UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 10, 2006

Memorandum

Subject: Response to Comments on EFED's July, 2004 Risk Assessment: "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach"

To: Susan Lewis, Branch Chief
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Through: Thomas Bailey, Ph.D., Branch Chief
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EFED has reviewed the comments submitted on the environmental risk assessment entitled "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach" dated July, 2004. Comments were received from more than 150 respondents, including 6 comments that requested a time extension for responding, and are contained in OPP's EDocket OPP-2004-0033. Respondents included Federal, State and local agencies; environmental coalitions/organizations; rodenticide registrants and the Rodenticide Registrants Task Force; pest control firms and organizations; consultants/advisors; and private citizens, and the comments are grouped by those categories. EFED is responding only to those comments that address the risk assessment. Some comments address the comparative analysis modeling conducted by the late D. Urban.

EFED acknowledges and appreciates the assistance of P. Durkin, Syracuse Environmental Research Associates, in compiling and summarizing the comments.

Attachments:

Attachment 1: EFED's July 17, 2004 Response to Public Comments on EFED's Risk Assessment: "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach", dated December 19, 2002
Attachment 2: Field uses of zinc phosphide, diphacinone, and chlorophacinone.
Attachment 3: EFED Response to USDA/APHIS' "Partner Review Comments: Preliminary Analysis of of Rodenticide Bait Use and Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: A Comparative Approach (June 9, 2004)", September 7, 2004

FEDERAL, STATE, AND LOCAL AGENCIES

U. S. Fish and Wildlife Service

Comment: Based on review of EPA's comparative risk assessment, published literature, and wildlife mortality reports, it is the opinion of the Service that continued use of rodenticides under current conditions presents a significant level of risk to birds and nontarget mammals. Further, the ever-increasing number of mortality events attributed to second-generation rodenticides indicates that current restrictions placed on these pesticides (baiting of commensal rodents in and around buildings, transport vehicles, and inside sewers, and indoor use only for brodifacoum and difethialone in non-urban areas) is insufficient to prevent exposure to nontarget organisms at levels consistent with adverse effects.

Widespread nontarget exposure to anticoagulants cannot be disputed. Based on a study of carcasses collected from 1998-2001 in New York State, including samples asymptomatic of anticoagulant exposure submitted for West Nile Virus surveillance, Ward Stone, Wildlife Pathologist for New York State Department of Environmental Conservation, concluded that anticoagulants were present in the majority of great homed owls, about half of the red-tailed hawks, and in a substantial fraction of other raptors in New York State (Stone et al., 2003)[1]. Detection of more than one rodenticide in a number of these carcasses indicates that a percentage of these birds are acquiring these residues through multiple exposures. For smaller species, the picture is less clear. Most incident reports tend to focus on large conspicuous species like predators and scavengers.

Due to their high nonselective toxicity and known involvement in the mortality of birds and nontarget mammals, the Service recommends the following mitigative measures to alleviate risk to nontarget organisms:

[1] Stone, W.B., J.C. Okonlewski, and J.R. Stedelin. 2003. Anticoagulant rodenticides and raptors: recent findings from New York, 1998-2001. Bull. Environ. Contam. Toxicol. 70:34-40

· All rodenticides considered in this assessment should be restricted to use by a certified applicator.

· Second-generation rodenticides should be limited to use inside buildings only, except in situations where the benefits to nontarget organisms outweigh the risks.

· To reduce risk associated with primary exposure, all rodenticides considered in this assessment should be made inaccessible to nontarget organisms by mandating the use of tamper-proof bait stations.

EFED Response: EFED thanks the Service for their comments.

New York State Department of Environmental Conservation (NYSDEC)

Comment: The July 2004 risk assessment clearly and unambiguously shows that there are distinct differences between the rodenticides and that brodifacoum is one of the more dangerous ones, which is consistent with the findings of New York's Wildlife Pathologist.

EFED Response: EFED thanks the NYSDEC and commends it and its' Wildlife Pathologist for providing much of the incident data cited in the assessment.

Comment: Kaukeinen et al. (2000)[2] suggest that most incidents probably result from misuse by non-certified applicators. However, the potential for misuse cannot be separated from the inherent toxicity of brodifacoum, and rodenticides with less toxicity pose lower risks whether misuse is intentional or unintentional.

EFED Response: EFED agrees. The RRTF's presumption that incidents occur due to misuse by non-certified applicators seems to be an argument that the most highly toxic rodenticides shouldn't be sold over the counter at outlets such as supermarkets where they can be purchased by non-certified applicators. Several other respondents have stated a similar concern. [see also Attachment 1, Comments 4, 5, 11 and EFED Responses]

Comment: Overall, the risk assessment is an excellent study that fairly evaluated the data available and utilized alternate methods of analysis (comparative analysis model; lines of evidence approach) to assess the risks of rodenticides and reach solid, objective, and defensible conclusions. The NYSDEC suggests the following mitigation measures:

· Segregate indoor, homeowner use products from outdoor products.
· Make outdoor products restricted use.

[2] Kaukeinen, D.E., C.W. Spraggins, and J.F. Hobson. 2000. Risk-benefit considerations in evaluating commensal anticoagulant rodenticide impacts to wildlife. Proc. Vertebr. Pest Conf. 19:245-256. Rodenticide Registrants Task Force presentation.

- Construct bait stations out of plastic or metal so they cannot be easily opened by wildlife.
- Provide more warnings and instructions to advise how to use the products more safely
- Reformulate products to reduce the concentration of active ingredient.

EFED Response: EFED appreciates the comments of the NYSDEC.

California Department of Pesticide Regulation (CDPR)

Comment: CDPR recommends that the observation period following subacute exposure be extended to 10 to 14 days. In addition, NOAEC determination should include necropsy as well as behavioral observations.

EFED Response: For the anticoagulant rodenticides, EFED requires that test animals in subacute (i.e., 5-day dietary exposure) and acute-oral studies be observed for at least 15 days and even longer if mortality occurs during the last three observation days. These requirements are mentioned in the risk assessment [see test descriptions under "**Terms and Definitions**"]. Behavioral observations and signs of toxicity also must be reported. EFED agrees that an extended observation period is critical in these tests, because death can be delayed for up to two weeks or more after a lethal dose has been ingested via the diet or gavage. Adding supplemental Vitamin K to the basal diet also is an issue that influences toxicity of anticoagulant rodenticides in the laboratory. As indicated in the risk assessment, many of the toxicity values obtained from the open literature (e.g., Godfrey 1986)[3] are questionable, because the length of the observation period and vitamin supplementation of the basal diet are not reported.

Comment: California data (R. Hosea; DFG) indicates that brodifacoum poses a significant hazard to nontarget wildlife, particularly in urban and suburban areas. We recommend EPA consider restricting brodifacoum use to PCO's and/or indoor use only to reduce risk to nontarget birds and mammals.

EFED Response: EFED thanks CDPR for these comments.

Comment: CDPR recommends that registrants be required to fill the data gaps (relating to toxicity and kinetics) as a condition of registration.

EFED Response: EFED agrees that data gaps should be addressed. However, whether or not a Data Call-In is issued is decided by SRRD.

[3] Godfrey, M.E.R. 1986. An evaluation of the acute-oral toxicity of brodifacoum to birds. Proc. Vertebr. Pest Conf. 12:78-81

Comment: Recommend that total body burdens rather than blood and liver levels be used to determine nontarget hazard due to secondary poisoning.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: The risk assessment identifies measures issued by the USFWS to protect endangered species from rodenticides. The CDPR, the Department of Fish and Game (DFG) and the Department of Food and Agriculture (CDFA) have developed a County Bulletin program, which has been reviewed and approved by the FSW as an acceptable alternative to the FSW's Biological Opinion.

EFED Response: California's County Bulletins do not supersede the requirements for EPA to address risks to listed (i.e., endangered and threatened) species from potential pesticide exposure. As noted in the risk assessment, the Endangered Species Act (ESA) requires that "A Federal agency is required to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat." Possible risks to listed species will be addressed by OPP in accordance with OPP's Overview Document[4] and, if necessary, in consultation with the U. S. Fish and Wildlife Service and the National Marine Fisheries Service in compliance with the ESA. See also the following comment by CDFG and EFED's response.

California Department of Fish and Game (DFG)

Comment: Twenty-six (26) San Joaquin kit foxes *Vulpes macrotis mutica*, a state and federally listed endangered species, have been recovered from the Bakersfield, California, area with residues of brodifacoum.

EFED Response: First, EFED wishes to acknowledge R. Hosea, DFG, for providing information on the kit fox incidents as well as many other rodenticide incidents in California. EFED agrees that finding brodifacoum residues in carcasses of the endangered San Joaquin kit fox is a concern and says the following in the risk assessment:

"Of particular concern are findings over the past several years that the listed San Joaquin kit fox is being exposed to rodenticides, especially brodifacoum. From 1999 to 2003, liver tissue from 32 dead kit foxes has been screened for rodenticide residues by the

[4] USEPA. 2004. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U. S. Environmental Protection Agency: Endangered and Threatened Species Effects Determinations. Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs, Washington, D.C.

Pesticide Investigations Unit of the California Department of Fish and Game and by the U. S. Fish and Wildlife Service (R. Hosea, pers. comm.). Anticoagulant rodenticide was detected in the liver of 27 (84%) foxes. Brodifacoum was detected in all 27 individuals. Bromadiolone also was detected along with brodifacoum in 2 of those foxes, and chlorophacinone and pival were found with brodifacoum in 1 fox each. Pival is no longer registered but may have been used under existing-stocks provisions."

As noted in the previous response, OPP is required by the ESA to address listed species and, as necessary, consult with the Services to mitigate risks.

Comment: We urge EPA to consider reproductive effects during the re-registration process.

EFED Response: EFED agrees that reproductive effects should be considered, and we believe that avian reproduction[5] and rat two-generation reproduction[6] studies would provide useful information for assessing risks. Hopefully, OPP will require those studies to reduce uncertainties in the risk assessment that relate to adverse affects from sublethal exposure. [see also Attachment 1, Comments 21 and 22 and EFED Responses]

Comment: Establishing a "toxicity threshold value" for post-mortem liver rodenticide concentrations, as proposed by the Rodenticide Registrant Task Force, is inappropriate and unreliable. Over 50% of the initial concentration of brodifacoum is metabolized and eliminated from the body within the first few days following exposure, prior to the death of the animal. Animals are sensitive to a compound over a range of concentrations. It is more appropriate to use detected tissue residues in conjunction with other observed clinical signs of toxicosis to assign the cause of death.

EFED Response: EFED agrees. We discuss the Rodenticide Registrant Task Force's (RRTF) concept of a "toxicity threshold value" in the risk assessment and disagrees with what the RRTF proposes. Findings from the field and the incident data discussed in the risk assessment indicate that the liver is an appropriate organ for detecting exposure of birds and mammals to anticoagulant rodenticides. However, establishing a toxicity threshold of 0.7 ppm for mortality seems to be inappropriate and is not supported by the available data.

Comment: DFG concurs that data are needed to determine the degree that brodifacoum and other second generation anticoagulant rodenticides bioaccumulate from repeated sub-lethal exposures. Repeated sub-lethal exposures may lead to toxicosis and significant tissue or organ damage and may increase the susceptibility of the animal to other causes of mortality.

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[5] 40 CFR §158.490 *Wildlife and Aquatic Organisms Data Requirements*, Guideline Reference No. 71-4

[6] 40 CFR §158.340 *Toxicology Data Requirements*, Guidelines Reference No. 83-4

EFED Response: EFED agrees. The potential for brodifacoum to bioaccumulate has been recognized by researchers as well as by the registrant. As discussed in the risk assessment, "Eason and Murphy (2001)[7] emphasize that the risk of brodifacoum is magnified by its persistence, which could lead to accumulation on repeated exposure. A compound that is rapidly metabolized or excreted from a primary consumer may result in a lesser risk than one that bioaccumulates with repeated sublethal exposure, even if repeated exposure occurs weeks or even months after the initial exposure. Those compounds more rapidly cleared from the body are less likely to pose such long-term risk."

In the 1980s, ICI Americas Inc. (now Syngenta Crop Protection) was the sole registrant of brodifacoum, marketed under the product names Talon and Havoc. At that time, product labels contained the telephone number of ICI's emergency assistance team and the number for the National Animal Poison Control Center. Callers received advice from either source in the case of ingestion of these products by nontarget animals. ICI's report for 1982-1985[8] contains information on numerous nontarget exposures and poisonings, primarily dogs but also cats, chickens, and several other species, including a horse. In response to a case in 1983 where Talon was used to control rats, chickens were dying from feeding on dead rats and possibly bait. ICI "**Advised TALON can accumulate in body.**" In another incident in 1983 in which a kitten had access to bait and had been bleeding for two days, ICI stated that ". . . **repeated ingestion probably makes it more toxic**."

