated by dividing the estimated doses by adjusted LC_{50} values to account for differences in body weight between the tested species and the assessed species. This approach assumes that baits contain an insignificant amount of water, and therefore, the dry weight food intake rate equations are used. The food intake rate is multiplied by the concentration of zinc phosphide present in baits (i.e., 20,000 mg a.i./kg) and then divided by the weight of the assessed animal to calculate dose-based EECs. Dose-based RQs for birds range from 70 to 546, which all exceed the acute LOC of 0.5. These RQs assume that the exposed birds consume 100% of their daily diet as zinc phosphide bait. If the assessed birds consume 0.09-0.72% of their daily diet as bait, the LOC would not be exceeded (i.e., <10% of exposed birds would be estimated to die). However, if the birds even consumed 0.18-1.44% of their daily diet as bait, they would receive a dose equivalent to the LD_{50} (i.e., where 50% of exposed birds died). Considering the small percentage of their daily diet that would need to be consumed to receive a dose equivalent to the LD_{50}, zinc phosphide baits pose a risk concern for primary avian exposure.

In addition, LD_{50}s are available for four other test species, with values ranging from 13.8-67.4 mg a.i./kg-bw. Given the proximity of these values to the bobwhite quail value used to derive RQs (i.e., 12.9 mg a.i./kg-bw), estimated doses also exceed toxicity values for the other four tested avian species.

In an open literature semi-field (pen) study, ring-necked pheasants and California quail kept in outdoor pens were exposed to zinc phosphide bait. Sixty-nine percent (18 of 26) of exposed pheasants died, but all exposed quail survived. In several field studies, no clear evidence of bird carcasses was observed following applications of zinc phosphide bait. However, the results of these studies are limited by few replicates and difficulty in finding carcasses.

Although not all observations point to mortality, due to the high toxicity of zinc phosphide and dose-based RQ exceedances, there are risks of concern to birds through primary consumption of zinc phosphide.

Reptiles and Terrestrial-Phase Amphibians

Birds are typically used as surrogates for terrestrial-phase amphibians and reptiles. Some reptile species (e.g., turtles) are herbivores and may directly consume bait. Therefore, risks identified for birds may extend to reptiles who consume bait. However, terrestrial-phase amphibians typically eat other animals, and are thus unlikely to consume bait. Since birds eat more daily than reptiles, there is some uncertainty in using birds as surrogates for estimating exposure to reptiles. If a reptile-specific food intake rate is considered, zinc phosphide EECs of herbivore reptiles are orders of magnitude lower than EECs for birds. However, those EECs still exceeded available LD_{50} values for birds (12.9-67.4 mg a.i./kg-bw) and an LD_{50} of 28 mg a.i./kg-bw for American alligators. An acute oral LD_{50} for alligators is within the range of available LD_{50} values for birds, indicating that reptiles and birds may have similar sensitivity to zinc phosphide. When considering reptile-specific food intake rates and toxicity data, there are still risks of concern for reptiles that consume bait containing zinc phosphide.

Secondary Exposure:

Consumers that eat entire carcasses of contaminated prey are more at risk of secondary exposure than consumers that avoid the consumption of the gastrointestinal tract. In a study where voles were exposed to zinc phosphide bait in the lab and field, the majority of the zinc phosphide residues were located in the digestive tracts. In the laboratory portion of the study, 24 organisms had residues of 1,030 ppm in the gastrointestinal tract, while only 1.7 ppm was detected in the rest of the body. In another study, black-tailed prairie dogs were fed zinc phosphide bait, the majority (99.9%) of zinc phosphide measured in prairie dogs was contained in the gastrointestinal tract. In both studies, the majority (≥90%) of the measured residues in the gastrointestinal tract were found in the stomach. Thus, secondary consumers that eat the entire carcass would be more likely to be at risk than those secondary consumers who avoid consumption of the gastrointestinal tract (especially the stomach) of their prey.

Mammals

There are risks of concern to secondary consumers that eat the entire carcass of an exposed animal, including the intestinal tract. To calculate dose-based exposures, the concentrations in mammals that have consumed bait (primary consumers) are multiplied by the food consumption rate of the assessed mammal and then divided by its body weight. Generic body weights representing predatory mammals were used to assess risks to small, medium, and large secondary consumer mammals. Food intake rates for all mammal species are calculated for these three body weights using allometric equations. Although the primary exposure approach assumed that the water content of bait was insignificant, that is not the case for secondary exposure. In this approach, it is assumed that the water content of mammals is 68%. RQs are calculated by dividing estimated doses by adjusted LD_{50} values to account for differences in body weight between the tested species (i.e., laboratory rat) and the assessed species. The food intake rate is multiplied by the concentration of zinc phosphide present in primary consumer

mammals and then divided by the weight of the assessed animal to calculate the dose-based EEC. Dose-based RQs for mammals that consume mammals that consumed zinc phosphide bait range from 20 to 42, which exceed the acute LOC of 0.5. These RQs assume that the exposed mammal eats 100% of their daily diet in mammals that consumed zinc phosphide. If the assessed mammals only consume a part of a mammal that has consumed its daily diet as zinc phosphide bait, they would be dosed equivalent to the LD_{50}, which exceeds the LOC. Because zinc phosphide is concentrated in the intestinal tract of an exposed animal, there is risk of concern to a secondary consumer that eats an entire exposed animal, including the intestinal tract.

As noted in the discussion regarding mammalian risk from primary exposure, LD_{50}s are available for several test species. Given the proximity of these values to the laboratory rat value used to derive RQs (i.e., 21 mg a.i./kg-bw), estimated doses also exceed toxicity values for the other tested animal species.

Secondary exposure from consumption of bait or tracking powder could also be assessed by assuming that the primary consumer consumed a dose equivalent to the mammalian LD_{50} (21 mg a.i./kg-bw). RQs calculated with this approach (dose-based RQs range from 0.2-0.3) do not exceed the LOC. There is a range of LD_{50} values available for mammals (i.e., 18-59 mg a.i./kg-bw). If the primary consumer consumed a dose equivalent to 59 mg a.i./kg-bw, there would be risk concerns for secondary consumers.

Birds

Zinc phosphide poses a risk of mortality to birds from secondary exposures. Dose-based EECs reported above for mammals consuming bait can be used as concentration-based EECs for birds. The doses above are divided by the LC_{50} for birds (i.e., 458.5 mg a.i./kg-diet) to derive dietary-based RQs for secondary consumers (e.g., hawks). Dietary-based RQs for secondary consumers range from 1.3-8.3, which all exceed the LOC of 0.5. If the LC_{50} for mallard of 1,285 mg a.i./kg-diet were used to calculate RQs, they would still exceed the LOC. However, if the rat LD_{50} (21 mg a.i./kg-diet) was used to represent the body burden for primary consumer of bait or tracking powder, the resulting RQ would be 0.46, which is below the LOC.

To calculate dose-based exposures for secondary consumers, the concentrations in mammals that have consumed bait (primary consumers) are multiplied by the food consumption rate of the assessed bird and then divided by its body weight. Generic body weights representing predatory birds are used to assess risks to small, medium, and large secondary consumer birds. Food intake rates for all bird species are calculated for these three body weights using allometric equations. As described above in the mammal section, RQs are calculated by dividing estimated doses by adjusted LD_{50} values to account for differences in body weight between tested species (i.e., bobwhite quail) and the assessed species. Dose-based RQs for birds that consume mammals that consumed zinc phosphide bait range from 7 to 100, which again exceed the acute LOC of 0.5. The RQs assume that the exposed birds eat 100% of their daily diet in mammals that consumed zinc phosphide. If the assessed birds only consume a part of a mammal that has consumed its daily diet as zinc phosphide bait, they would be dosed equivalent to the LD_{50}, which exceeds the LOC. Because zinc phosphide is concentrated in the intestinal tract of an exposed animal, if a

secondary consumer eats one entire mammal that consumed zinc phosphide (including the gut), there would be a risk of concern to the secondary consumer.

