February 13, 2023

Melanie Biscose
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Re: Comments on the Rodenticide PIDs and Supporting Documentation

Dear Ms. Biscoe,

Established in 1933, CropLife America (CLA) represents the developers, manufacturers, formulators, and distributors of pesticides and plant science solutions for agriculture and pest management in the United States. CLA represents the interests of its registrant member companies by, among other things, monitoring legislation, federal agency regulations and actions, and litigation that impact the crop protection and pest control industries and participating in such actions when appropriate. CLA's member companies produce, sell, and distribute virtually all the pesticide and biotechnology products used by American farmers.

CLA appreciates the opportunity to comment on the proposed Biological Evaluation for rodenticides produced by the Environmental Protection Agency (EPA or the Agency). Should you have any questions or comments, please feel free to contact me at mbasu@croplifeamerica.org or (202) 296-1585.

Sincerely,

Manojit Basu
Vice President, Science Policy
CropLife America

CC: Jan Matuszko, Acting Division Director, EPA EFED
Kimberly Nesci, Director, USDA OPMP

CropLife America Comments on the Proposed Interim Registration Review Decision for Eleven Rodenticides and Supporting Documents

CropLife America (CLA) is a representative of developers, manufacturers, formulators, and distributors of pesticides for agriculture and pest management in the United States. As such, we are uniquely positioned to assist the Environmental Protection Agency (the EPA or the Agency) in their efforts to implement an enhanced pesticide registration review process in keeping with the EPA workplan released April 12, 2022. The EPA released the proposed interim registration review decision (PID) for a group of 11 rodenticides on November 29, 2022 for public comment. CLA had the opportunity to review the rodenticide PIDs and much of the supporting documentation and offers the comments contained in this report.

CLA would like to recognize the work that the EPA has undertaken to develop the PIDs and the supporting documents. This effort is recognized as being complex given that the rodenticide PIDs group many rodenticides from different classes into one regulatory document. We understand the EPA's desire to group pesticides where possible to meet legal and regulatory timelines, particularly given the revised approach to addressing Endangered Species Act (ESA) consultations as part of the registration review process. CLA and its member companies hope to continue to provide the EPA with the support necessary to ensure a predictable, scientifically defensible, and consistent process for all stakeholders while also benefitting the environment.

We have identified some issues during our review of the rodenticide PIDs and supporting documentation. In particular, the rationale provided for the proposed ESA mitigations in the PIDs had technical issues that require addressing prior to issuing the final Interim Decision (ID). The technical issues include several incorrect assumptions, use of inappropriate toxicity surrogates, and errors in the toxicity endpoint and risk quotient calculations.

CLA fully agrees with the need to move toward strengthening protections for ESA-listed species and their designated critical habitat, as well as maintaining the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard of causing no unreasonable adverse effects. Any proposed mitigations should be scientifically defensible and well supported. To this end, we intend the comments provided here to assist the EPA and other relevant agencies in moving this process forward.

INTRODUCTION

Eleven rodenticides are currently undergoing the registration review process. The EPA has released a proposed interim registration review decision for the rodenticides (EPA, 2022a) and supporting documentation including a pilot Biological Evaluation (pilot BE) for three pilot threatened or endangered (i.e., listed) species and one critical habitat that are potentially exposed to the rodenticides for public comment (EPA, 2022b). CLA has reviewed the PID and pilot BE for the rodenticides and provides the following comments. Our focus is on the species-specific draft effects determinations, and predictions of potential Jeopardy/Adverse Modification (J/AM). We also provide comments on the proposed mitigations to avoid jeopardy or adverse modification. The goal of our comments is to help the EPA improve the interim decision (ID) for these rodenticides and provide input on the pilot BE elements that are likely to be applied to other rodenticides and listed species in the future.

POLICY CONSIDERATIONS FOR THE AGENCY

Stakeholder engagement is a key requirement of the registration review process, particularly with the addition of the endangered species component to the process. Stakeholders familiar with the rodenticides, including registrants and applicators, can provide the EPA with much needed context and expertise during the registration review process, including the endangered species component. Registrants have broad information about their products, including where the best available data may be found, and can provide expertise and knowledge on product use, sales, and other information that is critical to EPA biological evaluations and development of preliminary mitigations. In addition, pesticide users / applicators can also provide critical information related to existing best management practices used during the application of specific pesticides.

CLA looks forward to continuing and expanding opportunities for collaboration with the EPA, the US Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS) (together, the Services), and the US Department of Agriculture (USDA) to achieve a registration review and endangered species program that provides predictable, scientifically defensible, and consistent results for stakeholders while benefitting the environment.

TECHNICAL CONSIDERATIONS

1.1 Overall Assessment Approach

CLA recognizes and commends the work that the Agency has accomplished in the PIDs and supporting documentation. For these comments, we have focused on the pilot BE (EPA, 2022b) and how the Agency accounted for the differences in mode of action and application methods of the 11 rodenticides. This work directly links to the mitigations proposed in the PID (EPA, 2022a). To some extent, rodenticide usage in the species ranges of the three pilot listed species (i.e., Stephen's kangaroo rat, Attwater's prairie chicken, and the California condor as well as the latter's critical habitat) was considered, although more could be done, as acknowledged by the Agency. The pilot BE also considered species-specific information such as exposure routes, diets, foraging behavior and preferred habitats. CLA believes that the overall approach is logical and sound. CLA does, however, have comments and concerns regarding some of the technical details of the analyses conducted by the Agency as outlined in the following section.