Contra Costa Mosquito and Vector Control District (CA)

Comment: Our inspectors/technicians find many unsafe applications of rodenticides by the public. Over the counter sales of rodenticides should be required to be accompanied by a tamper proof bait station; many vendors (e.g., supermarkets) do not stock bait stations.

EFED Response: We appreciate this information. It is an issue that has been emphasized by other respondents and needs to be addressed in mitigation

City of San Francisco, DEC

Comment: Evaluating groups of chemical alternatives together will yield the most accurate comparisons between the chemicals, and such comparisons are most practical for informing the choices we need to make in our IPM program.

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[7] Eason, C.T. and E. Murphy. 2001. Recognising and reducing secondary and tertiary risks associated with brodifacoum. Pages 157-163 in J. J. Johnston (ed.), Pesticides and Wildlife. American Chemical Society Symposium Series 771

[8] ICI Americas Inc. 1986. Emergency Call Reports for ICI Americas' Rodenticides Talon and Havoc 1982-1985. 15 pp. EPA Accession No. 262910

EFED Response: EFED agrees and appreciates the comment.

Comment: An aquatic risk analysis is needed. The widespread use of rodenticides in sewers and along creeks provides a plausible pathway for these chemicals to reach surface waters.

EFED Response: The current assessment is limited to birds and nontarget mammals. EFED realizes that there is some potential for rodenticides to reach aquatic bodies and would appreciate any information that applicators or other stakeholders could provide regarding exposure and risks to aquatic organisms. Possible risks to Federally listed species, including aquatic species, will be addressed by OPP in accordance with OPP's Overview Document (cited in footnote #4) and, if necessary, in consultation with the U. S. Fish and Wildlife Service and the National Marine Fisheries Service. This analysis should also provide insight into possible exposure of non-listed species as well.

Comment: There is need for data on the risks from sub-lethal exposures to rodenticides by off-target species. EPA correctly states that some data exist showing adverse effects from sub-lethal exposures to anticoagulants and that warfarin is a reproductive toxicant.

EFED Response: EFED agrees and states the following in the risk assessment:

for birds: "No guideline data are currently available for any of the rodenticides. OPP will be requiring avian reproduction tests with the mallard and northern bobwhite to fulfill this guideline requirement (40 CFR §158.490 Wildlife and Aquatic Organisms Data Requirements, Guideline Reference No. 71-4). EFED notes that there is a published abstract reporting the deaths of 2 turkey vulture (*Cathartes aura*) offspring that were fed brodifacoum-poisoned mice by their parents (Borst et al. 2000). The possibility exists that young animals may be more susceptible to rodenticide poisoning than are adults (see also the section on "*Mammalian reproduction/sublethal effects*"). EFED will assess the potential for adverse reproductive and chronic effects when the guideline studies become available.", and

for mammals: "EFED typically utilizes the rat two-generation reproduction test to assess reproductive risks to mammals. This study (40 CFR §158.340 Toxicology Data Requirements, Guidelines Reference No. 83-4) is required by HED to support registration of pesticides with food uses or where use of the product is likely to result in human exposure over a significant portion of the human lifespan. This study is not currently available for any of the 9 rodenticides. HED also requires other subchronic/chronic studies, but most (e.g., dermal, inhalation, oncogenicity, neurotoxicity) provide measurement endpoints not relevant to assessing risk to nontarget mammals other than humans.

Some evidence exists that sublethal doses can have adverse effects. The Warfarin RED (EPA 1991a) notes that warfarin is a teratogen, and product labels are required to warn

that "Exposure to warfarin during pregnancy should be avoided. Warfarin may cause harm to the fetus, including possible birth defects." The Rodenticide Cluster RED (EPA 1998a) reports developmental toxicity (e.g., vaginal bleeding, hypotonicity) in rats and rabbits exposed to bromadiolone at about two orders of magnitude less than the LD50 dose. In brodifacoum studies, internal hemorrhage and significantly prolonged prothrombin time of rabbits was reported for those dosed during gestation at about two orders of magnitude less than the LD50 dose. More recently, Munday and Thompson (2003) detected brodifacoum in two dog pups that died a few hours after birth. Of 13 pups from a single litter, eight were born dead or died within 48 hours of birth. Three puppies that died shortly after birth were necropsied. Two exhibited hemorrhage in the thoracic and peritoneal cavities, intestinal serosa, and meninges, and brodifacoum was detected in the liver of both puppies. The mother did not have any clinical signs of coagulopathy before or subsequent to whelping, and the authors suggest that fetuses may be more susceptible to brodifacoum than are adults."

There also is the issue of adverse effects resulting from repeat sublethal doses [see EFED Response to the California Department of Fish and Game].

RODENTICIDE REGISTRANTS AND RODENTICIDE REGISTRANTS TASK FORCE (RRTF)

Syngenta Crop Protection, Inc.

Comment: The scientific basis and the methodology behind EPA's comparative ecological risk assessment are flawed, and EPA's benefits analysis is not adequate. Syngenta, along with three other rodenticide manufacturers, has conducted a probabilistic ecological risk assessment (ERA). This assessment was submitted in September of 2004. We believe that the agency would benefit greatly from the use of the probabilistic ERA, as it is a scientifically-based assessment that follows the current EPA guidelines for ecological risk assessments.

EFED Response: EFED reviewed and responded to the probabilistic risk assessment for brodifacoum[9] that was sponsored by Syngenta and three other registrants (Bell Laboratories, Liphatech, and Reckitt Benckiser). That assessment claimed to quantify secondary risks to birds and mammals while overlooking primary risks to birds and nontarget mammals. EFED's Executive Summary of that review[10] is presented below.

[9] Giddings, J. and W. Warren-Hicks. 2004. A Probabilistic Assessment of the Risk of Brodifacoum to Non-target Predators and Scavengers. Conducted by The Cadmus Group, Inc., Chapel Hill, NC. Submitted to EPA by Syngenta Crop Protection, Inc., Greensboro, NC.

[10] "OPP Evaluation of Cadmus/Brodifacoum Registrants (C/BR) Probabilistic Risk Assessment Model for Brodifacoum", August 24, 2005, was supported by the following two reviews:

"Brodifacoum is a second-generation anticoagulant rodenticide primarily used to control Norway and roof rats and house mice. In 1998, EPA issued a Reregistration Eligibility Decision (RED) for the rodenticide cluster, which included an assessment of human and ecological risks of brodifacoum and other rodenticides. However, the RED noted that EPA had received recent wildlife incident reports and that the Agency would continue to evaluate the risks of labeled uses of brodifacoum to nontarget birds and mammals. In 2001 (updated in 2004), EPA completed a comparative assessment of nine rodenticides used in the United States and concluded that brodifacoum labeled uses pose high potential primary and secondary risks to birds and nontarget mammals.

The 1998 RED and 2004 comparative assessment evaluated risks based on a lines of evidence and comparative-analysis model approach. In an attempt to estimate the probability and magnitude of potential ecological effects of brodifacoum, four rodenticide registrants (Bell Laboratories, Inc., Liphatech, Reckitt Beneckiser, and Syngenta Crop Protection) contracted The Cadmus Group, Inc. to conduct a probabilistic ecological risk assessment. The Cadmus Group used a dietary dose model to develop distributions to estimate daily dose to nontarget predator species as a function of the body weight and food ingestion rate of animals, the concentration of residue in food, and the fraction of food in the diet containing brodifacoum. They also used an uptake-depuration model "to estimate the cumulative dose over time." Effects data used to develop the distributions were taken from published and unpublished sources. Finally, exposure and effects distributions were combined to estimate the probability of mortality to nontarget predator organisms. In their risk assessment, C/BR claimed low secondary risk of brodifacoum-induced mortality to coyote, red fox, and red-tailed hawk and inferred the same conclusion to other species of birds and mammals with similar sensitivity and diet. They also claimed that the secondary risk from brodifacoum was only slightly higher for the kit fox and great horned owl. Primary exposure of nontarget organisms was not addressed nor were risks to scavengers addressed explicitly. In characterizing the ecological risk of brodifacoum, C/BR acknowledged that risk estimates were limited by the lack of data and were subject to a number of uncertainties and assumptions.

After reviewing the C/BR probabilistic risk assessment of brodifacoum, EPA has concluded that the probabilistic risk assessment does not provide sufficient evidence to

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Goodrum, P., M. E. Dakins, M. Mastriano, and P. Durkin. 2005. Peer Review of Brodifacoum (PP581) Assessment WA 2-10, Syracuse Environmental Research Associates, Inc., Fayetteville, New York

P. Durkin. 2005. An Exploratory Physiologically Based Pharmacokinetic Model for Brodifacoum, Attachment to: *Peer Review of Brodifacoum (PP581) Assessment WA 2-10*, SERA TR-46-2-10-1e, Syracuse Environmental Research Associates, Inc., Fayetteville, New York.

alter EPA's risk conclusions in the deterministic risk assessment. Similar to EPA's assessment, the C/BR assessment identifies information and data gaps that lead to major uncertainties in quantitatively assessing risks from secondary exposure to predators. The uncertainties identified in the C/BR report suggest that risks could range from a minimal likelihood of mortality to a high likelihood of significant mortality, depending on the extent to which predators consume rodenticide-exposed prey. Data that would help reduce the uncertainties in the risk assessments include information on local baiting practices, dietary composition and foraging behavior of birds and mammals when bait and/or dead and dying animals supplement the natural food supply, toxicity data for predatory and scavenging species, concentrations of brodifacoum in target rodents and nontarget birds and mammals, and information on the retention, storage, and elimination of brodifacoum in nontarget birds and mammals. Because data are very limited for quantifying exposure under expected and typical use patterns, there is a large amount of uncertainty in the estimation of risk. As acknowledged in the C/BR assessment, risk depends strongly on local conditions and the foraging behavior and habitat use of predators and scavengers. Because of the spatial and temporal variability in all of these considerations, it becomes extremely difficult to quantify exposure and risk on a national scale."

California Department of Food and Agriculture (CDFA)[11]

Comment: The Revised Comparative Ecological Risk Assessment (RCEA) is poorly written, the data are used selectively and inappropriately, the analysis of the data is inaccurate and not reproducible, and the conclusions biased.

EFED Response: EFED cannot comment on such vague assertions. CDFA needs to be specific when referring to inaccuracies and improper analysis of data.

Comment: The Agency's risk assumptions are based on a selective and limited data set and completely ignores field studies, operational control programs, incident reports, and whole body residue data of primary consumers.

EFED Response: That CDFA states that this information is "completely ignored" is simply wrong. The available field studies, information from operational control programs, incident reports, and whole body residue data of primary consumers are discussed in the assessment. As stated in the introduction of the risk assessment, this information is used to help characterize risks and complies with EPA's "Guidelines for Ecological Risk Assessment"[12] and recommendations of the Avian Dialogue Group[13].

[11] CDFA is a registrant of zinc phosphide, chlorophacinone, and diphacinone products for use in California

[12] EPA. 1998. Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F, April 1998, Final. 171 pp. http://www.epa.gov/ncea/ecorsk.htm

Comment: Without specifically stating so, the ecological assessment evaluates the nine rodenticide active ingredients as if they were identical, interchangeable products, ignoring the fact that there are dozens of different products on the market with different formulations and use patterns (e.g., bait sizes, target species, use sites, application methods).

EFED Response: As stated in EFED's July 17, 2004 "Response to Public Comments on EFED's Risk Assessment: "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach", dated December 19, 2002" (attached), product-specific factors can be considered when OPP considers mitigation options, providing that the registrants have provided sufficient information on the various aspects of individual products that might reduce risk. As EFED stated in the Executive Summary of the risk assessment, "specific use information by formulation, including typical amounts applied by use site, seasonally, and annually; distances applied from buildings; amounts used in rural versus urban areas; use by Certified Applicators versus homeowners and other non-certified applicators; and other such relevant information" is needed; however, that information has not been provided.

There are approximately 250 registered rodenticide products. Most of those have multiple target species with different baiting practices for each species, many allow different baiting practices on the same label, some allow for different baits. EFED has added an Attachment to the risk assessment that specifies all field uses, target pests, application methods, and application rates when they can be determined from product labels. That information is also attached to this memorandum (Attachment 2). As can be seen from that summary of product labels for field uses, much relevant information for assessing risks is not provided on the product labels. For example, many labels allow various application methods, from aerial broadcasting to hand-placements of baits, to application in bait stations, most have multiple target species, some allow use of different baits, many allow an unlimited number of applications and specify no application interval. [see also Attachment 1, Comment 17 and EFED Response and Attachment 3, EFED Response to Comment 1 of USDA/APHIS]

Comment: Lack of Exposure Assessment - it is stated in the RCEA Executive Summary that "an assumption is made that birds and nontarget mammals are likely to be exposed to the pesticide via consumption of contaminated foods, which ingestion of the formulated bait is the route of exposure". Yet the US EPA completely ignores the quantitative measure of the likelihood of exposure. The US EPA made no attempt to quantitatively estimate secondary exposure at all, except to use blood and liver retention times as potential surrogates.