LD_{50}s are available for four other test species (mallard duck, bantam chicken, horned lark, and ring-necked pheasant), which values ranging from 13.8 to 67.4 mg a.i./kg-bw. Given the proximity of these values to the bobwhite quail value used to derive RQs (i.e., 12.9 mg a.i./kg-bw), estimated doses also exceeded toxicity values for the other four tested avian species.

Secondary exposure from consumption of bait or tracking powder could also be assessed by assuming that the primary consumer consumed a dose equivalent to the mammalian LD_{50} (21 mg a.i./kg-bw). For smaller secondary consumers (100 g), the dose-based RQ of 0.7 exceeds the LOC. RQs for medium and large secondary consumers do not exceed the LOC (0.1-0.2). There are a range of LD_{50} values available for mammals (i.e., 18-59 mg a.i./kg-bw). If the primary consumer eats a dose equivalent to 59 mg a.i./kg-bw, there would be risk concerns for medium-sized secondary consumers.

Reptiles and Terrestrial-Phase Amphibians

There are risks to terrestrial-phase amphibians and reptiles that consume dosed mammals. Many reptiles and terrestrial-phase amphibians consume mammals, and therefore secondary exposure risks identified for birds may also extend to those species. It should be noted that there is some uncertainty in using birds as surrogates for reptiles because birds typically eat more food on a daily basis than reptiles. When considering a reptile-specific food intake rate, zinc phosphide EECs of insectivore reptiles (EECs range from 8-41 mg a.i./kg-bw) are orders of magnitude lower than EECs for birds (EECs range from 142-1,178 mg a.i./kg-bw). However, those EECs still exceed available LD_{50} values for birds (12.9-67.4 mg a.i./kg-bw) and an LD_{50} value of 28 mg a.i./kg-bw for American alligators. When considering reptile-specific food intake rates and toxicity data, there are still risk concerns for reptiles that may consume mammals consuming bait formulations of zinc phosphide.

Other Taxa:

Terrestrial Invertebrates

EPA relies on data about honeybees as a surrogate for terrestrial invertebrate species. Based on the available data, EPA has determined that zinc phosphide application methods and uses do not present risks of concern to honeybees. Because of the use and application pattern, exposure to bees is expected to be negligible.

The ecological risk assessment considers risks of zinc phosphide to soil-dwelling terrestrial invertebrates using a newly submitted earthworms toxicity study with zinc phosphide, which is available for earthworms exposed to 440 mg a.i./kg soil. In this study, a 15% average decrease in body weight (relative to controls) was observed at the end of the 18-day observation period. There were no effects to mortality or growth rate at this exposure level. At the maximum single application rate for zinc phosphide (0.2 lbs a.i./A), a 6-inch soil depth would have an estimated concentration of 0.1 mg a.i./kg soil (assuming a soil density of 1.5 L/kg). The estimated exposure is three orders of magnitude lower than exposure in the toxicity study.

There is uncertainty associated with the available toxicity study because a No Adverse Effect Concentration (NOAEC) was not established. Given that no mortality was observed and that the test level was three orders of magnitude higher than the estimated environmental exposure, it is unlikely that zinc phosphide would pose a risk of substantial effects to soil dwelling invertebrates.

Terrestrial Plants

Exposure to plants is expected to be negligible due to zinc phosphide's use pattern (above-ground outdoor uses as bait, and powders closely associated with building and manmade structures) and fate properties (unlikely to be systemic since it is highly insoluble in water). Therefore, effects to plants are not quantified and risks of concern are not expected.

Aquatic Risks

Exposure to aquatic organisms is expected to be negligible since there is no spray application and the material is applied as a formulated bait or tracking powder. Zinc phosphide is bound in the formulated bait and little is expected to be available for runoff or leaching. Therefore, effects to aquatic organisms are not quantified and risks of concern are not expected.

2. Ecological Incidents

EPA reviewed zinc phosphide incidents reported to the Incident Data System (IDS), which provides information on the available ecological pesticide incidents. As of EPA's latest search on June 1, 2020, IDS showed a total of 73 incidents reported from 1960 to 2019. Of the incidents reported, 30 were associated with registered uses, 33 had unknown legality and 10 were illegal uses or misuses. Of the 63 incidents associated with registered or unknown legality uses, more than half (39) had a certainty index of highly probable. Eighteen incidents had a certainty index of probable and six had a certainty of possible.

Forty of the incidents included analytical confirmation of the presence of zinc phosphide or phosphine in the crop or gizzard of birds. In cases where phosphine was detected, the incident may have been associated with zinc or aluminium phosphide. Overall, there is a high degree of confidence, based on certainty index, that the majority of the reported incidents were associated with zinc phosphide exposure.

Fifty-eight of the incident reports, registered or unknown legality, included mortalities of birds. The majority (54) of those incident reports involved turkeys and geese, resulting in hundreds of dead turkeys and thousands of dead geese across all the reported incidents. Over a hundred ducks were also reported across three different incidents. Other bird species observed included: horned lark, chicken, and peacock. When considering the diets of the species reported in the incidents and the presence of bait confirmed in the crops or stomachs of many of the birds, it is likely that the birds were exposed to zinc phosphide through direct consumption of bait (primary consumption). Since none of the bird species in the incident reports have diets that include mammals, it is assumed that there were no avian mortality incidents for secondary exposure.

For mammals, there were six incident reports. Five incidents included mortalities of different mammal species, including raccoon (*Procyon lotor*), red fox (*Vulpes fulva*), and grey squirrel (*Sciurus carolinensis*). There were 25 mammal mortalities reported across the five incidents, with 20 being grey squirrels. The majority of these incidents were reported after the 1998 RED. Because of grey squirrels' diet, it is most likely that the reported deaths were associated with direct consumption of bait. There was also one incident reported where two dogs were observed bleeding, which was possibly associated with zinc phosphide. The incident with the red fox confirmed secondary poisoning through consumption of mice killed by zinc phosphide. Since the diets of raccoons and dogs may include either bait or small mammals, primary or secondary exposure may have been associated with the incidents involving those species.

All of the ecological incidents associated with registered uses or those with unknown legality involved mortalities to birds or mortalities of effects to mammals. There were no reported incidents for other taxa (e.g., fish, plants, bees).

Between 1999 and 2018, four wildlife (e.g., birds, mammals) aggregate incidents (including wildlife, plants, other non-targets and domestic animals) were reported. The incidents were associated with uses of baits. One incident in 2014 reported mortality of 22 birds in Oregon. No other information is available on the wildlife incidents. There were no incident reports in the aggregate database that involved plants or other wildlife (bees). The aggregate database also includes 505 incidents involving domestic pets, which included 41 fatalities. Unlike the ecological incidents, few details are provided on the aggregate incidents and a certainty index is not defined for these incidents.

Incidents reported to IDS are evidence that non-target species are being exposed to zinc phosphide resulting in poisonings via primary and secondary exposure. The number of actual incidents associated with zinc phosphide may be higher than what is reported to the Agency. Incidents may go unreported since effects may not be immediately apparent or readily attributed to the use of a chemical. The Agency intends to monitor ecological incidents for zinc phosphide and will conduct additional analyses if necessary.

