

Update to the *Overview of the Rodenticide Comparative Ecological Assessment*

September 9, 2004

Introduction

This document serves to update the *Overview of the Rodenticide Comparative Ecological Assessment*, dated January 16, 2003, which summarized the Environmental Protection Agency's (EPA's) preliminary comparative assessment of potential risks to birds and nontarget mammals posed by nine rodenticides. This update has been placed in the public docket along with the Revised Comparative Ecological Assessment and other related documents, in conjunction with the opening of Phase 5 of the reregistration process. The availability of these documents has been announced in the *Federal Register*.

Revisions to the Comparative Ecological Risk Assessment

The Comparative Ecological Assessment for Rodenticides was developed following the issuance of Reregistration Eligibility Decisions (REDs) in 1998 for the rodenticide cluster and zinc phosphide. In those REDs, EPA noted concern about potential adverse effects to birds and non-target mammals, and announced its plan to further evaluate the potential risks before issuing final decisions about reregistration eligibility. In a public meeting in October 1999, EPA announced that it would employ a comparative approach for further evaluating potential ecological risks posed by rodenticides, and committed to use a public participation process to ensure broad stakeholder input on the assessment and any resulting risk mitigation options.

The comparative ecological assessment compares and ranks the potential severity of risk posed by nine rodenticide active ingredients. The nine rodenticides included in the assessment are those addressed in the Reregistration Eligibility Decisions (REDs) for zinc phosphide and the Rodenticide Cluster (brodifacoum, bromadiolone, bromethalin, chlorophacinone, diphacinone),¹ as well as warfarin, difethialone, and cholecalciferol. The preliminary version of the assessment, "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach," dated December 19, 2002, was released to the public through a Federal Register Notice dated January 29, 2003.

EPA accepted public comments on the preliminary assessment, and revised the assessment, in part, based on some of the comments received. The individual comments received on the comparative assessment are available through the pesticide docket or from the EPA website at www.epa.gov/pesticides/rodenticidecluster. The revised comparative assessment, dated July 2004,

¹ In addition to brodifacoum, bromadiolone, bromethalin, chlorophacinone, diphacinone, the 1998 Rodenticide Cluster RED also presented EPA's reregistration decision for pival and its sodium salt, which were determined to be ineligible for re-registration.

may be obtained electronically from the EPA website.² EPA's response to public comments, dated July 17, 2004, EPA's response to comments from USDA/APHIS, dated September 9, 2004, and a document discussing the importance of rodent control pesticides and detailing the use patterns for the nine rodenticides, titled "Analysis of Rodenticide Bait Use," dated September 2, 2004, are also available on the EPA website.

The majority of the data and information used to derive the risk estimates in the ecological assessment are summarized in the January 2003 *Overview of the Rodenticide Comparative Ecological Assessment*. This document, an update to the *Overview*, provides the major changes between the preliminary and revised versions of the assessment. The revisions – primarily, the incorporation of additional data and some formatting adjustments – have not significantly changed the assessment conclusions. The major revisions reflected in the revised assessment are as follows.

1. *Addition of a section and attachment on endangered species considerations*

A new section in the assessment discusses endangered species considerations and provides general information about EPA's Section 7 consultation with the United States Fish and Wildlife Service (FWS). A new attachment – Attachment E – presents the jeopardy determinations from FWS' 1993 Biological Opinion for eight of the nine rodenticides addressed in the comparative assessment.

2. *Addition of rat dietary data and mammalian risk quotients for five of the anticoagulant rodenticides*

To reduce the uncertainty associated with mammalian risk estimates, EPA incorporated data from a rat dietary (LC₅₀) study conducted at EPA's former toxicology laboratory in Beltsville, Maryland. Multiple tests were conducted with brodifacoum, bromadiolone, chlorphacinone, diphacinone, and warfarin. The tests consisted of a five-day acclimation period, a five-day exposure period, and a post-treatment observation period lasting at least nine days.

3. *Addition of diphacinone residue data from a field study*

In response to comments received on the preliminary assessment, EPA incorporated into the comparative assessment data from a diphacinone field test in which residues were determined in ground squirrels.

² EPA notes that although a revised version of the assessment is currently being released, it may be refined and/or revised significantly in the future based on comments or additional data.

4. *Inclusion of additional secondary-toxicity information on chlorophacinone*

EPA incorporated into the comparative assessment data from a laboratory trial in which secondary toxicity to ferrets was studied using prairie dogs poisoned with chlorophacinone bait.

5. *Inclusion of additional rodenticide incident data*

Incident data received by EPA after publication of the preliminary version of the comparative assessment has been incorporated into the revised assessment.

6. *Reference to pet incident data compiled for rodenticides by the American Society for the Prevention of Cruelty to Animals (ASPCA)*

In response to a comment received on the preliminary assessment, EPA referenced data from the ASPCA's Poison Control Center in the section titled "Incident Data: Birds and Nontarget Mammals." The ASPCA data is a compilation of incident reports involving potential exposure of pets (primarily dogs) to rodenticides. These data supplement the wildlife incident data and are relevant in considering the effectiveness of product label restrictions in preventing exposure to nontarget animals.

7. *Rearrangement of some of the hazard and risk information in the text*

In an effort to improve clarity and organization, EPA moved certain information from the Potential Primary Risks section to the Primary Hazards Data section.

8. *Inclusion of 40 Code of Federal Regulations (CFR) study guideline reference numbers where guideline studies are cited in the "Terms and definitions" section*

To improve clarity, EPA has included 40 CFR references where guideline studies are cited.

Endangered Species Considerations

EPA is working with the United States Fish and Wildlife Service and the National Marine Fisheries Service to further evaluate the potential effects of rodenticides on endangered species. In response to a formal consultation requested by EPA in 1991 under Section 7 of the Endangered Species Act, the United States Fish and Wildlife Service issued a Biological Opinion in 1993, titled *Effects of 16 Vertebrate Control Agents on Threatened and Endangered Species*. The Biological Opinion included jeopardy determinations for mammals, birds, and reptiles potentially exposed via primary or

secondary exposure to brodifacoum, bromadiolone, chlorophacinone, diphacinone, warfarin, bromethalin, zinc phosphide, and cholecalciferol. The species addressed, jeopardy and no-jeopardy determinations, and the Service's reasonable and prudent alternatives and/or measures for each of the 8 rodenticides are provided in Attachment E of the Comparative Ecological Risk Assessment.

EPA believes that it may be necessary to reinitiate consultation with the Services to supplement and reevaluate the 1993 Biological Opinion because (1) the original consultation did not include difethialone (which was registered in 1995), (2) additional species have been listed since the previous consultation, and (3) some carcasses of endangered species have been found to contain rodenticide residues.

EPA invites interested parties to comment on the 1993 Biological Opinion, including the jeopardy determinations and the "reasonable and prudent alternatives/measures" to minimize take. In light of comments received, the Agency will consider whether to pursue implementation of the 1993 Biological Opinion as an interim measure in advance of re-consultation with the Services.

Next Steps

During the public comment period, EPA plans to work with the United States Department of Agriculture, the Centers for Disease Control and Prevention, the United States Fish and Wildlife Services, the National Marine Fisheries Service, the United States Department of Defense, and other interested stakeholders to identify and propose mitigation measures to reduce risks while maintaining the key benefits of the rodenticides. If you wish to participate in this process, please contact the Chemical Review Manager for the Rodenticides: Kelly White at 703-305-8401 or at white.kelly@epa.gov.