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[13] Rymph, B. (ed.). 1994. Assessing Pesticide Impacts on Birds: Final Report of the Avian Effects Dialogue Group, 1988-1993. RESOLVE Center for Environmental Dispute Resolution, Washington, DC. 156 pp.

EFED Response: The extensive incident database clearly demonstrates that a wide variety of birds and nontarget mammals are being exposed to rodenticides by both primary and secondary exposure and probably tertiary exposure as well for some species. Such exposure cannot be overlooked simply because it is difficult to quantify. EPA's Risk Assessment Guidelines note that

> ". . . quantitation of risks is not always possible. It is better to convey conclusions (and associated uncertainties) qualitatively than to ignore them because they are not easily understood or estimated" *(*PART A, page 1, paragraph 3).

Refining the exposure assessment to establish a quantitative measure of likelihood of exposure and effects would require a much more extensive data set than registrants have submitted for their rodenticides and for the nontarget species potentially at risk. The Agency provided the preliminary risk assessment to rodenticide registrants in October, 2001 and posted it in the EDocket on EPA's website for public comments from January 29 to May 30, 2003. No additional data or relevant information to refine the exposure assessment has been provided by the registrants or other stakeholders. The necessary data have been outlined in a section on *"Uncertainty and Data Needs*" in the refined assessment. EFED's response to the previous comment also indicates the information lacking for quantifying an exposure assessment for field products. {see also Comment 1 and EFED Response in Attachment 1]

As discussed above in EFED's response to Syngenta, The Cadmus Group, under contract from Syngenta, Liphatech, HACCO, and Bell Laboratories, attempted to conduct a probabilistic risk assessment for brodifacoum. The purpose was to quantify exposure and secondary risks. However, due to lack of data, they were unable to do so and simply made assumptions about exposure. They were successful only in demonstrating that a quantitative exposure assessment is not possible until further data are generated.

Comment: Issues With the Data Used in the Assessment - the studies incorporated many different species (both as the target and nontarget), exposure levels, feeding regimens, and even different bait strengths (including bait strengths not registered for use in the United States). This is a biased and unscientific use of data.

EFED Response: The rodenticides have been in the reregistration process for more than 10 years to date, and registrants have had ample opportunity to propose any standardized testing for any of the rodenticides if they believe that is necessary to support their products. Standardized studies for each rodenticide would provide useful comparative information; but, until registrants conduct and submit such studies, EFED must rely on the best available data.

Some of the available studies were conducted under similar protocols and with the same test species, and some studies (e.g., Mendenhall and Pank 1980)[14] have tested the same test species under the same test protocol to compare the hazards of different rodenticides. Other studies have used different protocols, test species, and sample sizes. What is readily apparent when examining the variety of data available is that some rodenticides exhibited mortality and other adverse effects in many or most test animals in almost every study, despite the differing protocols and/or test species used in the study. When looking at an individual rodenticide, having a variety of studies with a variety of test species is quite useful and relevant for assessing the hazards of that rodenticide. EFED also emphasizes that potential secondary risks are not based solely on the secondary-hazards studies. As stated in the introduction to the comparative risk assessment, assessments of potential secondary risk are made based on mortality and other adverse effects reported not only in laboratory studies, but also in field studies and operational control programs, incident reports, toxicokinetic data, and residue levels reported in primary consumers. [see also Comment 6 and EFED Response in Attachment 1]

Comment: EPA used non-comparable data for certain blood and liver retention times in its analysis. Some values used were from studies with humans, while others were from studies with rats, pigs, and even cattle. Metabolism and thus retention times can and do vary significantly between species, therefore it is inappropriate to base measures of effect on these factors unless data are from the same species and were generated under similar testing conditions and protocols. An even more significant problem is that half-lives and retention times cannot be used interchangeably, as was done throughout the US EPA's analysis. The half-life for a compound is independent of dose (unless elimination kinetics are saturated), but the retention time is not. Therefore, the study design and dosing regimen will affect the retention time more than the half-life. Again, because conditions were not standardized and comparable in the studies from which retention time data were derived, this causes a bias in the dataset. Furthermore, it must be kept in mind that the retention time will always be longer than half-life for a given compound, therefore, use of retention times will bias the data set for certain compounds unless this data is used for all compounds in the analysis.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: In some cases the US EPA did not have the actual scientific study (WHO 1995) to evaluate for accuracy and methodology, and simply cited the data.

EFED Response: The source of all data is clearly cited in the assessment.

[14] Mendenhall, V.M. and L.F. Pank. 1980. Secondary poisoning of owls by anticoagulant rodenticides. Wildl. Soc. Bull. 8:311-315

Comment: Subchronic mammalian toxicity data were not utilized despite the availability of a large set of subchronic mammalian toxicity studies, including studies on most, if not all, of the nine active ingredients. EPA has not utilized (or even discussed) this data in the RCEA. ...

EFED Response: CDFA should be specific about what studies they believe have been overlooked. Neither avian or mammalian reproductive data are available for any of the nine rodenticides, and this is discussed in the risk assessment. See also EFED's Response to California Dept. Fish and Game Comment. on this topic.

Comment: The US EPA typically uses rat and mouse toxicity data as a surrogate for wild mammals in its ecological risk assessments, but did not do so in the RCEA. CDFA requested that the US EPA use the available mammalian toxicity data that it has required registrants to generate in order to improve the risk assessment, but the US EPA ignored this request.

EFED Response: The rat (or mouse) acute toxicity data were used to calculate risk quotients for primary risk to mammals as is done for all risk assessments conducted by EFED.

Comment: The US EPA's evaluation of primary risks to birds does not take into account the fact that dyes that are added to the CDFA's rodent grain baits in order to deter consumption by birds. A black dye is added to the zinc phosphide baits and a blue or red dye is added to the baits containing chlorophacinone and diphacinone. There is a large body of research that shows that these dyes will deter consumption of grain by birds.

EFED Response: The literature indicates that many variables likely influence how food color affects feeding behavior of birds. Some birds may prefer some colors over others if given a choice, but this is not consistent across species and also may depend on other factors of the food (e.g., size, shape, texture) and its availability. Even if some colors are preferred over others or over uncolored food, a sufficient amount might still be eaten to provide a lethal dose. For example, in a laboratory situation a bird might eat 20 red-dyed grains and only 13 green-dyed grains, which may be a significant statistical difference. However, if a lethal dose or more of pesticide was contained in only a single grain or two, there may be no significant biological difference.

Kalmbach (1943)[15] tested the reaction of captive quail to colored grains and found that "When naturally colored food was unavailable the majority of the quail accepted the dyed grain regardless of color." Moran (1999)[16] offered dyed and undyed wheat and sorghum

[15] Kalmbach, E.R. 1943. Birds, rodents and colored lethal baits. Trans N. Amer. Wildl. Conf. 8:408-416

[16] Moran, S. 1999. Rejection of dyed field rodent baits by feral pigeons and chukar partridges. Phytoparasitica 27:9-17

grains to pigeons and partridges. The pigeons preferred undyed wheat grains, but did not differentiate among dyed or undyed sorghum grains. Partridges preferred undyed and black grains to all other colored grains; black color was not a deterrent. EFED also notes that sunflower seeds are black, and they are a common ingredient of bird-seed mixes sold for pet birds.

Comment: The US EPA does not differentiate between different types of grains in its analysis. Use of “lightly” rolled oats for the bait minimizes the presence of fine, broken grain particles which are too small for rodents to manipulate, but may be acceptable to small seed-eating birds.

EFED Response: CDFA has provided no data to support the contention that "lightly" rolled oats are not acceptable to birds.

Comment: The US EPA’s analyses of primary risks to both birds and mammals incorrectly assumes that all rodent baits weigh 0.2 g per pellet or kernel.

EFED Response: EFED makes no such assumption. As stated in the risk assessment and in EFED’s previous “Response to Public Comments” dated July 17, 2004, EFED assumes that a typical rat-bait pellets weighs 0.2 g based on information provided by Syngenta as cited in the refined comparative risk assessment. We did calculate the number of 0.2-g pellets needed to provide an LD50 dose to a bird or nontarget mammal weighing 25 g, 100 g, and 1000 g. However, we realize that some bait pellets or grains may be smaller or larger than the typical rat-bait pellet, and some are formulated as meal or wax blocks. Therefore, we also calculated the amount of bait that would need to be eaten by a bird or nontarget mammal to provide an LD50 dose, and we calculated what percent of the diet that would comprise. The later calculations are independent of pellet or grain size.

HACCO

Comment: EPA’s "comparative analysis modeling" is scientifically inadequate, inconsistent with Scientific Advisory Panel (SAP) recommendations (i.e. the SAP recommends using the concept of "hazard" and not "risk" to characterize what the report is about), and scientifically unproved.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: EPA’s reliance upon an unfounded correlation between low-level liver residues of rodenticides in animals and animal mortality (EPA is assuming that because residues were found in roadkill coyote, the rodenticide caused the death.) is indefensible and indicative only of exposure, not causality.

EFED Response: HACCO statement is erroneous and misleading. Nowhere in the risk assessment does EFED say "that because residues were found in roadkill coyote, the rodenticide caused the death.". However, the documented fact that very highly, biologically persistent anticoagulant rodenticides are being detected in a wide variety of birds and nontarget mammals is and should be of concern. Such widespread exposure of nontarget species is occurring not only in the U.S.[17], but also in other countries[18], suggesting that this is no local concern limited to New York and California. In the U.S., anticoagulants have been detected in dead foxes, including numerous endangered kit foxes, mountain lions, bobcats, coyotes, deer, raccoons, skunks, opossums, squirrels, rabbits,

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[17] Stone, W.B., J.C. Okonlewski, and J.R. Stedelin. 2003. Anticoagulant rodenticides and raptors: recent findings from New York, 1998-2001. Bull. Environ. Contam. Toxicol. 70:34-40.

Stone, W.B., J.C. Okonlewski, and J.R. Stedelin. 1999. Poisoning of wildlife with anticoagulant rodenticides in New York. J. Wildl. Diseases 35:187-193.

Hosea, R.C. 2000. Exposure of non-target wildlife to anticoagulant rodenticides in California. Proc. Vertebr. Pest Conf. 19:236-244.

Riley, S. P. D., R.M. Sauvajot, T.K. Fuller, E.C. York, D.A. Kamradt, C. Bromley, and R.K.Wayne. 2003. Effects of urbanization and habitat fragmentation on bobcats and coyotes in southern California. Conservation Biol.17:566-576.

[18] Mineau, P., P.A. Martin, L.K. Wilson, J. Duffe, J.R. Stedelin, and B. Puschner. 2003. Extensive exposure of Canadian birds of prey to the second-generation anticoagulant rodenticides brodifacoum and bromadiolone. Presented at the Symposium Wildlife Toxicology and Persistence of Pollutants and Contaminants, 3rd International Wildlife Management Congress, Christchurch, New Zealand.

McDonald, R.A., S. Harris, G. Turnbull, P. Brown, and M. Fletcher. 1998. Anticoagulant rodenticides in stoats (*Mustela erminea*) and weasels (*Mustela nivalis*) in England. Environ. Pollution 103:17-23.

Shore, R.F., J.D.S. Birks, A. Afsar, C.L. Wienburg, and A.C. Kitchener. 2003. Spatial and temporal analysis of second-generation anticoagulant rodenticide residues in polecats (Mustela putorius) from throughout their range in Britain, 1992-1999. Environ. Pollution 122:183-193.

Burn, A.J., I. Carter, and R.F. Shore. 2002. The threats to birds of prey in the UK from second-generation rodenticides. Aspects Appl. Biol. 67:203-212.

Carter, I. and A. Burn. 2000. Problems with rodenticides: the threat to red kites and other wildlife. British Wildl., February, 2000, pp. 192-197.

chipmunks, owls, hawks, eagles, vultures, crows and ravens, geese, and other birds. As emphasized by Mineau et al. (see footnote #14), "The high level of exposure despite stringent labelling requirements raises serious questions about possible effects and correlates of this contamination."

Some, but certainly not all, of the dead animals submitted to the New York State Department of Environmental Conservation and California Department of Fish and Game were found dead along roadsides. That should not be surprising, because, as noted by several researchers[19], carcasses of animals that die in the wild are rarely found except along roadsides where they are more visible than if they die inside burrows, crevices, or under dense vegetation.