3. Ecological and Environmental Fate Data Needs

The ecological and environmental fate database for zinc phosphide is considered sufficient for the purposes of registration review. Submission of additional data for passerine and secondary consumer bird species would serve to address uncertainties associated with extrapolating from northern bobwhite quail.

Furthermore, no chronic reproduction data are available for birds or mammals exposed to zinc phosphide, and these data are needed to fully characterize the risks to animals that are exposed to zinc phosphide but survive those exposures. Chronic exposures to birds and mammals were not assessed due to a lack of chronic toxicity data. Since multiple lines of evidence suggest that zinc phosphide poses a risk of mortality to birds and mammals, a lack of consideration of chronic exposures and risks is not expected to have a substantial impact on the overall conclusion that zinc phosphide poses a risk to non-target vertebrates.

The Agency previously required the following data (GDCI-088601-1623). The registrants have not fulfilled the data requirements and requested waivers of the data requirements.[12] The Agency did not find that waiving the avian data requirements were supported by the scientific rationale provided by the registrant. However, EPA has determined that available data were sufficient to conduct the 2020 ecological DRA and are sufficient to support this PID because the mode of action and toxicity profile of zinc phosphide is well understood. EPA issued data waivers for the avian data requirements in December 2021 and the study classifications are listed in the table below. However, these data could be helpful in better refining assumptions made in future listed species assessments.

Guideline Number	Study Title	MRID	Study Classification
850.3100	Earthworm Subchronic Toxicity Test	51759801	Supplemental (additional data not needed)
850.2300	Avian reproduction test	50981102	Waived
850.2100	Avian acute oral toxicity test	50981101	Waived
870.3200	21/28-day dermal toxicity	---	Waived

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).[12] 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 jeopardy and adverse modification 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 zinc phosphide.

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 zinc phosphide. The proposed mitigations are intended to reduce (through avoidance and minimization) potential

[12] During registration review, the registrants may request a waiver of data requirements by requesting an extension of an existing waiver or by requesting a new waiver from EPA. 40 C.F.R. § 152.91.

exposures, effects, and take[13], 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 the zinc phosphide poses risks to mammals and birds that are primary and secondary consumers. 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*)[14];
- Attwater's prairie-chicken (*Tympanuchus cupido attwateri*)[15]; and the
- California condor (*Gymnogyps californianus*)[16].

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.

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 bait that are

[13] 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.
[14] Entity ID 39
[15] Entity ID 83
[16] Entity ID 66

formulated as grains. APC was chosen as a pilot species 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 1980's; 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[17] 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 zinc phosphide;
- 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 jeopardy and adverse modification. These draft determinations and predictions are based on currently registered uses of the rodenticides.

[17] USFWS. 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
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

The analyses led to initial predictions of the likelihood of jeopardy for the Stephens' kangaroo rat, Attwater's prairie-chicken, and the California condor for zinc phosphide. Only one of the species (the California condor) has a final designated critical habitat and EPA initially predicted a likelihood of adverse modification of designated critical habitat for the California condor for zinc phosphide. 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

Zinc phosphide is important for control of a variety of vertebrate pests, including rats, mice, moles, voles, pocket gophers, ground squirrels, and prairie dogs, in a variety of use sites which include residential areas, urban and commercial areas, livestock operations, vessels, golf courses, rangeland and pastureland, crop agriculture, and islands. The purpose of controlling rodents is to protect 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.

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 their particular pest problems. Chemical rodenticides, including zinc phosphide, are most important for controlling rodents when non-chemical methods of control, such as sanitation, exclusion, and mechanical traps alone are insufficient, such as in outdoor settings like crop agriculture and golf courses, and in highly rodent-attractive settings, like livestock facilities and food-handling establishments.

Zinc phosphide has several benefits compared to other rodenticides. Zinc phosphide acts quickly and has a broad pest spectrum, with numerous products and formulations available for many use sites. In several crops, such as alfalfa, dry beans, and sugarbeet, zinc phosphide is the only registered rodenticide, meaning its benefits are particularly high in these use sites because rodents, like voles, can cause significant damage to the crop. Because zinc phosphide is an acute toxicant, it is not subject to the same resistance concerns as its alternatives, including the anticoagulant rodenticides, meaning zinc phosphide may be used where rodenticide resistance is a concern.

For more information on the benefits of zinc phosphide, please see *Use and Benefits of 11 Rodenticides and Impacts of Potential Risk 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 use, non-target human health and ecological exposure incidents continue to occur. The Agency has determined that additional human health mitigation measures are necessary to further reduce the potential for human health exposures from occurring, including exposures to children. Proposed mitigation measures to address human exposures are also expected to address potential risks to domestic pets. Similar to what EPA is proposing for the other rodenticides, EPA is likewise proposing to classify all zinc phosphide products as RUPs, prohibit refillable bait stations and consumer-sized zinc phosphide products, as well as prohibiting spot- and broadcast application of zinc phosphide products in turf, lawns, parks, campsites, and other recreation areas where children and pets may be exposed. 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 HHRA identified the potential for dermal and inhalation exposures to occupational handlers using products that are loose formulations, including granules, tracking powders, grain meals, waxy/paraffinized and non-paraffinized pellets. The Agency has determined that additional personal protective equipment (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 secondary exposure to non-target organisms continued to occur. Building upon the mitigation measures implemented as a result of the 1998 Zinc Phosphide RED, 1998 Rodenticide Cluster RED, 2008 RMD, and the 2012 Rozol Prairie Dog Bait and Kaput-D Prairie Dog Bait Biological Opinions, the Agency has determined that additional ecological mitigation measures are necessary as part of registration review to further reduce non-target exposures. EPA is proposing to classify zinc phosphide products as RUPs, adding 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, as well as prohibiting spot- and broadcast application of zinc phosphide products in turf, lawns, parks, golf courses, campsites, and other recreation areas where non-target wildlife may be exposed.

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 zinc phosphide. Additionally, the Agency is committed to identifying and incorporating early mitigation for 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 that it initially predicted a likelihood of jeopardy or adverse modification. EPA intends to publish these early-ESA species mitigation measures, once they are finalized, in Bulletins Live! Two (BLT),[18] and is proposing to add a link to BLT to all product labels. The Agency anticipates completing the draft BEs for all 11 rodenticide active ingredients in 2023 and the final BEs in 2024.

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

Finally, in this PID, EPA is 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 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 programs will highlight the importance of best management practices for zinc phosphide 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 zinc phosphide, see *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

It is well understood that zinc phosphide is highly toxic. 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 agricultural users and professional pest control operators. To minimize children's exposure to zinc phosphide 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. Currently, consumer size products intended for use in and around residential structures include zinc phosphide sold in packages ≤ 1 lb. of bait. Zinc phosphide products sold in packages ≥ 4 lbs. of bait are intended for agricultural/professional use by pest control operators. Despite these minimum packaging size requirements, non-target incidents (including children, domestic pets, and non-target wildlife, including listed species) have continued to occur.

Currently, there are zinc phosphide products classified as RUP due to hazard to non-target organisms (as specified in 40 CFR 152.170(c)). EPA proposes that the remaining zinc phosphide products 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)) and is therefore proposing that all zinc phosphide products be classified as RUP.

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 secondary consumption involving non-anticoagulant rodenticides. Risk concerns are further supported by ecological risk

estimates calculated for zinc phosphide exceeding the Agency's levels of concern for both primary and secondary exposure for birds and mammals.