1.2 Technical Comments

Our review of the pilot rodenticide BEs identified calculation errors for toxicity endpoints and acute risk quotients, shortcomings in data selection, and several unsubstantiated assumptions. We discuss these issues below. We also briefly discuss the proposed mitigations developed by the EPA.

1.2.1 Toxicity Endpoints and Acute Risk Quotients

For this issue, we focused on the risk analyses conducted for the Stephen's kangaroo rat that are summarized in Table 2 of the pilot BE (EPA, 2022b – Page 17). This table lists the rodenticide bait concentrations and the corresponding test LD50s from rat studies as well as the adjusted median lethal doses (LD50s) calculated by the EPA assuming a mammal body weight of 35 g (the average body weight of the Stephen's kangaroo rat is 65 g). The bait concentrations and adjusted LD50s were then used by the EPA to calculate acute dose-based risk quotients (RQs) assuming 1 and 6 days of feeding exclusively on rodenticide baits by the Stephen's kangaroo rat. Numerous errors were found in this table:

- The adjusted LD50s were the same for 7 of the 11 rodenticides (i.e., 4.4 mg a.i./kg bw) even though the test LD50s for these 7 rodenticides differed (ranging from 0.42-3 mg a.i./kg bw), which is unlikely;

- The adjusted LD50s assumed a body weight of 35 g (one of the standard body weights for mammals in EPA's Terrestrial Residue Exposure model (T-REX)[1]) even though the average body weight of the Stephen's kangaroo rat is 65 g;
- The acute dose-based RQ assuming 1 day of feeding is reported as a single value for bromethalin (i.e., 4.3) even though the concentration in bait was reported as a range (i.e., 100-250 mg a.i./kg bait); and
- EPA used the acute RQs to estimate the probabilities of mortality for an individual Stephen's kangaroo rat feeding exclusively on rodenticide bait. This analysis assumed a default probit slope of 4.5 for each rodenticide even though the original study reports either reported calculated probit slopes or included the raw data that would enable the calculation of probit slopes.

Using the information in Table 2 (EPA, 2022b) and the standard equations in T-REX, CLA calculated the correct adjusted LD50s and acute dose-based RQs assuming 1 day of exclusively feeding on rodenticide bait (Table1). The analysis in Table 1 below was done for 35 g generic mammals as done by the EPA, and for 65 g Stephen's kangaroo rat as should have been done by the EPA. Our results indicate that EPA's acute RQs varied by factors ranging from 0.83- to 29-fold for 35 g mammals and 0.73 to 26-fold for 65 g Stephen's kangaroo rat.

Although we did not repeat the analysis summarized in Table 1 for the Attwater's prairie chicken and California condor, we identified several problems with the analysis conducted by the EPA for these two listed species. These errors in the risk calculation for the Attwater's prairie chicken and California condor may eventually lead to inefficient mitigations.

Specifically, for the Attwater's prairie chicken, the EPA used a passerine food ingestion rate (FIR) to estimate exposure, even though a FIR for Galliformes, the taxonomic order to which the Attwater's prairie chicken belongs, is readily available as is an FIR for all birds (the latter is used in T-REX). Also, for the Attwater's prairie chicken, the EPA relied on the most sensitive avian LD50 reported for each rodenticide. A more scientifically defensible approach would be to use LD50 for bobwhite quail, which is available for each rodenticide, because the bobwhite quail and Attwater's prairie chicken belong to the same taxonomic order.

[1] Models for Pesticide Risk Assessment | US EPAc

There was insufficient detail provided in the pilot BE (EPA, 2022b) on the analyses conducted by the EPA for the California condor. For example, no information was provided in the text describing how the concentrations were determined for each rodenticide in California condor prey items that are reported in Table 8 of the pilot BE (EPA, 2022b). The footnote in the same Table 8 also notes that the chronic No Observed Adverse Effect Concentration (NOAEC) from a mallard duck study conducted for chlorophacinone was used as the NOAEC for all 11 rodenticides. There is no scientific justification for such an extrapolation, particularly given the differing modes of action among the rodenticides and the wide range of acute LC50s (i.e., 0.56 to 906 mg a.i./kg diet, Table 8 in the pilot BE) reported for them.

The most important assumption in the EPA's risk analyses for the rodenticides was that each listed species only consumed rodenticide bait. Such an assumption is perhaps reasonable for acute exposure of a small mammal (e.g., Stephen's kangaroo Rat) or bird with a limited foraging range and a preferred diet that resembles the bait formulation (e.g., treated seeds). Even then, we suggest that the EPA determine how many treated bait items would need to be consumed to produce toxic effects and compare that calculated value to the quantity of bait items available within the foraging range of the species of interest (either when broadcast applied or in bait stations). If the amount that an individual could reasonably expect to find and ingest within its foraging range over a short period of time is below the dose that could cause adverse effects, then there is, realistically, no acute risk issue. The assumption of exclusively foraging on treated bait is even less realistic for species with broadly varied diets (e.g., Attwater's prairie chicken, California condor) and large foraging ranges (e.g., California condor), particularly for determining chronic risks.