Comment: EPA's relative ranking of rodenticides in descending order of those purported to pose the greatest risk to birds and nontarget mammals is misleading and scientifically indefensible because the ranking is based principally on the relationship of acute toxicity among the nine rodenticides) does not take into account whether the birds and nontarget mammals actually are exposed at the levels used in EPA's assessment.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

PM Resources

Comment: EPA compares the nine rodenticides as if all are used in the same manner and form (e.g., broadcast vs . structural-only use and pellet forms vs. other forms (i.e, meal, wax, water soluble, etc.).

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[19] McDonald, R.A., S. Harris, G. Turnbull, P. Brown, and M. Fletcher. 1998. Anticoagulant rodenticides in stoats (*Mustela erminea*) and weasels (*Mustela nivalis*) in England. Environ. Pollution 103:17-23.

Shore, R.F., J.D.S. Birks, A. Afsar, C.L. Wienburg, and A.C. Kitchener. 2003. Spatial and temporal analysis of second-generation anticoagulant rodenticide residues in polecats (*Mustela putorius*) from throughout their range in Britain, 1992-1999. Environ. Pollution 122:183-193.

Newton, I., R.F. Shore, I. Wyllie, J.D.S. Birks, and L. Dale. 1999. Empirical evidence of side-effects of rodenticides on some predatory birds and mammals. Pages 347-367 in D.P. Cowan and C.J. Feare (eds), Advances in Vertebrate Pest Management. Filander Verlag, Fürth.

Carter, I. and A. Burn. 2000. Problems with rodenticides: the threat to red kites and other wildlife. British Wildl., February, pp. 192-197

EFED Response: EFED realizes differences occur in the baits, target species, use sites, application rates and methods of the various field rodenticides (see Attachment 2), and these differences will be considered qualitatively during mitigation if adequate data exists. If PM Resources and other registrants believe that these factors need to be considered quantitatively, registrants should have provided the necessary information for EFED to do that. [see also Comments by CDFA; and, Attachment 3, EFED Response to Comment 1 by USDA/APHIS]

Comment: EPA's "comparative analysis modeling" is scientifically inadequate, inconsistent with the Scientific Advisory Panel (SAP) recommendations (i.e., SAP recommends using the concept of "hazard" and not "risk" to characterize what the report is about) and scientifically unproved.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: EPA's reliance upon an unfounded correlation between low-level liver residues of rodenticides in animals and animal mortality (EPA is assuming that because residues were found in roadkill coyote, the rodenticide caused the death.) is indefensible and indicative only of exposure, not causality.

EFED Response: See EFED Response to HACCO regarding this comment.

Comment: EPA's relative ranking of rodenticides in descending order of those purported to pose the greatest risk to birds and nontarget mammals is misleading and scientifically indefensible because the ranking is based principally on the relationship of acute toxicity among the nine rodenticides) does not take into account whether the birds and nontarget mammals actually are exposed at the levels used in EPA's assessment.

EFED Response: See EFED Response to HACCO regarding this comment.

Comment: EPA's reliance on a dated US Fish and Wildlife Service Biological Opinion that was neither mentioned nor relied upon in the 1998 Rodenticide Cluster RED is legally flawed and inappropriate.

EFED Response: The USFWS Biological Opinion of 1993 is discussed in the Rodenticide Cluster RED. Why PM Resources considers that Biological Opinion to be "legally flawed and inappropriate" is not stated in their comments and thus serves no useful purpose. As previously noted, OPP will be addressing listed species and, as needed, consulting with the Services to address risks and mitigation for listed species. [see also Attachment 3, EFED Response to Comment 2 by USDA/APHIS]

Comment: EPA's reliance upon incident data to support claims of risk to birds and nontarget mammals is unfounded and misleading (i.e., EPA assumes that any exposure involves an unacceptable risk).

EFED Response: See EFED response to HACCO.

Liphatech

Comment: Fails to make any assessment, even qualitatively, of exposure: Without a valid assessment of "exposure," it is not possible to assess risk (see previous discussion of this topic).

EFED Response: Liphatech makes a misleading and erroneous statement. A discussion of exposure is presented in EFED's risk assessment, including uncertainties due to lack of adequate data and identifying data that would be needed to reduce those uncertainties. Liphatech is one of four registrants that sponsored a probabilistic risk assessment for brodifacoum that purported to quantify exposure and risks to avian and mammalian predators and scavengers. That assessment identified some of the information that would be needed to quantify exposure (e.g., baiting practices, foraging behaviour and food habits of birds and mammals) but overlooked that information, failed to quantify exposure, and simply relied on assumptions of the registrants that lead to presumptions of low exposure. See EFED Response to Syngenta regarding the purported probabilistic assessment sponsored by Liphatech, Syngenta, HACCO, and Bell Laboratories. [see also Attachment 1, Comment 1 and EFED Response]

Comment: EPA has not used the exposure data that is available. EPA could easily determine that more than 59% of the bait sold by Liphatech in 2003 was in the "wax block" form. These "wax block" forms of bait have minimal attractiveness to birds, and cannot be ingested by the small birds. This type of qualitative exposure analysis would have a significant impact on the CRA's estimate of primary risk to birds. One of the assessment endpoints used, "Inverse of the LD50 for a 100 g bird (number of bait pellets)" is rendered meaningless when the bait is not a pellet.

EFED Response: Simply stating that 59% of Liphatech's baits are wax blocks is not very useful. EFED agrees that wax blocks can help reduce exposure of seed-eating birds that might be attracted to loose pellets, and that can be considered as a mitigation proposal. However, not all formulations are wax blocks, and many wax blocks are formulated only for use inside sewers. EFED concurs that few birds are likely to be feeding inside sewers. What about the other 41% of Liphatech's baits? What about in other years? Prior to issuance of the Rodenticide Cluster RED in July, 1998, OPP requested information from registrants on the quantities and relative proportions of various bait formulations, geographic and seasonal information on use, baiting practices, and other relevant information, but none of that information was provided. The types of information that

would be needed to obtain better information on usage by rodenticide have been identified in the risk assessment.

Comment: Uses speculation (pages 30, 81, 86, 105, and 149), unsubstantiated anecdotal data (such as the Munday and Thompson paper mentioned on page 30, golden eagle incident on pages 99-100), and various other unsupported assumptions (pages 10, 90, 91,) that support a pre-determined point of view.

EFED Response: The data from both Munday and Thompson[20] and the golden eagle incident[21] are not speculation but are published data cited as such in the risk assessment. The following abstract is taken directly from Munday and Thompson (2003):

"**Abstract.** Eight out of a litter of 13 puppies were either born dead or died within 48 hours of birth. Three puppies that died shortly after birth were necropsied. Two puppies had hemorrhage in the thoracic and peritoneal cavities, intestinal serosa, and meninges. The third puppy was smaller than the other two puppies but did not have detectable hemorrhage. Brodifacoum, a second-generation coumarin anticoagulant, was detected in livers from the two puppies with hemorrhage. The dam did not have clinical signs of coagulopathy before or subsequent to whelping. The owners were confident that the dog had not been exposed to rodenticide for at least 4 weeks before whelping. A presumptive diagnosis of in utero brodifacoum toxicity was made. To the authors' knowledge this is the first time a second-generation coumarin anticoagulant has been detected in the liver of a newborn animal. This case is also unique because the dam was unaffected, suggesting that fetuses are more susceptible to brodifacoum toxicity than adult animals."

The following information on the golden eagle, presented in the risk assessment, is taken directly from Hosea et al. (2001):

"The carcass of an adult Golden Eagle was recovered from its breeding territory in Contra Costra County on March 11, 1999 (DFG case accession # P-2060A). The bird had been part of a long term radio telemetry study of eagles in the area. Based on telemetry data the breeding territory consisted mainly of open rangeland and random outbuildings with some areas of urban development.

[20] Munday, J.S. and L.J. Thompson. 2003. Brodifacoum toxicosis in two neonatal puppies. Vet. Pathol. 40:216-219

[21] Hosea, R.C., B.J. Finlayson, and E.E. Littrell. 2001. Forensic investigative techniques to identify impacts (primary and secondary) from three groups of pesticides on raptors in California. Pages 38-51 in J. J. Johnston (ed.), Pesticides and Wildlife. American Chemical Society Symposium Series 771

The bird was not recovered in the vicinity of power lines and the feathers did not have the "singed" odor characteristic of accidental electrocution. The necropsy indicated no other evidence of physical trauma. The animal was skinned to determine the presence of puncture wounds from conflicts with other eagles or from a gunshot. The pericardial sac contained serum and blood. Approximately 65% of the surface of the heart muscle was haemorrhagic. The major vessels associated with the heart contained unclotted blood. The lung tissue was haemorrhagic, bleeding from a cut surface. The cerebro-spinal fluid was blood stained, indicating cranial haemorrhage. These clinical signs were consistent with previously published symptoms of anticoagulant toxicosis in raptors (Hegdal et al. 1988, Mendenhall and Pank 1980, Newton et al. 1990, Radvanyi et al. 1988). Liver tissue was analyzed for residues of anticoagulant rodenticides. Kidney tissue was also analyzed for lead concentrations. Kidney tissue had a lead concentration of 1.1 ppm, well below the level that would indicate acute toxicosis (Aiello 1998). Liver tissue had a brodifacoum concentration of 0.04 ppm. The presence of the rodenticide in liver tissue alone does not support a diagnosis of anticoagulant toxicosis. However, if considered in conjunction with the observed clinical signs consistent with anticoagulant toxicosis, a diagnosis of anticoagulant toxicosis is supported."

Comment: Has not been properly peer-reviewed: A “peer review” was conducted, in a manner that does not comply with EPA’s own guidelines, on a preliminary draft of the document which was substantially different from the current CRA, by a small number of persons who appear to share the bias that appears throughout this CRA document. Even after this, the CRA retains important scientific errors that were pointed out by these reviewers.

EFED Response: Liphatech is incorrect. This peer-review issue was addressed in a letter from Lois Rossi, Director, Special Review and Reregistration Division, to Lynn L. Bergeson, Bergeson & Campbell, P.C., representative for the Rodenticide Registrants Task Force as follows:

"**Your May 22, 2002, letter** expresses your concerns regarding the January 2001 peer review that was conducted on EPA’s draft preliminary assessment. Included in your letter are excerpts from EPA’s “Peer Review Handbook” from which you based your arguments. *In response*, the Agency has summarized and responded to the peer review comments consistent with guidance provided in the Agency’s Peer Review Handbook (updated December 2000). The peer review comments and EPA’s responses are available in the public docket."

The peer reviewers of the risk assessment were Dr. Raymond O'Connor, Dr. Elwood Hill, and Dr. Charles Eason. The qualifications of these reviewers is presented below. Their qualifications and peer reviews are available in the public EDocket (OPP-2002-0049). As noted in the public docket, many revisions were made to the final risk assessment in response to the comments and suggestions of the peer reviewers. For Liphatech to imply otherwise and to accuse the reviewers of being biased is simply wrong and inappropriate.

Dr. Elwood Hill has conducted research on wildlife toxicology since 1966 with the National Communicable Disease Center, Patuxent Wildlife Research Center and as a private contractor. He has published widely on the hazards of agricultural pesticides to wildlife, and on development and validation of wildlife testing protocols. Dr. Hill has routinely served as a toxicology consultant to the U.S. Fish and Wildlife Service, U.S. Environmental Protection Agency, various State environmental programs, and the private sector. On many occasions, he has been an ad hoc member of the U.S. Environmental Protection Agency's Scientific Advisory Panel (FIFRA) for issues from wildlife testing protocols and pesticide registration through development of probabilistic risk assessments. Dr. Hill is a long-standing member of the Society of Toxicology, a charter member of the Society of Environmental Toxicology and Chemistry, a Certified Wildlife Biologist, and has been an Adjunct Professor at the University of Maryland (Program in Toxicology) and the University of Nevada (Center for Environmental Sciences and Engineering).

Dr. Raymond O'Connor has been Professor of Wildlife Ecology at the University of Maine since 1987. His research has focused on the ecology of farmland birds (particularly in relation to pesticide use), on ecological indicators, on biodiversity modeling, and on the human dimensions of the environment. Dr. O'Connor has authored two books and more than 150 scientific papers and reports. He has been an invited member of numerous workshops and working groups, including meetings and Panels on the environmental risks of pesticides and their assessment organized by the U.S. Environmental Protection Agency Society, by the Environmental Toxicology and Chemistry, by National Audubon Society, and by NAFTA. He also has served widely as a consultant on bird population issues, including work for the U.S. Fish and Wildlife Service, U.S. EP, Canadian Wildlife Service, and for various non-governmental organizations and commercial firms.