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 and non-target species are being exposed to zinc phosphide resulting in poisonings via primary and secondary exposure. For more detailed information regarding zinc phosphide 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 reduces the potential for exposure to non-target organisms.

In summary, zinc phosphide meets the standard for restricted use because:

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

Therefore, EPA is proposing to classify zinc phosphide products as restricted use. By doing so, the retail sale and use of zinc phosphide 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 zinc phosphide products that are already RUP, the Agency is proposing that these labels are updated to be consistent with Chapter 6 of the Label Review Manual[19] which covers Restricted Use Classification and labeling.

The Agency anticipates that classifying all zinc phosphide products as RUPs, will limit non-certified users to either products containing less than one pound of first-generation anticoagulant rodenticide (FGAR), bromethalin, or cholecalciferol bait in a single-use, tamper-resistant bait stations and products containing less than one pound of bromethalin bait for use in burrows to control moles. This change 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 certification. The Agency anticipates residential consumers could replace zinc phosphide with products that are not restricted for most residential needs; however,

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

this mitigation may increase the cost of control due to the requirement of single-use 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 and equine operations who need to control burrowing pests like 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 zinc phosphide and other RUP 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.

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

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 personal protective equipment for occupational handlers is necessary to minimize dermal and inhalation exposure to the greatest extent possible.

New Respirator and Gloves Requirement for Zinc Phosphide Rodenticide 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 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[20] for products that are meal baits, tracking powders and 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 has determined that

[20] 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.

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 zinc phosphide 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.[21]

EPA's HHRA assumes National Institute for Occupational Safety and Health (NIOSH) protection factors[22] in estimating the inhalation risks and the risk reduction associated with different respirators.[23] If the respirator does not fit properly, EPA's proposed PPE mitigation for zinc phosphide may not reduce risks as detailed above and may result in unreasonable adverse effects for the pesticide handler.

The Agency also proposes requiring gloves for zinc phosphide rodenticide handlers. The new glove statement should be consistent with Chapter 10 of the Label Review Manual[24].

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 employing 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.

Updated Respirator and Gloves Requirement for Zinc Phosphide Rodenticide Handlers

In addition to the proposed new PPE requirements, the Agency proposes updating the gloves statements currently on zinc phosphide labels, consistent with Chapter 10 of the Label Review

[21] 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 a zinc phosphide 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).

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

[23] 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.

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

Manual.[25] 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.[26] The proposed clarification does not fundamentally change the PPE that workers currently must use.

The Agency proposes updating the respirator statement currently on zinc phosphide 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[28] for products that are meal baits, tracking powders and 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: Zinc Phosphide Products Registered for Use in Turf, Lawns, Parks, Golf Courses, Campsites, and Other Recreation Areas

The 2008 RMD required that non-anticoagulant rodenticide and FGAR products be applied using bait stations wherever children, or non-target wildlife may be exposed. As part of registration review, EPA concluded that zinc phosphide poses an acute and chronic risk to non-listed mammals, birds, reptiles and amphibians through primary and secondary exposure, supported by risk assessment and review of wildlife incidents. Additionally, based on the Agency's most recent incident reviews, non-target primary exposures, including those to children and domestic pets, have also continued to occur. The Agency is proposing to prohibit spot and broadcast applications of zinc phosphide to turf, lawns, parks, golf courses, campsites, and other recreation areas to reduce the potential for non-target exposure, which is consistent with the risk management goals established in both the 2008 RMD, as well as this registration review.

The Agency anticipates that prohibiting spot and broadcast uses of zinc phosphide and other rodenticides in turfgrass and recreation areas, including golf courses and campsites, could negatively affect rodent management, especially in golf courses. This mitigation measure would limit site managers to bait stations and to below-ground rodenticide applications, or to non-chemical methods of control such as mechanical traps. The prohibition of application methods in these sites would have high impacts, particularly on golf courses, where spot and broadcast rodenticide applications to control ground squirrels are important for protecting turf as well as reducing the risk of rodent encounters to workers and golfers. Impacts of this mitigation measure could include reduced ground squirrel control or increased costs of control from having to implement more expensive or more laborious measures, i.e., installing adequate numbers of traps and/or bait stations for equivalent control.

---

[25] https://www.epa.gov/sites/default/files/2016-02/documents/chap-10-feb-2016.pdf
[26] For specific label language, see Appendices B and D.
[27] For specific label language, see Appendices B and D.
[28] 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.

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 zinc phosphide labels. This language will allow users to access the ESA species-specific mitigation measures (proposed in Section IV.B and Appendix D) 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[29], which allows users to more easily find the information they need for a particular pesticide product. The Agency has also developed a tutorial[30] 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.

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

Appendix E provides guidance for zinc phosphide 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 has determined that additional post-application follow-up statements are necessary for zinc phosphide 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 and risks to listed and non-target species and EPA has determined that these statements are necessary for other rodenticide products, including zinc phosphide.

EPA has determined that mandatory carcass search, collection, and disposal requirements are necessary for all zinc phosphide products. EPA has determined that carcass searches should be performed starting 4 days after the first bait application and continue at 1–2-day intervals for at least 2 weeks after the last application of bait, or longer if carcasses are still being found. Although not required, a greater frequency of searches will help to minimize the risk of secondary poisoning to predators and scavengers. Collected carcasses may be disposed of by methods permitted by state and local authorities to ensure that carcasses are inaccessible to predators and scavengers. Where practical, carcasses may be buried either on-site, in holes dug at least 18 inches deep, or in inactive burrows, then the holes/burrows should be packed with soil to avoid scavenging. Removal of carcasses from the site is the preferred option to reduce secondary poisoning. EPA proposes adding the following mandatory post-application follow-up carcass search, collection, and disposal requirements to all zinc phosphide products:

> *"Search the application site and surrounding area to monitor the effects of treatment and to collect and dispose of dead carcasses of target pests or other non-target animals. Search for carcasses 4 days after first application and at subsequent intervals of 1 to 2 days for at least 2 weeks after the last bait application, or longer if carcasses are still being found. While wearing gloves, collect and properly dispose of visible carcasses by burial, dispose of in the trash, or dispose of according to the Pesticide Disposal instructions. Carcasses buried on site must be buried a minimum of 18 inches below the ground surface, preferably deeper. Use leakproof plastic bags or other suitable containers for transporting carcasses not buried on site."*

The Agency anticipates that requiring carcass search and disposal on a specified schedule (e.g., every two days for two weeks or until carcasses are no longer found) for zinc phosphide products would substantially increase labor costs for the use of chemical rodenticides in crop agriculture as well as in pastureland and rangeland. This mitigation measure is expected to increase the costs of rodent control in these sites by increasing the amount of time, labor, and fuel spent on site returns. Affected 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, it is very difficult to control rodents over large areas with mechanical traps alone, and 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.

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

The Agency has determined that additional post-application follow-up statements addressing spilled bait and/or bait kicked out of burrow systems are necessary for zinc phosphide products registered for use in fields and other non-structural use sites. 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 zinc phosphide products registered for use 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."*

The Agency anticipates that requiring additional post-application follow-up measures for zinc phosphide could increase labor costs for the use of zinc phosphide products registered for use in fields and other 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 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, it is very difficult to control rodents over large areas with mechanical traps alone, and 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 all zinc phosphide products:

> *"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."*

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 zinc phosphide products and update them if needed when the Agency requests amended labels in conjunction with this registration review.