Table 4-1. Acute toxicity endpoints and risk quotients calculated by EPA and by CLA for the Stephen's kangaroo rat (SKR).

Active Ingredient	Concentration in Bait (mg a.i./kg bait)	LD50 - Rat (mg a.i./kg bw)	EPA's Reported LD50 - SKR (mg a.i./kg bw)	Adjusted LD50 - 35 g Mammal (mg a.i./kg bw)	Adjusted LD50 - 65 g SKR (mg a.i./kg bw)	EPA's Acute Dose-based RQ (1-d Feeding)	CLA's Acute Dose-based RQ (1-d Feeding) – 35 g Mammal	CLA's Acute Dose-based RQ (1-d Feeding) – 65 g SKR
Brodifacoum	25	0.42	4.4	0.747	0.640	0.75	22.1	19.7
Bromadiolone	25	0.6	4.4	1.07	0.914	0.75	15.5	13.8
Difenacoum	50	1.8	4.4	3.20	2.74	1.5	10.3	9.17
Difethialone	25	0.55	4.4	0.978	0.838	0.75	16.9	15.0
Chlorophacinone	50	0.8	4.4	1.42	1.22	1.5	23.2	20.6
Diphacinone	50	1.9	4.4	3.38	2.89	1.5	9.77	8.69
Warfarin	50	3	4.4	5.33	4.57	7.49	6.19	5.50
Zinc phosphide	20000	21	37.3	37.3	32.0	71	353	315
Bromethalin	100-250	2.11	3	3.75	3.21	4.3	17.6-44.0	15.7-39.1
Cholecalciferol	750	11.8	7.35	21.0	18.0	13.4	23.6	21.0
Strychnine	5000-9726	2.2	3.91	3.91	3.35	169-328	844-1641	751-1460

1.2.2 Proposed Mitigations

On page 29 of the pilot BE (EPA, 2022b), the EPA proposed to prohibit broadcast applications of chlorophacinone and zinc phosphide baits to grassland, pasture and rights-of-way areas located within defined pesticide sensitive areas of the Attwater's prairie chicken. However, chlorophacinone was deemed "not likely jeopardy" for the species because of low overlap between where the product may be used and the species range. Thus, it is unclear why mitigations are required for chlorophacinone to protect the Attwater's prairie chicken given the not likely jeopardy conclusion. In the rodenticide PID (EPA, 2022b), the EPA indicates that the effect determination of likely to adversely affect (LAA) may justify the use of mitigations in the species range despite the not likely jeopardy decision. The LAA effect determination is based on an entirely different protection goal (i.e., more than one individual of the species) whereas the likely jeopardy call is based on a population-level protection goal. In the remainder of the pilot BE (EPA, 2022b), mitigations were only proposed for rodenticides for which a likely jeopardy conclusion was reached for the listed species being considered.

In general, the proposed mitigations for the rodenticides should substantially reduce exposure to the Stephen's kangaroo rat, Attwater's prairie chicken, and California condor. CLA is, however, concerned that several mitigations may not be feasible (e.g., searching for carcasses in the California condor range for up to 2 weeks after rodenticide application) or make economic sense (e.g., developing Stephen's kangaroo rat-excluding bait stations that would only be used in a small fraction of the country, i.e., the species range). CLA also remains concerned that some mitigations have been proposed where none were necessary, had the appropriate risk analyses been conducted (see Section 4.2.1).

CONCLUSION

As a representative of developers, manufacturers, formulators, and distributors of pesticides for agriculture and pest management in the United States, CLA appreciates the opportunity to provide comments on the rodenticide PIDs and supporting documentation. We recognize the work that goes into such an effort and commend the EPA for the many improvements that have taken place in recent years regarding the ESA process. We intend the comments provided here to assist the EPA and the Services in moving towards an efficient and scientifically defensible process that is protective of the environment and provides certainty in the registration review process for our members and pesticide users.

REFERENCES

EPA (US Environmental Protection Agency). 2022a. Proposed Interim Registration Review Decision for Seven Anticoagulant Rodenticides. Case Numbers 2100, 2205, 0011, 2755, 2760, 7630, and 7603. Office of Pesticide Programs, US Environmental Protection Agency, Washington, D.C. November 14, 2022.

EPA (US Environmental Protection Agency). 2022b. 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. Office of Pesticide Programs, US Environmental Protection Agency, Washington, D.C.

EPA (US Environmental Protection Agency). 2023. Response to Requests to Extend the Public Comment Period for the Rodenticide Proposed Interim Registration Review Decisions. January 12, 2023. Office of Pesticide Programs, US Environmental Protection Agency, Washington, D.C. EPA-HQ-OPP-2015-0767-0103.