Dr Charles Eason is Toxicologist and Research Team Leader of the Pest Control and Wildlife Toxicology Team and Environmental Health Programmes, Landcare Research New Zealand Ltd. He is co-founder of the Centre for Environmental Toxicology and team leader of the Pest Control and Wildlife Toxicology team. Dr. Eason has more than 10 years extensive research and practical experience in vertebrate pesticide toxicology and has published over 100 papers relating to the efficacy, safety, and comparative risks of vertebrate pesticides. He has received numerous awards, honors, and distinctions. His work includes assessment of the environmental impact of pesticides and contaminants, using novel techniques and providing novel improved toxicants, baits, and pest control strategies, toxicity testing of pesticides to minimize environmental and nontarget risks.

Comment: Significant Errors in Table 41: Table 41 (page 82) purports to show the "measures of effect values" for secondary risk to birds. We note, however, that two of the three measures of effect use values derived from mammals, not birds. For the remaining measure of effect (mean mortality), difethialone is assigned 80% of the value for brodifacoum because no actual data exists. In the other case where no data exists (for bromethalin), the

table simply notes “No data”. There is no explanation offered for why these two compounds are treated differently.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: Significant Errors in Table 42: In Table 42, the “measures of effect values” for difethialone are identical to those in table 41, yet the reported “summary value” is completely different. We have expended considerable time and effort to determine how the “summary value” can be different, but are unable to do so because the CRA fails to show any of the calculations used to generate these values.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: Raw data is presented in a biased and misleading manner. “Mean % mortality of secondary lab studies” is used as an “assessment endpoint” and is given the most weight in the analysis of secondary hazard. This is raw data, taken from many different studies that were all performed under widely different conditions and protocols, without any consideration of these wide variations. The authors and sponsors of these studies expend much time and effort in design, because it is so critical to the usefulness of the studies. The CRA ignores the extensive planning and analysis conducted in the course of this research; it simply presents the raw data in a manner that best supports a pre-determined point of view. Other similar statements on bias follow.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: Uses inappropriate “measure of effect”: The document even states (page 5) that one of the chosen “measures of effect” is “not a direct measure of effect”. We are not aware that there was any stakeholder input during the planning stages of this CRA, and EPA has failed to respond to the comments submitted by Liphatech, RRTF and others on the problems and deficiencies in these “measures of effect”.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: Uses a method that it specifically states it will not use: The CRA briefly discusses (page 149) some findings of EPA’s FIFRA Science Advisory Panel (SAP) concerning comparative assessments such as this one. It clearly states that a critical concern of the SAP was that “risk quotients -risk indices that are used to express risk from pesticides to nontarget organisms, should never be combined (added);..... following this advice, no risk quotients or indices have been added together for this analysis”. The CRA then shows how it

uses risk quotients and other risk indices (page 150 and 151) as “measures of effect”, and then (page 152) how they are added together to create a “summary value”!

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: In July of 2003, the California Department of Food and Agriculture submitted an ecological risk assessment on chlorophacinone and diphacinone baits. This risk assessment was reviewed by the author of this CRA, yet there is no mention of the document or it’s contents in the CRA!

EFED Response: That statement is incorrect. EFED reviewed the field study but not the risk assessment. A risk assessment conducted by a registrant would be reviewed only if SRRD requested EFED to do so, but the assessment done by the CDFA was not sent to EFED for review. EFED’s risk assessment does cite both the residue data[22] and the field study[23] conducted by CDFA. EFED’s review of the field study concluded the following:

- the study was designed primarily to assess the efficacy of 0.01% ai and 0.005% ai chlorophacinone and diphacinone baits for controlling ground squirrels; evaluation of nontarget risks was mainly limited to carcass searches for dead animals on the treatment plots, camera inspection of carcasses on the ground surface, and, at one site, camera probes inside squirrel burrows

- because ground squirrels apparently moved among the various treatment plots[24], as indicated by the fact that 23 individuals that had residue of both diphacinone and

[22] Goodall, M.J., T.M. Primus, and J.J. Johnston. 2002. Determination of chlorophacinone and diphacinone residues in California ground squirrels and non-target animals. Unpubl. report QA 976, National Wildlife Research Center, Fort Collins, CO, submitted to EPA by the California Department of Food and Agriculture, Sacramento. 119 pp.

[23] Salmon, T.P., D.A. Whissom, and W.P. Gorenzel. 2002. Field efficacy studies comparing 0.005% and 0.01% diphacinone and chlorophacinone baits for controlling California ground squirrels (*Spermophilus beecheyi*). Unpubl. report submitted to EPA by the California Department of Food and Agriculture, Sacramento. 131 pp.

[24] Because the study report (Salmon et al. 2002) states that "We saw no evidence of squirrels traveling between plots during the 24-day period of our trials on each site.", EFED asked CDFA how they accounted for the fact that some squirrels had residues of both rodenticides. CDFA’s letter of November 6, 2003 indicates that observations of ground squirrels were not continuous during the study and that "Squirrel movement between site plots is considered a natural behavioral occurrence within squirrel populations." The presence of residue of both rodenticides in individual ground squirrels also could result from contamination of bait-mixing or application equipment if the same equipment was used for both rodenticides.

chlorophacinone and because dead squirrels were found in control plots, differences in carcass residues due to bait strength (0.005% and 0.01% ai) or application method (spot treatment and broadcast) cannot be evaluated.

· more than 40% of camera-monitored carcasses and those collected during the daily plot searches had been scavenged, and more may have been removed by predators and scavengers. The number of scavenged carcasses clearly indicates that scavengers were attracted to poisoned ground squirrels

· although the study authors stated that most squirrels died underground, only 31 dead ground squirrels were observed in the 654 ground squirrel burrows probed by camera

· based on carcass searches, sufficient information was obtained to conclude that some small granivorous mammals (e.g., kangaroo rats, mice) will be killed when chlorophacinone and diphacinone baits are applied by ground broadcast or spot-baiting for ground squirrel control; however, no methods were employed (e.g., mark-recapture, radio-telemetry) to determine the extent of this mortality.

Rodenticide Registrants Task Force (RRTF)

Comment: EPA's approach ignores the role of probability in determining the frequency and magnitude of potential consumption or exposure and does not produce a reliable comparison of even "potential" overall risk.

EFED Response: Refer to EFED's Responses to comments from Syngenta, HACCO, CDFA, PM Resources, and Liphatech where EFED has addressed this question. [see also Attachment 1, Comment 1 and EFED Response]

Comment: The Conclusions in the RCA Are Based on Speculative Assumptions That Are Contrary to Peer Review Principles and Other Federal Initiatives To Improve the Quality of Information on Which Regulatory Agencies Rely... Like the PCA before it, the RCA fails to consider comprehensively all available evidence regarding the question of sublethal effects, including information previously submitted by the RRTF. Until the speculation and statements of opinion are eliminated from the RCA, it cannot be considered to present a balanced, scientifically sound, and defensible analysis of sublethal effects.

However, the presence of dead ground squirrels in 5 of the 8 control plots (Salmon et al. 2002) suggests that movement among plots, as suggested by CDFA, was the most likely reason.

EFED Response: Such vitriolic comments serve no useful purpose.

Comment: EPA's Comparative Risk Assessment of Potential Risks to Bird and Nontarget Mammals Is Critically Flawed and Should Be Withdrawn ...

Measuring exposure by comparing active ingredient percentage results only in a comparison of hazard, at best;

EFED Response: The assessment is not limited to comparing active ingredient percentage, and it is misleading to say so.

EPA's approach ignores the role of probability in the frequency and magnitude of potential consumption or exposure;

EFED Response: Addressed in previous comment. [see also EFED Response to Syngenta]

EPA relies inappropriately on island restoration and field studies to characterize exposure from commensal uses;

EFED Response: EFED disagrees. These studies demonstrate that exposure has adverse affects. As previously discussed, the incident data confirm that exposure is widespread. From that, one can conclude that widespread exposure of nontarget organisms can have adverse affects.

EPA relies inappropriately on irrelevant field studies conducted outside the United States (e.g., in New Zealand).

EFED Response: Much useful information on the risks of rodenticides has been reported from other countries. This information is not irrelevant. See, for example, EFED's response to HACCO.

Comment: ... a peer reviewer of the RCA, who was also a member of the SAP panel that reviewed the Methodology in 1998, concurs in the SAP's criticisms and also agrees that this methodology was inappropriate when applied to the RCA. Additionally, the sensitivity analysis conducted by EPA is wholly inadequate to provide any understanding of the potential variability inherent in the comparative analysis of nine rodenticides.

EFED Response: As stated in EFED's previous "Response to Public Comments" on July 17, 2004 (see Attachment 1), one of the three expert peer reviewers raised a concern about use of the comparative analysis model as presented in an earlier draft of the risk assessment. D. Urban made extensive changes in response to that reviewer's concerns. As

previously noted (see EFED Response to Liphatech Comment), the three expert peer reviews and the qualifications of the peer reviewers are available in the public EDocket.

The same peer reviewer mentioned above also stated the following:

"The bulk of the material in the document addresses the development of the weight of evidence argument. In general this part of the document is well developed and it is hard to argue with the evident conclusion about each of the nine chemicals. These conclusions are largely implicit in the text since the task of deriving a formal assessment for each chemical is passed over to the decision support analysis. The case about each chemical is thoroughly and logically developed in this part of the document and the document is commendable in showing how the Agency staff have been able to develop the weight of evidence approach as a viable approach to the synthesis of a complex body of evidence."

Comment: EPA's Comparative Analysis Model Is Flawed, and Its Use of the Modified Simple Multi-Attribute Rating Technique (SMART) Is Scientifically Indefensible. Although the "Comparative Analysis Model" methodology was reviewed by the SAP in 1998, in the ensuing years EPA has failed to incorporate fundamental changes recommended by the SAP, resulting in an RCA that is scientifically indefensible. While EPA incorporated minor adjustments to the methodology by adding a sensitivity analysis, the RCA still embodies many fundamental errors identified by the SAP in the preliminary version. For example, despite the SAP's recommendation that risk quotients (RQ) (which the SAP advised should be called "hazard quotients") not be added, such "risk quotients" were included in the RCA.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: The RCA only provides RQ values for acute dietary risk, and the majority of the analysis is based upon "measures of effect" (with no measures of exposure) that, for the most part, are not true measures of effect but measurements of pharmacokinetic and fate parameters (e.g., half-lives in various tissues). Thus, the RCA provides even a weaker estimate of risk (more appropriately termed "hazard") than the document previously reviewed and strongly criticized by the SAP as presenting not a risk assessment but a "hazard assessment." ... It is misleading to refer to these rodenticide properties as effects, however, and inappropriate to rely on these values to rank the risks of rodenticides.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: The methodology used in the RCA "double-counts" hazards two separate times. First, the two measures of effect used in the RCA to estimate primary risk to birds (dietary RQ and amount of bait needed to produce an LD50) are not truly independent measures of effect. Both are based on the inherent toxicity of the active ingredient and, though different, are highly correlated. This amounts to "double-counting" of the same measure of effect, which skews the analysis. The second "double-counting" in EPA's methodology occurs when it uses the same measures of effect for evaluating secondary risks to both birds and non-target mammals. Because the values for the blood and liver retention times are the same for both the bird and nontarget mammal analyses, this leads to double weighting of these factors when the overall summary values are calculated.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: EPA assigned all measures of effect, except for two, a "high" degree of importance for the analysis (with a factor of 10 assigned). The two to which EPA assigned "medium" importance (half-lives in blood and liver with a factor of 2.5 assigned) are correlated so that "persistence" was also indirectly given a "high" weighting due to double-counting. If it is assumed that all the measures of effect have a "high" degree of importance, there is no need to weight them at all.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: Attachment C of the RCA provides the method and approach used for the Comparative Analysis Model, including a table of the input values. These data can be used to reconstruct the comparative analysis conducted by EPA. While Table 6 of Attachment C of the RCA presents the "Greatest Overall Risk to Birds and Mammals," supposedly based on the input values from Table 1, the RRTF was not able to calculate the same values. Table 1 below presents the EPA values in the first column and the RRTF calculations in the second column. There are only a few large discrepancies, but with a thoroughly transparent system, the values calculated by the RRTF should be identical.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban.

Comment: Another discrepancy in the logic relates to the method employed when data were missing or limited. EPA assumed that no calculations could be made in the absence of data, thus favoring those chemicals for which there were less data. For example, there were no data for zinc phosphide on liver and blood retention times, so those values are zero in EPA's calculations.

EFED Response: This comment pertains to the comparative analysis conducted by the late D. Urban

Comment: EPA's "Lines of Evidence" Approach Is Unjustified and Scientifically Indefensible – it is inappropriate not to provide justification for the decisions made in assigning those rankings. EPA's rankings are presented in Table 49 of the RCA without any discussion of why the primary risk to birds is high for difethialone and low to moderate for chlorophacinone or why the secondary risk to mammals is moderate for warfarin but high for diphacinone. These may be the appropriate rankings, but it is impossible to determine their suitability without additional details that are lacking.