9. Specific Label Updates: 56228-6

Through the review of zinc phosphide labels in conjunction with the development of this PID EPA has determined that registration number 56228-6 requires additional revisions to comply with the 2008 RMD. This label should have the following statements, in addition to what is being proposed in this PID:

"Bait stations are mandatory for outdoor, above-ground use. Tamper-resistant bait stations must be used if children, pets, non-target mammals, or birds may access the bait."

"READ THIS LABEL: Read entire label and follow all use directions and use precautions. Use only for the sites, pests, and application methods described on this label."

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 these 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 California condor's designated critical habitat.

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[31] of mammals, birds, reptiles, and amphibians that may be exposed to rodenticides through primary or secondary consumption. For zinc phosphide, 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,[32] 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

[31] 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.
[32] https://www.epa.gov/endangered-species/bulletins-live-two-view-bulletins

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 referencing BLT and using the product consistent with all appropriate bulletins 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 zinc phosphide, see *Use and Benefits of 11 Rodenticides and Impacts of Potential Mitigation* (October 27, 2022), available in the public docket.

1. Proposed Mitigation for Stephens' Kangaroo Rat

The Agency's pilot ESA assessment led to draft predictions of jeopardy for the Stephens' kangaroo rat for zinc phosphide. 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 zinc phosphide within the species' range. Additionally, the Agency is proposing to require zinc phosphide 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 Stephen's 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 aboveground applications not in bait stations (broadcast, spot, and baiting at burrow hole opening) of zinc phosphide in areas with specific listed species may force users to use bait stations or trapping resulting in increased costs for turf and golf course control and for control in and around agricultural fields and orchards.

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 Attwater's Prairie-Chicken

The Agency's pilot ESA assessment led to a draft effects determination of LAA and made a draft prediction that jeopardy is likely for exposure of Attwater's prairie-chicken to zinc phosphide, based on potential effects to individuals. To minimize take of individuals, EPA is proposing to prohibit broadcast applications of zinc phosphide to grassland, pasture, and rights-of-way areas located within the FWS-defined pesticide sensitive area of this species.

Other zinc phosphide applications may still be allowed within the pesticide sensitive areas if they are applied directly into burrows or contained within tamper-resistant bait stations. The Agency anticipates that individuals affected by this mitigation could apply alternative rodenticides instead of zinc phosphide or use different application methods (i.e., bait stations).

3. Proposed Mitigation for the California Condor

The Agency's pilot ESA assessment led to initial predictions of likelihood of jeopardy for the California condor and adverse modification of its designated critical habitat for zinc phosphide.

To address the prediction of a likelihood of jeopardy for the California condor and the adverse modification of the condor's designated critical habitat, EPA is proposing to prohibit broadcast uses of zinc phosphide within and near its range and designated critical habitat:

> *"Do not apply via broadcast application within 200 yards by air or 40 yards by ground upwind from California condor range and critical habitat when air currents are moving toward those areas. When air is calm or moving away from the range or critical habitat, apply on the side nearest those areas and proceed away*."

Prohibiting broadcast applications of zinc phosphide within set distances of occupied California condor range and critical habitat would reduce the potential of rodenticide consumption by the prey of the condor, thereby reducing the likelihood of effects in California condors that could occur from secondary exposure. Applications of zinc phosphide are allowed if they are applied directly into burrows or contained within tamper-resistant bait stations. Prohibiting broadcast applications of zinc phosphide in areas with specific listed species may force users to use bait stations or trapping, resulting in increased costs for turf and golf course control and for control in and around agricultural fields and orchards.

Additionally, to address the prediction of likelihood of jeopardy for the California condor and the adverse modification of the condor's designated critical habitat, EPA is also proposing the following mandatory carcass searches and disposal for areas treated with zinc phosphide within its range and designated critical habitat:

> *"Search the treated area to collect and dispose of dead carcasses of target pests or other non-target animals. Search for carcasses 3 days after first application and continue searches daily for the first 4 days of searching. After day 6, continue searches at subsequent intervals of 1 to 2 days for at least 2 weeks after the last bait application, or longer if carcasses are still being found. While wearing gloves, collect and properly dispose of visible carcasses by burial, dispose of in the trash, or dispose of according to the Pesticide Disposal instructions. Carcasses buried on site must be buried a minimum of 18 inches below the ground surface, preferably deeper. All carcasses must be disposed of in a way inaccessible to wildlife."*

This language is similar to the carcass search and disposal language that is being proposed for the product labels. However, it involves an earlier initial search (3 days after application instead of 4 days) and more frequent searches for the initial monitoring period (daily instead of every 1-2 days). EPA is proposing more frequent searches to increase the likelihood of finding carcasses and reduce the likelihood of secondary exposure to this listed species. EPA expects implementing carcass searches to reduce the potential that California condor(s) will consume a carcass contaminated with zinc phosphide, and therefore reduce the likelihood of lethal and sublethal effects to California condors from secondary exposure to rodenticides.

This mitigation may impose a substantial burden on individuals or operations in remote locations who employ pest control operators (PCOs) for structural control. PCOs may have to return more frequently to inspect sites as a result of this mitigation and may charge higher fees to do so. For information on the impacts of search requirements, refer to the impacts for the FIFRA search requirements in Section IV.A.1 or in *Use and Benefits Assessment for 11 Rodenticides and Impacts of Potential Risk Mitigation* (October 27, 2022).

C. Proposed Updates to the Terms and Conditions of Registration

While the Agency is proposing that all zinc phosphide products 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, 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.

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 zinc phosphide.

The Agency requests 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 the rodenticides, and zinc phosphide, compared to the general population or who may otherwise be disproportionately affected by the use of zinc phosphide.

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 zinc phosphide, and the Agency requests additional information on the potential impacts of these proposed mitigation measures.

E. Tolerance Actions

The Agency plans to exercise its FFDCA authority to update the tolerance expression to appropriately cover the metabolites and degradates of zinc phosphide and to specify the residues to be measured for each commodity for enforcement purposes. EPA anticipates amending the tolerance expression to read as follows:

> "Tolerances are established for residues of the insecticide phosphine, including its metabolites and degradates, resulting from the application of zinc phosphide. Compliance with the tolerance levels specified below, is to be determined by measuring only phosphine, in or on the commodity."

The uses on alfalfa, barley, dry bean, sugar beet, timothy, potato, and wheat to kill rodents are supported by field trial data that support tolerances with regional registration. Therefore, the tolerances for alfalfa, barley, dry bean, and sugar beets should be deleted from 40 CFR 180.284(a) and moved to 40 CFR 180.284(c), which is for tolerances with regional registrations. The Agency has no objection to maintaining U.S. tolerance for grapes, grass, potato, sugarcane, timothy, and wheat in 40 CFR 180.284(a) as there were no residues above the limit of quantification (LOQ) (<0.05 or <0.1 ppm) in these commodities. The residue data for barley and dry beans support the stated use region of WA, OR, and ID. Residue data for alfalfa and sugar beets also supports registered uses in CA, WA, OR, and ID. Residue data for alfalfa also supports registered uses in MT, NV, and UT. Residue data for barley also supports registered uses in MT. The regional restrictions will remain on alfalfa, barley, dry beans, and sugar beets unless registrants provide additional residue data to support a nationwide tolerance..

There are no international harmonization issues associated with this action since there are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of phosphine from use of zinc phosphide on any crop.

The Agency also plans to exercise its FFDCA authority to modify the tolerances for zinc phosphide as summarized in Table 2, below.

Table 2. Tolerance Summary for Phosphine Resulting from Use of Zinc Phosphide and Anticipated Tolerance Actions

Zinc Phosphide 40 C.F.R. § 180.284: Summary of Anticipated Tolerance Actions			
Commodity	Established Tolerance (ppm)	Anticipated Tolerance (ppm)	Comments
40 CFR 180.284(a)			
Alfalfa, forage	0.2	Remove	Move to 40 CFR 180.284(c)
Alfalfa, hay	0.2	Remove	Move to 40 CFR 180.284(c)
Barley, grain	0.05	Remove	Move to 40 CFR 180.284(c)
Barley, hay	0.2	Remove	Move to 40 CFR 180.284(c)
Barley, straw	0.2	Remove	Move to 40 CFR 180.284(c)
Bean, dry, seed	0.05	Remove	Move to 40 CFR 180.284(c)
Beet, sugar, leaves	--	0.2	Move to 40 CFR 180.284(c)
Beet, sugar, tops	0.2	Remove	Commodity definition correction
Beet, sugar, roots	0.05	Remove	Move to 40 CFR 180.284(c)
Grape	0.01	0.01	
Grass, forage	--	0.1	Commodity definition correction
Grass, rangeland, forage	0.1	Remove	
Grass, hay	--	0.1	Commodity definition correction
Grass, rangeland, hay	0.1	Remove	
Potato	0.05	Remove	Move to 40 CFR 180.284(c)

Zinc Phosphide 40 C.F.R. § 180.284: Summary of Anticipated Tolerance Actions			
Commodity	Established Tolerance (ppm)	Anticipated Tolerance (ppm)	Comments
Sugarcane, cane	0.01	0.01	
Timothy, hay	0.5	Remove	Move to 40 CFR 180.284(c)
Timothy, forage	0.5	Remove	Move to 40 CFR 180.284(c)
Wheat, grain	0.05	Remove	Move to 40 CFR 180.284(c)
Wheat, hay	0.05	Remove	Move to 40 CFR 180.284(c)
Wheat, forage	0.05	Remove	Move to 40 CFR 180.284(c)
Wheat, straw	0.05	Remove	Move to 40 CFR 180.284(c)
40 CFR 180.284(c)			
Alfalfa, forage		0.2	
Alfalfa, hay		0.2	
Artichoke, globe	0.01	0.01	
Barley, grain		0.05	
Barley, hay		0.2	
Barley, straw		0.2	
Bean, dry, seed		0.05	
Beet, sugar, leaves	0.02	0.2	
Beet, sugar, roots	0.04	0.05	
Potato		0.05	
Timothy, hay		0.5	
Timothy, forage		0.5	
Wheat, grain		0.05	
Wheat, hay		0.05	
Wheat, forage		0.05	
Wheat, straw		0.05	

F. Proposed Interim Registration Review Decision

The Agency is issuing this PID in accordance with 40 CFR §§ 155.56 and 155.58. The Agency has made the following proposed interim decision: (1) EPA proposes that no additional data are required at this time; and (2) EPA proposes that zinc phosphide does 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 a detailed draft HHRA and Eco DRA. In these risk assessments, EPA identified potential occupational handler and non-target organism risks from the continued registration of zinc phosphide without additional mitigation measures. The Agency identified the potential for dermal and inhalation exposures to occupational handlers using zinc phosphide products that are loose formulations. Additionally, EPA has identified potential risk for non-target exposures from zinc phosphide to children, domestic pets, and non-target wildlife, including listed species. EPA has determined 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 RUP classification for all zinc phosphide products, the prohibition of

certain application methods of zinc phosphide products (spot- and broadcast- application to turf, lawns, golf courses, parks, and other recreation areas), 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.

The Agency also assessed the benefits of the use of zinc phosphide and determined that continuing to register zinc phosphide provides numerous benefits for controlling a variety of vertebrate pests in a variety of use sites, thereby protecting people, animals, structures, and the environments 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."[33] Here, EPA proposes that zinc phosphide does not meet the FIFRA registration standard without the changes to the affected registrations and their labeling described in Section IV.A, Appendices A and B, and the terms and conditions specified in Section IV.C and Appendix C. EPA is proposing that the addition of these mitigation measures to zinc phosphide labels is necessary in order to meet the risk-benefit standard.

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 zinc phosphide. 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 zinc phosphide. As noted in Section IV.B., using its authorities under FIFRA, EPA is also proposing mitigation for three pilot listed species for which the Agency predicts that the currently registered uses of zinc phosphide have a likelihood of jeopardizing these species and adversely modifying their designated critical habitat. 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 will make an EDSP determination before issuing a final registration review decision for zinc phosphide. For more information, see Appendices F and G.

[33] 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).

G. Data Requirements

EPA does not anticipate calling-in additional data for zinc phosphide'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 zinc phosphide PID and open a 75-day comment period.

Appendix A: Summary of Proposed Actions for Zinc Phosphide

Registration Review Case #: 0026
PC Code: 088601
Chemical Type: Rodenticide
Chemical Family: Non-anticoagulant Rodenticide
[Mode/Mechanism] of Action: hydrolysis reaction to produce the toxic gas, phosphine, into the bloodstream

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
Infants, children, pets	Dietary	Ingestion and incidental oral	Acute	Acute toxicity	Require RUP classification for all zinc phosphide products Prohibition of spot- and broadcast-application to turf, lawns, parks, and other recreation areas Require mandatory bait spill/kick out statements
Occupational Handlers	Air and dermal contact	Inhalation Dermal absorption	Short- and intermediate- term	Inhalation and dermal toxicity	Require half-mask elastomeric respirators Gloves
Mammals, Birds, Terrestrial-phase amphibians and reptiles	Dietary	Ingestion	Acute	Acute toxicity	Require RUP classification for all zinc phosphide products Require mandatory carcass search and disposal statements Require mandatory reporting statements Require mandatory bait spill/kick out statements Prohibition of spot- and broadcast-application to turf, lawns, golf courses, parks, and other recreation areas
ESA Pilot Species					
Stephens' kangaroo rat (*Dipodomys stephensi*)	Dietary	Ingestion	Acute	Acute toxicity	Prohibit broadcast and in-burrow applications within the species' range

					Require specially modified bait stations designed to exclude the Stephens' kangaroo rat be used within the species' range
Attwater's prairie-chicken (*Tympanuchus cupido attwateri*)	Dietary	Ingestion	Acute	Acute toxicity	Prohibit broadcast applications of zinc phosphide in grassland, pasture, and rights-of-way within the "pesticide sensitive area" of the species' range
California condor (*Gymnogyps californianus*)	Dietary	Ingestion	Acute	Acute toxicity	Prohibit broadcast application of zinc phosphide within and near the species' range and critical habitat Require carcass search and disposal within the species' range

Appendix B: Proposed Labeling Changes for Zinc Phosphide Rodenticide Products

Description	Proposed Label Language	Placement on Label
	End Use Products	
Restricted Use Pesticide Statement for all zinc phosphide products	"Restricted Use Pesticide" "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[34]
Restricted Use Pesticide Statement for all zinc phosphide products	"Restricted Use Pesticide"	Directions for Use
Requirement for Gloves for products that are meal baits, tracking powders, grain meals, and waxy/paraffinized or non-paraffinized pellets	For products that are meal baits, tracking powders, 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, tracking powders, grain meals, and waxy/paraffinized or non-paraffinized pellets	For products that are meal baits, tracking powders, 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.	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Updated Respirator Language	[**Note to registrant**: If your end-use product only requires protection from particulates only (low volatility), use the following language:]	In the Personal Protective Equipment (PPE) within the Precautionary Statements

[34] 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.