EFED Response: The RRTF is not specific as to which "details" are lacking. The justification for primary risks to birds and mammals is based on the risk quotients and whether they exceed the Agency's Levels of Concern; the number of pellets (or g food) that provide an LD50 dose; and any relevant information from pen and field studies demonstrating exposure and adverse affects. For example, difethialone has avian dietary RQs of 50 and 18 for the northern bobwhite and mallard, respectively. Avian dietary RQs are 0.9 and 0.3, respectively, for those species for chlorophacinone. The LOC is 0.5 for acute risk to non-listed birds. Additionally, difehtialone can provide an LD50 dose to a 25-g bird consuming <2 rat-bait pellets, whereas a 25-g bird would need to eat 645 pellets of chlorophacinone bait (50 ppm), which is not physically possible in a single feeding. The potential for bioaccumulation of repeat sublethal doses also would be much higher for difethialone than for chlorophacinone.

Comment: EPA'S EIIS (Environmental Incident Information System) - Data Are Misrepresented and Incorrectly Interpreted – The RCA frequently misconstrues these data, by inferring from the presence of rodenticide residues at any level -- specifically anticoagulant residues -- that the anticoagulant is the causative agent in the observed animal mortality.

EFED Response: EFED disagrees. See EFED Response to HACCO on this subject. [see also Attachment 1, Comments 2, 10, 13, 15, and 30]

Comment: EIIS is Inaccurate – Historically, moreover, the summary numbers for the EIIS have been questionable. A full analysis conducted in 2001 by the RRTF of the EIIS database and the underlying reports, primarily from California and New York, showed that the database was inaccurate and misleading in a number of respects. For example, of 105 incidents then listed in the EIIS, only 68 were unique, while 37 were redundant reports. In at least one specific instance, the EIIS data were plainly misrepresented. That instance involved eight coyotes and two raccoons that had been live trapped by California Department of Fish and Game personnel as "healthy" animals and then euthanized as part of an effort to evaluate the levels of rodenticide exposures in wildlife and to remove individual animals from some areas. The coyotes and raccoons in these instances were listed inaccurately in the EIIS database as if they had been brodifacoum-related mortalities.

EFED Response: EFED disagrees. The EIIS is simply a database containing all incident information submitted to the Agency. As we previously noted, neither the RRTF nor any

rodenticide registrant has been able to identify even a single redundant incident in the risk assessment, because there are none. All redundant information in the EIIS was accounted for and removed when the risk assessment was prepared.

Regarding the coyotes (n=3) and raccoons (n=2) that were live-trapped, euthanized, and analyzed for rodenticide residues, the RRTF statement is highly misleading. The risk assessment does not state that these coyotes and raccoons were "brodifacoum-related mortalities". However, all five animals were exposed to anticoagulant rodenticides, and none are target species. The incident report from the California Department of Fish and Game actually states the following regarding the exposures of the three coyotes and two raccoons:

> "All five of these animals carried residues of brodifacoum. Four of the five animals carried multiple residues of anticoagulant rodenticides. All of these rodenticides are registered for use to control commensal rodents and can be purchased "over the counter" by the public." and "The residue concentrations in these otherwise healthy animals may indicate background levels carried by urban carnivores in the Los Angeles and Orange County area.".

Note that the animals are not described as "healthy" but as "otherwise" healthy, a notable distinction. The animals were euthanized, and thus technically did not die due to anticoagulant exposure. However, that does not imply that the exposure might not have caused sublethal or lethal affects if the animals had not been sacrificed. Because death is delayed several days or more after ingestion of a lethal exposure of anticoagulant rodenticide, the fate of these animals is unknown had they not been sacrificed. Therefore, to suggest that this exposure was insignificant may or may not be correct but certainly is not known.

Several laboratory studies have noted that exposed test animals did not exhibit any signs of toxicity until shortly before death. In an acute-oral toxicity study, beagles were observed for up to a month after dosing for signs of toxicity and to calculate an LD50[25]. Symptoms of poisoning (subdued behavior, loss of appetite, pale, respiratory difficulties, hypothermia, blood in feces, minor external hemorrhage) were observed "only after approximately six days" in those dogs that died. Another acute-oral toxicity study with dogs reported that "Although death occurred more than five days after treatment, most dogs only showed ill effects within the last day before death and some showed no effect until immediately before death."[26] In separate acute oral tests with rabbits[27] and

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[25] Parkinson, G.R. 1976. WBA 8119: Acute Oral Toxicity. Report No. CTL/P/216 (revised). EPA MRID No. 00087134

[26] Godfrey, M.E.R., T.C. Reid, and H.J.F. McAllum. 1981. The acute oral toxicity of the anticoagulant brodifacoum to dogs. New Zealand J. Exper. Agric. 9:147-149

wallabies[28], clinical signs in 62 individuals that died within 2 to 25 days of dosing were only observed "just before death".

Comment: EPA Erroneously Looks to Liver Data To Affirm Causality Rather Than To Confirm Exposure – The role of anticoagulant residues in the liver is incorrectly characterized in the body of the RCA by EPA, ... The concentration of brodifacoum or other anticoagulants can be measured in a high-affinity, capacity-limited binding site in the livers of target and non-target vertebrate species and used as a biomarker of exposure. This binding site in the liver, however, is not the site of action for these compounds and is not directly linked to toxicity. As previously discussed by the RRTF, the cited 0.7 ppm liver residue figure does not represent a bright-line value but instead is a general benchmark between a biomarker of exposure (<0.7 ppm liver) from a potentially toxic residue (>0.7 ppm). In the RCA, by contrast, EPA takes the position that this threshold concept is based only on limited data, and it offers specific examples of liver residues less than 0.7 ppm that allegedly are associated with actual observed mortality. EPA's position is at odds with the brodifacoum residue data from the trapped and euthanized coyotes and raccoons described above. Brodifacoum liver residues ranged from trace levels to 0.66 ppm in six of the eight coyotes and in both raccoons, and the residues of other rodenticides also were detected. N post-mortem pathological lesions were observed. These animals clearly were not affected by the rodenticide residues present. EPA appears to treat any residue of anticoagulant as determinative of a causative agent, this is a mischaracterization of the EIIS database.

EFED Response: See EFED Response to the previous comment.

Comment: EIIS is Not Transparent – The underlying reports from state agencies are not generally publicly available, and the summary of data in Attachment D provides little, if any, background information. This database should be thoroughly reviewed and incidents added since 2001 should be scrutinized with the same rigor as the analysis reported by the RRTF in 2001.

EFED Response: According to the previous comment, the RRTF was able to obtain the EIIS data; to say that the data are "generally publicly unavailable" is simply incorrect.

Comment: EPA Cannot Rely Upon Incident Data Not Included in the EIIS Database – Data such as those from the American Society for the Prevention of Cruelty to Animals (ASPCA) involving domestic or companion animals should be excluded from any quantitative

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[27] Godfrey, M.E.R., T.C. Reid, and H.J.F. McAllum. 1981. The oral toxicity of brodifacoum to rabbits. New Zealand J. Exper. Agric. 9:23-25.

[28] Godfrey, M.E.R. 1984. Acute toxicity of brodifacoum to wallabies (*Macropus rufogriseus*). New Zealand J. Exper. Agric. 12:63-64.

discussion because EPA has taken them out of context and has not established that they are relevant to the RCA or to the related assessment process.

EFED Response: The previous comment from the RRTF indicated that EFED should not rely on the EIIS database, which seems to be contradicted by the current comment.

Comment: EPA Failed To Address Key Issues Raised by the RRTF after Its Errors- Only Review of the PCA

EFED Response: EFED disagrees. EFED responded in 2002 to the errors-only comments of the rodenticide registrants and the RRTF; in 2004 to the public comments, including additional comments of rodenticide registrants and the RRTF (see attachment); and is responding here once again. The previous responses are available in the EDockets (OPP-2002-0049 and OPP-2004-0033).

Comment: EPA Failed To Respond Satisfactorily to Public Comments on the PCA

EFED Response: See EFED Response to the previous comment.

Comment: EPA inappropriately infers risk from exposure.

EFED Response: As stated in the risk assessment, risk is a function of toxicity and exposure.

Comment: It is inappropriate to compare different modes of action.

EFED Response: This comment was addressed in July 17, 2004 “Response to Public Comments on EFED's Risk Assessment: "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach", dated December 19, 2002" (attached)

Comment: EPA Failed to Respond Satisfactorily to USDA/APHIS Comments on the RCA

EFED Response: EFED responded to USDA/APHIS comments during the "errors-only" comment period, during the public comment period (see Attachment 1), and again on September 7, 2004 in a 12-page response to USDA/APHIS’ “Partner Review Comments: Preliminary Analysis of of Rodenticide Bait Use and Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: A Comparative Approach (June 9, 2004)” (see Attachment 3). The RRTF needs to be more specific in identifying how EFED has failed to respond to USDA/APHIS.

ReckittBenckiser

Comment: EPA Confuses Risks and Hazards – The Agency's "comparative" approach provides an analysis based primarily upon indicators of potential hazard, not risks (although the secondary hazard indices do include some factors that imply exposure).

EFED Response: See EFED's July 17, 2004 Response to Public Comments (attached). [see also EFED's Response to Syngenta above]

Comment: Multiple Day Ingestion Model Should be Considered. A single dose model will tend to indicate that second generation anti-coagulants are most hazardous because they are designed to kill their target organisms in a single dose.

EFED Response: Dietary risk quotients are based on 5 days of feeding. Secondary-feeding tests are generally based on multiple-day feedings. These are presented and discussed in the risk assessment.

Comment: Primary Indices Need to Account For Exposure – If one rodenticide is ten times more toxic to rats than another, all things being equal, a consumer would use ten times less product. Thus as target toxicity increases, the volume of the product used will decrease and the opportunity for exposure of non-target organisms to the product decreases. ... At present the PCA assumes that only five times more warfarin active would be needed because it only takes into account the percent active ingredient in the formulation, 0.025% vs. 0.005%. Normalizing using toxicities instead of fraction active ingredient would mean that the warfarin primary MOEs would be multiplied by a factor of 2 to 180.

EFED Response: EFED disagrees. Simply because brodifacoum is more toxic does not mean that less bait will be eaten than if warfarin was applied. Even though the second-generation rodenticides are much more toxic and persistent than the first-generation anticoagulants, both groups result in most exposed animals dying after about 4 to 10 days. However, they may continue to feed, whether they have ingested a lethal dose or nor not, regardless of which anticoagulant is applied. For example, as discussed in the risk assessment, a rat feeding on brodifacoum bait may ingest as many as 80 LD50 doses in bait before it dies (average time to death was 6.5 days).

In accord with label directions for application of baits of warfarin, brodifacoum, or other anticoagulants, label directions for Norway and roof rats specify the following:

"Apply 4-16 oz. of bait (usually at intervals of 15-30 ft.) per placement. Maintain an uninterrupted supply of fresh bait for 10 days or until signs of rat activity cease."

and for the house mouse the following:

"Apply 1/4-1/2 oz. of bait per placement. Space placements at intervals of 8-12 ft. Larger placements (up to 2 oz.) may be needed at points of very high mouse activity.

Maintain and uninterrupted supply of fresh bait for 15 days or until signs of mouse activity cease."

Comment: Secondary Measures of Effect Indices – These secondary MOEs should not be combined with the primary MOEs without some account for exposure in the primary MOEs. Including exposure factors for secondary MOEs, but not including them in the primary MOEs, relatively underweighs the secondary toxicity measures.

EFED Response: This comment addresses the comparative analysis modeling conducted by the late Doug Urban.

Comment: Weightings Used Are Scientifically Indefensible – the secondary toxicity MOEs are underweighted by the current method.. EPA should produce an uncertainty estimate on the final output, so that internal and external reviewers and EPA decision makers can tell whether the predicted differences are significant.

EFED Response: This comment addresses the comparative analysis modeling conducted by the late Doug Urban.

Comment: Analysis of Certainty is Inadequate – EPA has done a sensitivity analysis that looks at variation of MOEs by plus or minus 50%. However, real uncertainties associated with the numbers involved in the MOEs are much greater than this. For instance, the LC50 data has 95% confidence intervals that span orders of magnitude. This means some MOEs are uncertain by factors of ten or more. The uncertainties need to be analyzed much more carefully by examining the confidence intervals of the input data. EPA should produce an uncertainty estimate on the final output, so that internal and external reviewers and EPA decision makers can tell whether the predicted differences are significant.

EFED Response: This comment addresses the comparative analysis modeling conducted by the late Doug Urban.

Comment: Conclusions Regarding Comparative Assessment – EPA's comparative analysis model is flawed and use of the modified Simple Multi-Attribute Ratings Technique (SMART) is inappropriate.

EFED Response: This comment addresses the comparative analysis modeling conducted by the late Doug Urban.

Comment: The Agency continues to rely heavily on incident data to determine the likelihood (risk) of adverse effects on birds and non-target mammals. There is no discussion in the document to provide a fair, objective presentation of the incident data. Incident data can be used to determine if exposure has occurred; however, the reviewers have neglected to put this information into proper perspective.

EFED Response: EFED disagrees. The incident are one piece of the risk characterization. As previously noted in EFED's Response to HACCO, the incident data confirm that a wide range of nontarget animals, including endangered species, are being exposed to anticoagulant rodenticides via primary, secondary, and probably even tertiary exposure. The number of incidents reported to date (more than 400 as of January 2006) clearly is sufficient to demonstrate a high level of known exposure of birds and nontarget mammals and raises serious questions about the extent of this contamination and its effects on individuals and populations.

Comment: Comparison of the absolute number of incidents observed for each product to draw a conclusion about hazard is invalid. The data must first be normalized for exposure. Thus, EPA must take into account the quantity of a product in distribution and use when evaluating the number of incidents reported. ... The incident data cited in the PCA (e.g. Table 43), cannot be interpreted properly without taking into account the differences in market share and packaging. The analysis of the incident data should at least be normalized for the amount of product used.

EFED Response: As stated in the risk assessment, and as emphasized in comments of the Environmental Coalition below, the absolute number of incidents is unknown but certainly far exceeds what has been reported. Regarding pesticide-related wildlife mortality, Vyas[29] notes that "Data show that most effects on wildlife are not observed, and much of observed mortality is not reported." This is certainly the case for rodenticides, for which most incidents in the EIIS have been reported by state agencies in New York and California. Even reporting from those two states tends to be sporadic, depending on funding and other commitments. Nevertheless, as previously noted, the number of incidents reported to date is sufficient to demonstrate a high level of known exposure of birds and nontarget mammals and raises serious questions about the extent of this contamination and its effects on individuals and populations. Also, ss also noted in the risk assessment, more product information is needed than simply the amount produced. When and where is it being used? Who is using it? How is it applied and for what duration? What is being exposed?

ENVIRONMENTAL GROUPS

Environmental Coalition (Defenders of Wildlife, American Bird Conservancy, TEDX, Inc., Beyond Pesticides/NCAMP, Northwest Coalition for Alternatives to Pesticides, Californians for Alternatives to Toxics, Rachel Carson Council, Inc., Virginia Polytechnic Institute and State University)

Comment: The EPA's chosen strategy of lumping all nine rodenticides together into a "comparative" risk assessment leaves the Agency without the ability to deal with one or more

[29] Vyas, N.B. 1999. Factors influencing estimation of pesticide-related wildlife mortality. Toxicol. Industrial Health 15:186-191.

of the most egregiously hazardous rodenticides. ..., close scrutiny of the most hazardous rodenticides is bypassed and the true hazards of individual rodenticides can be obfuscated or otherwise overlooked.

EFED Response: EFED disagrees. Each rodenticide is analyzed on its own just as would be done if only a single rodenticide was being assessed.

Comment: There are incredibly few data for toxicological tests that compare the toxicity and efficacy of these nine products side by side for a variety of species. This is particularly true for field studies, and we note that most of the available studies showed that the test compound did not work well or involved the use of compounds which are not included in this RED and/or are no longer registered. Without this direct comparison available, the EPA is piecing together indirect comparisons that may or may not be valid.

EFED Response: The Agency has used the best available data.

Comment: The risk assessment fails to consider sublethal effects.

EFED Response: EFED disagrees. The available data were considered and data gaps identified. [see also EFED Response to Comments above by the City of San Franciso and Liphatech as well as Attachment 1, Comments 21 and 22 and EFED Responses]

Comment: There is no consideration of the possible impact of prior exposure (tissue residues of one or more rodenticides) on subsequent exposure; there is some data to support the idea that non-target mammals already exposed to rodenticides have a greater susceptibility to subsequent exposure to rodenticides (Mosterd and Thijssen 1991).

EFED Response: EFED strongly agrees that there is a potential for bioaccumulation from repeat exposures of the biologically persistent second-generation anticoagulants; this is discussed in the assessment. [see also EFED Response to the California Dept. Fish and Game Comment above]

Comment: The EPA relies much too heavily on acute toxicity data for their comparative risk assessment; this is a problem because there are many reasons to be wary of acute toxicity studies of rodenticides.

EFED Response: EFED used the best available data. Although published data are cited to help characterize toxicity, EFED only used toxicity values from EPA guideline studies to calculate risk quotients. Those tests require an extended observation period and no supplemental vitamin K added to the basal diet. [see also EFED Response to Comment by the California Dept. Pesticide Regulation]

Comment: A significant source of uncertainty in the risk assessment is the fact that most of the laboratory studies have tested acute effects in species such as the northern bobwhite, mallard, laughing gull, ring-necked pheasant and domestic chicken. However, very little research has been presented to address either toxicity or exposure to small birds. These sources of variation (error?) should be addressed in the narrative. We believe that the exclusion of data on small birds from consideration in either the laboratory studies or the incident data has significant potential to underestimate the overall risk to birds of these rodenticides.

EFED Response: EFED's guideline test species are the mallard and northern bobwhite. Data from those species are extrapolated to a 25-g bird. We realize that there are uncertainties in making such extrapolations, but they are based on the best available data.

Comment: A weakness pointed out by the peer-reviewers and addressed in the 2002 document is that missing data and other uncertainties about toxicity limit the predictive capabilities of the assessment. ... the use of larger birds as surrogates for smaller birds is unwarranted.

EFED Response: EFED agrees that data gaps need to be addressed. See previous comment regarding use of northern bobwhite and mallard as surrogates for smaller birds.

Comment: The large number of incidents that actually found their way into the EPA EIIS database provides substantial evidence of a much larger problem as a direct result of the present system of rodenticide use.

EFED Response: EFED agrees. See also comments by the RRTF on incidents.

Comment: There is a serious paucity of both sales and usage data for rodenticides in the United States.

EFED Response: EFED agrees, and this is discussed in the risk assessment.

CONSULTANTS/ADVISORS, PRIVATE CITIZENS, AND OTHERS

Pest Control Services, Inc.

Comment: Previously a pest-control consultant to The Philadelphia Zoo, the respondent provides information on an incident that occurred at The Philadelphia Zoo in 1980 and another in 1991. Brodifacoum bait was applied in bait stations for mouse control. Several birds were killed, probably by exposure to cockroaches that removed bait from bait stations. Residue analysis was conducted on several dead birds.

EFED Response: EFED appreciates this information. The necropsy reports have been provided by the Director of Pathology, The Philadelphia Zoo, and added to the EIIS database.

Agricultural Sciences, Inc.

Comment: Rodenticide usage without doubt impacts nontarget species and the environment. Brodifacoum is one of the most toxic materials ever registered by EPA. At a very minimum these materials must be taken out of the general publics hands and only allowed to be used by professionals with adequate training.

Protect All Children's Environment

Comment: Expresses concern about risks to people, and cites personal illness from rodenticide exposure.

Pest Control Advisor (retired)

Comment: Must make sure that these materials are safe to man and nontarget entities.

Private Citizen and Agr. Consultant

Comment: Emphasizes that zinc phosphide bait is needed for vole control in alfalfa and hay.

Pest Management Consultant

Comment: Rodenticides are not an efficient management tool; they are not necessary, and they can be hazardous.

National Pest Control Association

Comment: When rodenticides are used by professionals in accordance with standard procedures they are extremely effective; in 22 years, has never had a child or pet come into contact with his rodenticide baits

University of Nevada Cooperative Extension

Comment: Variety of products are needed to maintain production of quality alfalfa and hay

Pest Management Training & Consulting Center

Comment: As a pest control consultant in NY and NJ, rely on these rodenticides to help clients control rodent infestations.

Ohio Pest Control Association

Comment: States that the current use of labeled rodenticides in tamper proof industry approved stations is safe as well as effective

Private citizen

Comment: Should be limited or banned; creating problems all over the world.

Private citizen

Comment: Rodenticides do more harm than good; get rid of all rodenticides.

Private citizen

Comment: Rodenticides should not be removed from professional use.

Private citizen

Comment: Rodenticides are too dangerous to nontarget animals, including humans; reports that rodenticide spread on beach for rats in the Los Angeles area killed pigeons, gulls, and other birds

Private citizen

Comment: Use Prozap to control rodents in alfalfa and hay and believes that rodenticide use is warranted due to minimal risks to birds and mammals.

Private citizen

Comment: Benefits far outweigh risks.

Private citizen

Comment: Would be a mistake to eliminate rodenticides from the market.

Anonymous

Comment: Most problems with nontarget species ingesting bait is due to homeowners.

Anonymous

Comment: Needs outweigh the risks.

Anonymous

Comment: Rodenticides are needed for health and safety.

Anonymous

Comment: Current labeling makes rodenticides safe.

PEST CONTROL FIRMS AND ORGANIZATIONS

The following respondents (many in a form letter) mainly stated that benefits largely outweigh risks, without providing any specific comments on the risk assessment or mitigation except as noted. Many of the responses were by form letter.

Anonymous
Anonymous (Pest Control Operator)
A. Aguirre (Pest Control Operator)
AA Professional Pest Services
ABS Pest and Lawn Services of DFW, Inc.
Accu Pest, LLC
Acme Exterminating Corp.
Action WDI Specialist, Inc.
Adam's Pest Control, Inc.
All Pest Control
All Pest Inc.
American Pest Control, Rockville, MD

Comment: Also state that properly anchored and placed rodent stations are the best defense

Arrow Pest Control, Inc., Lake Geneva, Wisconsin
Banks Pest Control, Inc.
Banks Pest Control

Comment: Also state that EPA should consider taking this product out of the hands of the over the counter users (home owners)

Better Way Pest Control
Big Town Pest Control

Comment: Also state that homeowners and unlicenced applicators are the biggest problem; has seen many occasions where home owner has placed bait in wrong places and it was accessible to animals and children

Blue Chip Exterminating
Border Pest Control, Inc.
Bruce Pest Control, Lakeland, FL
Carl's Pest Control
Cayce Exterminating Company Inc.
Central Oregon Hay Growers' Association
Catseye Pest Control, Inc., Minden, NV
Catseye Pest Control, Inc., Lenox, MA
Catseye Pest Control, Inc., East Schodack, NY
Coby Termite & Pest Control
Columbus Pest Control, Inc.
Crane Pest Control
Critter Control of Kansas City
Danny Myers
Edwards Pest Control Services, Inc.
Eradico Pest Control
Eradico Services, Inc.
Fisher Pest Control
Fowler Pest Control
General Pest Control Co.

Comment: Also state that baits should be applied in bait stations

Getem Termite & Pest Control
Golden Glove Pest Control
Gunter Pest Management, Inc.
Harry Connoyer
Hassman Termite and Pest Control Inc.
Hometeam Pest Control
Insecta X, LLC Termite and Pest Solutions
Insects Limited, Inc.
Jackie Dendy Cross Pest Control of Tampa
Jackson Pest Control
J.C. Ehrlich Co., Inc.
Jepsen Pest Control, Inc.
Jack Frost
John Frost
Kennedy Pest Control Inc.
Key Pest Control Company, Inc.
King Exterminating Co.
Kil-More Pest Management
Lone Star State Pest Control
McCloud Services
McKinney Independent School District (Pest Control Operator)

McKinzie Pest Control
North Jersey Exterminating Company
Olson's Pest Technicians
Organization of Kittitas Valley Timothy Hay Growers and Suppliers
Orkin, Inc.
Orkin Pest Control, Zionsville, IN

Comment: Also state that rodenticides need to be monitored closer than they have been

PARATEX Pied Piper Pest Control
PB Pest Management
PESCO Pest Control Services, Inc., Indianapolis
Pest Control 258
Pest Express, Inc.
Pest Management Training & Consulting Center
Pioneer Pest Control, Inc.
Powers Pest Management
Presto-X-Company, mason City, IA
Ron's Termite & Pest Control, Inc.
Rose Pest Solutions
Rose Pest Solutions, Clinton Twp., MI
Southern NH Pest Control, Nashua, NH
Stubbs Pest Control, Amarillo, TX
Target Pest Control, LLC
Terminix - Chicago Branch
Valley Pest Control
Ventura Pest Control, Inc.

Varment Guard Environmental Services, Inc.

Comment: Also state that no beneficial nontarget organisms have ever been exposed except due to misuse and that EPA should enforce labels rather than have more restrictive labeling

Weatern Exterminator Co.