	"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.	
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 registered for use in turf, lawns, parks, golf courses, campsites, and other recreation areas	Note to registrant - If your label has any of the application methods specified below, include the following statement(s) as applicable to your label. Remove reference to these application methods where they currently exist on labels. • For products registered for use in turf, lawns, parks, golf courses, campsites, and other recreation areas: "Do not apply through spot-applications or broadcast applications."	Restrictions Section Under Directions for Use
Endangered Species Language for all zinc phosphide products	"**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	Directions for Use, under the heading "ENDANGERED SPECIES PROTECTION REQUIREMENTS"

	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."	
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 for all zinc phosphide products	**"Carcass Search, Collection, and Disposal** Search the application site and surrounding area to monitor the effects of treatment and to collect and dispose of dead carcasses of target pests or other non-target animals. Search for carcasses 4 days after first application and at subsequent intervals of 1 to 2 days for at least 2 weeks after the last bait application, or longer if carcasses are still being found. While wearing gloves, collect and properly dispose of visible carcasses by burial, dispose of in the trash, or dispose of according to the Pesticide Disposal instructions. Carcasses buried on site must be buried a minimum of 18 inches below the ground surface, preferably deeper. Use leakproof plastic bags or other suitable containers for transporting carcasses not buried on site"	Directions for Use, after directions for specific sites, under the heading "Post-Application Follow-Up"
Mandatory Statements Regarding Post-Application Follow-Up of Spilled and/or Kicked Out Bait for all zinc phosphide products	"While wearing gloves and 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 all zinc phosphide products	**"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 as soon as possible."	Directions for Use, after directions for specific sites, under the heading "Post-Application 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
Updates for EPA Registration Number 56228-6	The label for EPA registration number 56228-6 requires revisions to comply with the 2008 RMD. This label should have the following statements: *"Bait stations are mandatory for outdoor, above-ground use. Tamper-resistant bait stations must be used if children, pets, non-target mammals, or birds may access the bait.*" *"READ THIS LABEL: Read entire label and follow all use directions and use precautions.* ***Use only for the sites, pests, and application methods described on this label.****"*	Directions for Use

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 (BLT) Use Limitation Language for Zinc Phosphide Rodenticide Products

Table 1: Proposed BLT Language for the Stephens' Kangaroo Rat (*Dipodomys stephensi*)

Active Ingredient	Use Limitation	Pesticide Use Limitation Area (PULA)
Zinc Phosphide	• 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 designated **range** of the Stephens' kangaroo rat (Appendix D Figure 1).

Table 2: Proposed BLT Language for the Attwater's Prairie Chicken (*Tympanuchus cupido attwateri*)

Active Ingredient	Use Limitation	Pesticide Use Limitation Area (PULA)
Zinc Phosphide	For products registered for use in grassland, pasture, and rights-of-way areas within the "pesticide sensitive area:" • Do not apply via broadcast application.	Within the "pesticide sensitive area" within the FWS designated **range** of the Attwater's prairie chicken (Appendix D Figure 2).

Table 3: Proposed BLT Language for the California Condor (*Gymnogyps californianus*)

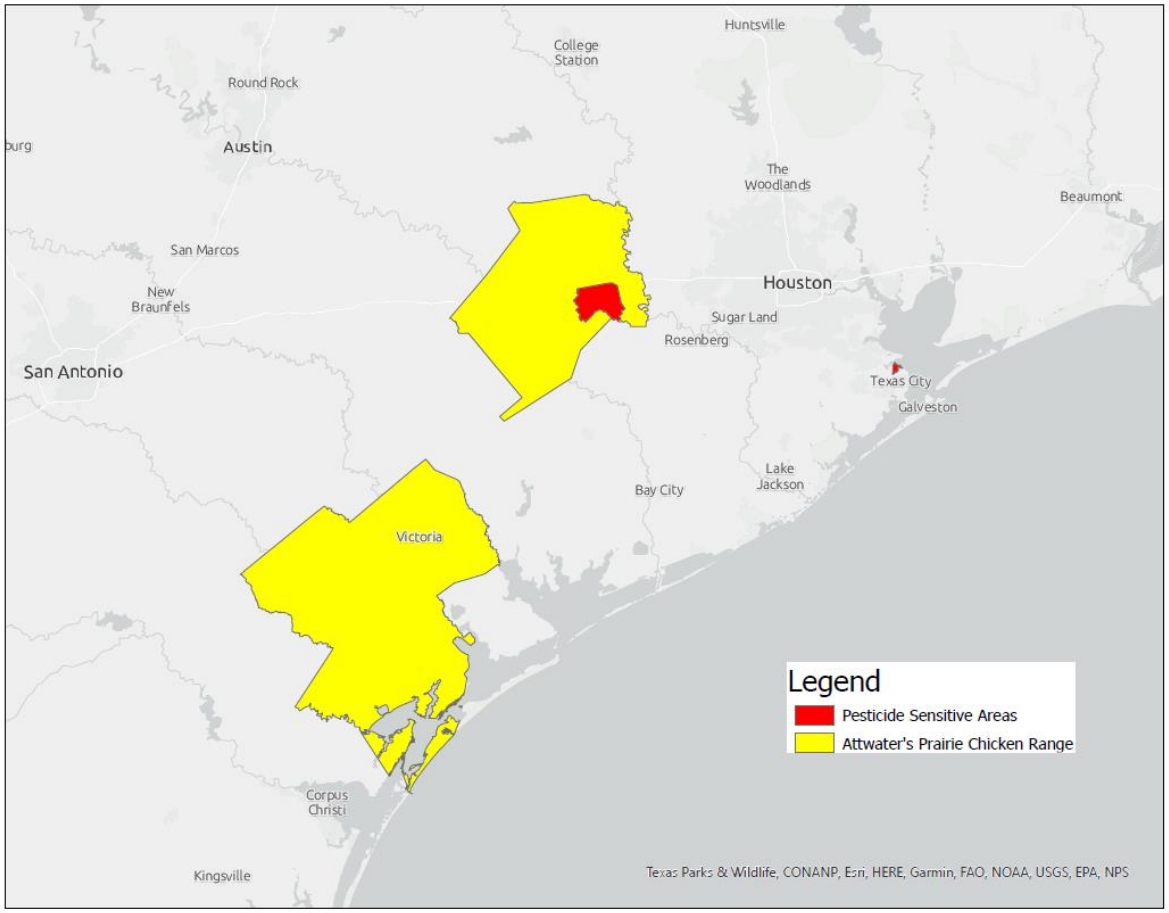
Active Ingredient	Use Limitation	Pesticide Use Limitation Area (PULA)
Zinc Phosphide	• Do not apply via broadcast application within 200 yards by air or 40 yards by ground upwind from California condor range and critical habitat when air currents are moving toward those areas. When air is calm or moving away from the range or critical habitat, apply on the side nearest those areas and proceed away. • Search the treated area to collect and dispose of dead carcasses of target pests or other non-target animals. Search for carcasses 3 days after first application and continue searches daily for the first 4 days of searching. After day 6, continue searches at subsequent intervals of 1 to 2 days for at least 2 weeks after the last bait application, or longer if carcasses are still being found. While wearing gloves, collect and properly dispose of visible carcasses by burial, dispose of in the trash, or dispose of according to the Pesticide Disposal instructions. Carcasses buried on site must be buried a minimum of 18 inches below the ground surface, preferably deeper. All carcasses must be disposed of in a way inaccessible to wildlife.	Within the FWS designated **range** of the California condor (Appendix D Figure 3).

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

Figure 1. Stephens' kangaroo rat (*Dipodomys stephensi*) range.[35]

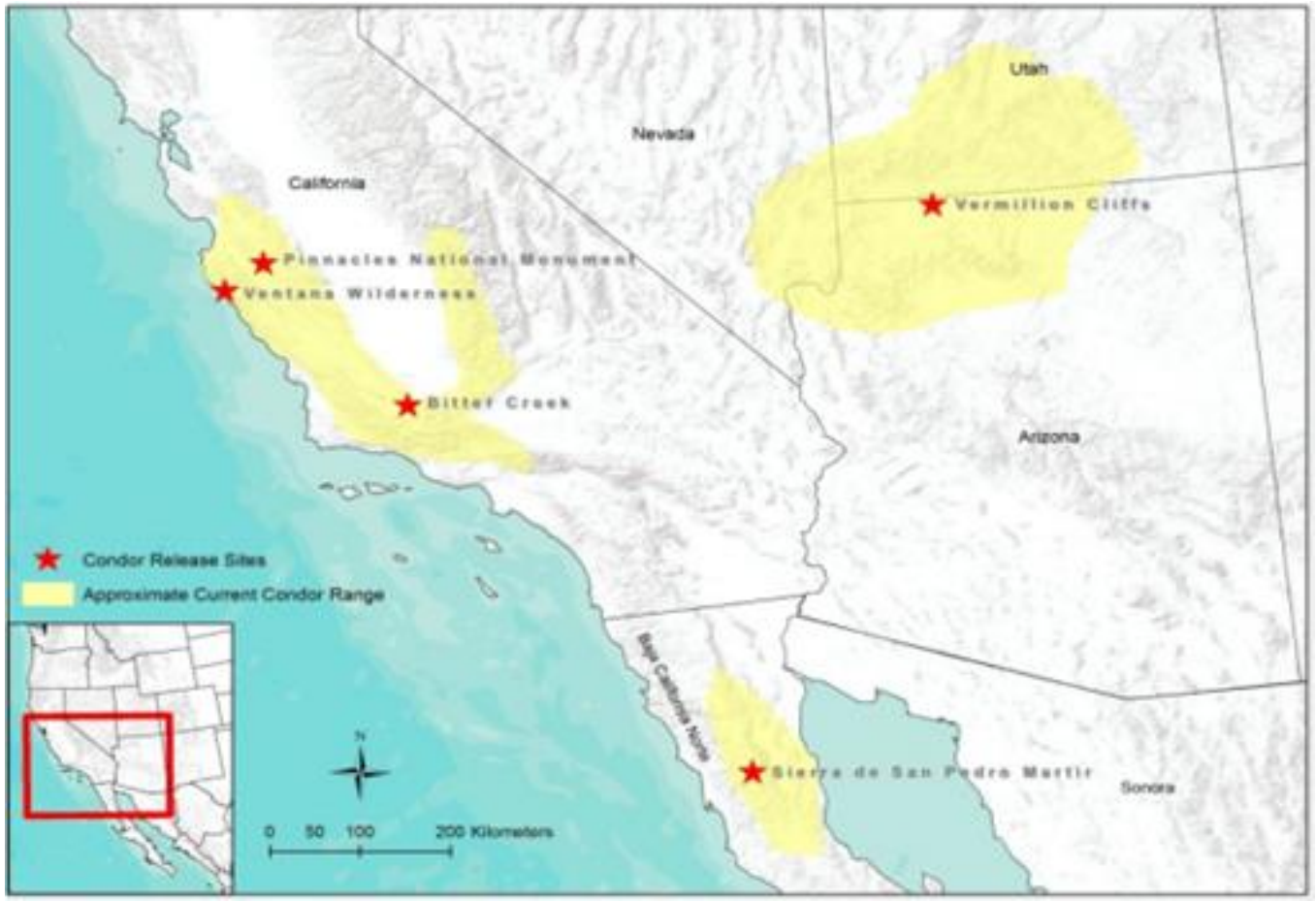
[35] U.S. Fish and Wildlife Service. 2021a. Species Report for the Stephens' kangaroo rat (*Dipodomys stephensi*). Version 1.2, August 2021. U.S. Fish and Wildlife Service, Pacific Southwest Region, Sacramento, California. xii + 121 pp.

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.[36]



[36] 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.[37]



[37] 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 zinc phosphide 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. Zinc phosphide 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.

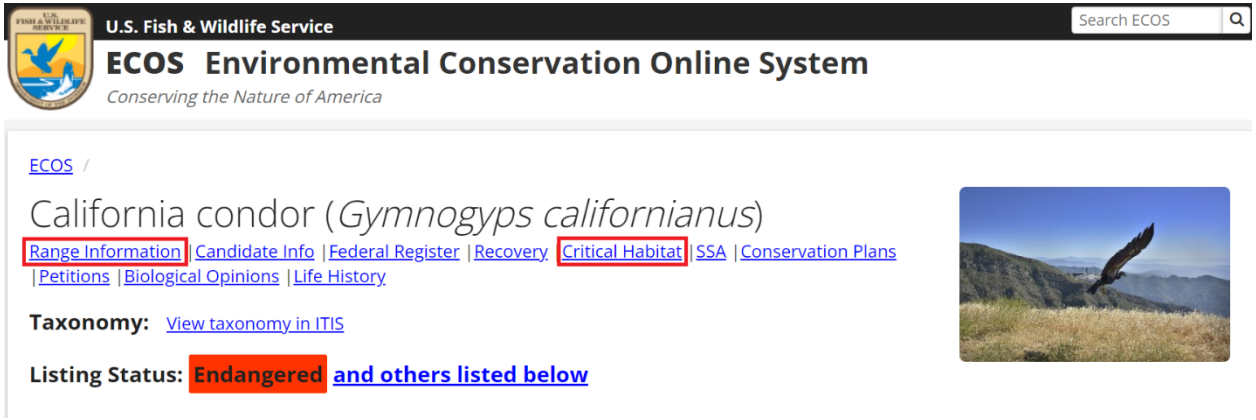


Figure 6. California condor range map.

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 Approaches

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 zinc phosphide appears at the conclusion of this Appendix.

Developing Approaches for ESA Assessments and Consultation 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[38] 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 pesticide's 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.[39]

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.[40]

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[41] from FWS in February 2022 and a final biological opinion from

[38] https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report
[39] https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0185-0084
[40] https://www.epa.gov/endangered-species/reports-congress-improving-consultation-process-under-endangered-species-act.
[41] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions

NMFS on malathion, chlorpyrifos and diazinon in June 2022[42]. The Agency plans to implement both biological opinions according to the 18-month timeframes specified in the 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

In January 2022, EPA announced a policy[43] 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 would 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.*[44] 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 the Anticoagulant Rodenticides

The non-anticoagulant rodenticide active ingredient zinc phosphide, as well as the anticoagulant rodenticide active ingredients brodifacoum, bromadiolone, and 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 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 a draft BE for these 11 rodenticide active ingredients for a 60-day public comment period by the end of November 2023.

[42] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions
[43] https://www.epa.gov/newsreleases/epa-announces-endangered-species-act-protection-policy-new-pesticides
[44] https://www.epa.gov/endangered-species

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 zinc phosphide, 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), zinc phosphide is 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[45] 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,[46] 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. Zinc phosphide is not on either list. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, visit EPA website.[47]

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

[45] 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.
[46] 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.
[47] https://www.epa.gov/endocrine-disruption

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 zinc phosphide. Before completing this registration review, the Agency will make an EDSP FFDCA § 408(p) determination."