ATTACHMENT 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

July 17, 2004

Memorandum

Subject: Response to Public Comments on EFED's Risk Assessment: "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach", dated December 19, 2002

To: Laura Parsons, Team Leader
Susan Lewis, Branch Chief
Reregistration Branch 1
Special Review and Reregistration Division

From: William Erickson, Biologist
Environmental Risk Branch 2
Environmental Fate and Effects Division

Through: Tom Bailey, Branch Chief
Environmental Risk Branch 2/Environmental Fate and Effects Division

EFED has reviewed the public comments submitted on the environmental risk assessment entitled "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach" dated December 19, 2002. Comments were received from 26 respondents, including the Rodenticide Registrants Task Force (RRTF), individual rodenticide registrants, user groups, state agencies, environmental organizations, and a private citizen. Comments addressed data and methodologies, processes, benefits, the lack of an open public process, mitigation issues, and others. EFED is responding to those comments relative to the data and methodologies used in the risk assessment. Some comments are raised by more than one respondent, and these comments were grouped together in this response. A numbered list of respondents has been provided to match their respondents with their comments. Many of the comments by the RRTF and individual registrants simply reiterate their "errors-only" comments provided after the risk

assessment was provided to the registrants in October of 2001. The comparative risk assessment,
external peer reviews of the assessment by three qualified experts, errors comments of the RRTF and individual registrants, and EFED's response to those errors comments are available in the Rodenticides EDocket: http://www.epa.gov/oppsrrd1/rodenticidecluster/index.htm

Respondents:

1. California Department of Fish and Game (CDFG)
2. New York State Department of Environmental Conservation (NYSDEC)
3. California Environmental Protection Agency, Dept. Pesticide Regulation (DPR)
4. Natural Resources Defense Council (NRDC)
5. Defenders of Wildlife, American Bird Conservancy, Rachel Carson Council, Northwest Coalition for Alternatives to Pesticides, and Steve Sheffield
6. Sierra Foothills Audubon Society (SFAC)
7. Grassroots Coalition
8. Beyond Pesticides
9. Private citizen
10. Rodenticide Registrants Task Force (RRTF)
11. Syngenta
12. Reckitt Benckiser
13. LiphaTech
14. Hacco, Inc.
15. Bell Laboratories, Inc.
16. United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA/APHIS)
17. The Zinc Phosphide Consortium (TZPC)
18. California Department of Food and Agriculture (CDFA)
19. Dodson Bros. Pest Control
20. J.C. Ehrlich Co., Inc.
21. County of Kings Department of Agricultural Commissioner
22. Alameda County Health Care Services
23. County of Fresno Department of Agriculture
24. American Farm Bureau Federation, American Institute of Baking, National Food Processors Association, North American Millers Association, Association of Structural Pest Control Regulatory Officials, ConAgra Flour Milling Company, and National Pest Management Association
25. Organization of Kittitas County Timothy Hay Growers & Suppliers
26. McCloud Services

Comment 1: The assessment is not an ecological risk assessment, only an assessment or ranking of hazards. A risk assessment must quantify exposure. EPA's Risk Assessment Guidelines define ecological risk assessment as "a process that evaluates the likelihood that

adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors."
[10, 11, 12, 13, 14, 15, 18, 21, 23, 24]

EFED Response to Comment 1: EFED's risk assessment is in accord with the Agency's Guidelines for Ecological Risk Assessment[30]. Registrants are correct in noting that the Guidelines state that "***Ecological risk assessment is a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors***"(PART A, page 1, paragraph 1). However, the Guidelines go on to state that "***Descriptions of the likelihood of adverse effects may range from qualitative judgments to quantitative probabilities. Although risk assessments may include quantitative risk estimates, quantitation of risks is not always possible. It is better to convey conclusions (and associated uncertainties) qualitatively than to ignore them because they are not easily understood or estimated***" *(*PART A, page 1, paragraph 3). Refining the exposure assessment to establish a quantitative measure of likelihood of exposure and effects would require a much more extensive data set than registrants have submitted for their rodenticides and for the nontarget species potentially at risk. The Agency provided the preliminary risk assessment to rodenticide registrants in October, 2001 and posted it in the EDocket on EPA's website for public comments from January 29 to May 30, 2003. No additional data or relevant information to refine the exposure assessment has been provided by the registrants or other stakeholders. The necessary data have been outlined in a section on *"Uncertainty and Data Needs*" in the refined assessment. Nevertheless, despite the lack of quantifiable data, the existence of substantial incident data along with liver-residue analysis confirms that birds and nontarget mammals are being exposed and adversely affected by applications of rodenticide baits. The fact that numerous species of birds and mammals, including predators and scavengers, have been found exposed to these baits indicates that both primary and secondary exposures are occurring.

EFED's risk conclusions are based on analyses of the available data by a "lines-of-evidence" approach and comparative-analysis modeling. Quantitative estimates of risk are used in both; however, the "lines-of evidence" assessment includes qualitative assessments of secondary risk based on mortality and other adverse effects reported in laboratory and field studies, operational control programs, and incident reports, as well as toxicokinetic data and residue levels reported in primary consumers. This approach is in concert with the Guidelines, which clearly state that professional judgement or other qualitative evaluation techniques are appropriate for ranking risks using categories such as low, medium, and high when exposure and effects data are limited or are not easily expressed in quantitative terms. A "lines-of-evidence" approach also has been

[30] EPA. 1998. Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F, April 1998, Final. 171 pp. http://www.epa.gov/ncea/ecorsk.htm

advocated by the Avian Effects Dialogue Group[31] for helping to interpret a wide variety of information.

EFED also notes that the methodology used is similar to that used in the Agency's "*Comparative Analysis of Acute Risk From Granular Pesticides*" (EPA 1992) and "*A Comparative Analysis of Ecological Risks from Pesticides and Their Use: Background, Methodology, Case Study*" (EPA 1998)[32]; both were reviewed by a FIFRA Scientific Review Panel. Concerning the latter analysis, the Panel noted the many scientific uncertainties in the method, yet agreed that it was a useful screening tool that provides a rough estimate of relative risk. The Panel made a number of helpful suggestions to improve the utility of the method, most of which are included in the risk assessment.

Comment 2: It cannot be emphasized enough that the number of nontarget rodenticide poisoning cases documented to date are indicative of a much larger problem. In suburban areas, people are not likely to pick up a dead animal and send it to a wildlife pathologist to find out why it died. In rural areas, birds and animals that succumb to rodenticide poisoning are simply not likely to be observed or detected. Small birds especially are not likely to be well represented in incident data. Bell Laboratories, Inc., however, disagrees with the conclusion that many incident victims are not found. [2, 5, 15]

EFED Response to Comment 2: EFED agrees with comments asserting that the number of incidents reported is likely only a small portion of nontarget exposure. In the "*Incident Data: Birds and Nontarget Mammals*" section of the comparative risk assessment, we note that most rodenticide incidents likely go undetected except in those rare instances when a predator carcass happens to be exposed in an open area (e.g., roadside) where it is observed by someone willing to take the time and effort to report it to the proper authorities. In many situations, carcasses might not be detected, death may be attributed to natural mortality, or an incident may not be reported for a variety of reasons, including ignorance, apathy, or failure of authorities to investigate and confirm the cause of death. Even if a carcass is found, a proper evaluation of rodenticide exposure requires necropsy of a dead animal by a wildlife pathologist. Liver tissue be extracted, frozen, and shipped to an analytical laboratory for analysis by high performance liquid chromatography. Because so few anticoagulant screens are conducted, exposure of birds to anticoagulants is likely much more widespread than the number of incidents suggests. Most of the incidents in the EIIS database occurred in New York and California, where state agencies have taken the time, effort, and expense of screening the liver of dead animals suspected to have been killed by rodenticides. Few other states appear to do so, although Wisconsin has reported several raptor incidents.

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[31] Rymph, B. (ed.). 1994. Assessing Pesticide Impacts on Birds: Final Report of the Avian Effects Dialogue Group, 1988-1993. RESOLVE Center for Environmental Dispute Resolution, Washington, DC. 156 pp.

[32] See December 8-9, 1998 http://www.epa.gov/scipoly/sap/1998/index.htm

It is inconceivable that New York, California, and Wisconsin are the only states with nontarget exposure, even though they represent over 95% of the avian exposure cases. Rather, we believe this distribution, coupled with active programs in these states, affirms EFED's assessment that smaller birds and nontarget mammals are less likely to be detected and reported to authorities than are larger individuals, such as raptors and canids, and they likely are substantially under represented in the incident database. The difficulty in finding animal carcasses, even if systematic searches are conducted, has been discussed by the Avian Effects Dialogue Group. It is important to note that, regardless of the spatial distribution, the incident data available (more than 300 rodenticide cases) do indicate that a wide variety of birds and nontarget mammals are being exposed to rodenticides, especially brodifacoum. As indicated by the RQ determinations for a 25-g bird in the comparative risk assessment, small birds are potentially at risk if they eat even a single bait pellet of brodifacoum, difethialone, or zinc phosphide. Taken together, we believe these factors make a compelling case for substantial occurrence.

Comment 3: The RRTF has provided data on over-the-counter sales of rodenticides to the general public. The Agency hasn't made use of production data. Many states collect detailed information on use of field rodenticides labeled restricted use. [10, 11, 13, 14, 16, 17]

EFED Response to Comment 3: Adequate information quantifying usage of rodenticide baits is lacking. EPA obtains data on the amount of each product produced annually, but production data provide no information on when, where, or how the product is used and thus provide little relevant information for assessing exposure and risk. The RRTF (Kaukeinen et al. 2000)[33] provided some limited information on the pounds of active ingredient produced or imported in 1996 and 1997 and the number of container/placement units for 4 of the 9 rodenticides. Usage of the other 5 rodenticides was not addressed. One problem with the information provided is that the RRTF does not distinguish between "containers" and "placement units", although they may differ substantially. According to product labels for brodifacoum and bromadiolone, a placement unit is 3 to 16 oz of bait for rats and 0.25 to 0.50 oz of bait for mice. However, according to rodenticide product catalogs, containers (e.g., 10-lb and 25-lb pails[34]; pails containing up to 80 50-g packs[35]) may contain many placement units. Differences in size among containers and between containers and placement units likely explains the discrepancies in the data provided by the RRTF. For example, both brodifacoum and bromadiolone are formulated as 0.005% ai food baits solely for commensal rat and mouse control. The data provided by the

[33] Kaukeinen, D.E., C.W. Spraggins, and J.F. Hobson. 2000. Risk-benefit considerations in evaluating commensal anticoagulant rodenticide impacts to wildlife. Proc. Vertebr. Pest Conf. 19:245-256

[34] www.belllabs.com/cgi/products.cgi

[35] www.hacco.com/2004_Catalog/RodenticideCatalog_2004.pdf

RRTF for 1996 indicate that 395 lb ai of brodifacoum was formulated into more than 40 million "container/placement units" (i.e., 3 oz bait per container/placement unit), whereas 233 lb ai of bromadiolone was formulated into few more than 275,000 container/placement units (i.e., 271 oz bait per container/placement unit). Such differences also occur for 1997 and for chlorophacinone and diphacinone (see Table 2 in the refined comparative risk assessment). Thus, these data provide little useful information for use in the risk assessment. Refining the exposure assessment would necessitate much better information for each rodenticide, including the amount of bait applied annually and seasonally; geographically by state or region; in field settings versus in and around buildings; in urban versus suburban and rural locales; indoor versus outdoor placements; applications for rats versus those for mice; use by the general public versus that by Certified Applicators; proportion of bait placements made in tamper-resistant bait stations; and, for chlorophacinone and diphacinone, use of 0.005% versus 0.01% ai baits.

Regarding state reporting of rodenticide usage, registrants and other stakeholders had the opportunity to provide any such data they believed would have been useful for the risk assessment [see also EFED Response to Comment 1]. Few states actually have any such reporting to our knowledge, and even the most comprehensive state reports[36] typically only provide the amount of rodenticide applied per crop without providing any information of the target pest, seasonal use, application method (e.g., broadcast versus bait station), or other such relevant factors. Moreover, homeowners and non-certified applicators do not report pesticide use. We also note that many of the Special Local Needs field products for chlorophacinone and diphacinone have not been labeled restricted use. Therefore, any reporting to date would not reflect use of non-restricted field products and thus could be misleading and inconclusive. The Rodenticide Cluster RED is requiring that all field baits be labeled as restricted use, and labels are currently being revised. However, even for those states that may report use of restricted-use products, there is a lag time in collecting, analyzing, and reporting annual data, and it may be several years before such data become available.

Comment 4: The greatest risk to nontarget wildlife is posed by rodenticides available over-the-counter for essentially unregulated homeowner use. Rodenticides should be classified as restricted use pesticides. [1, 5]

EFED Response to Comment 4: This issue will be addressed during the mitigation phase.

Comment 5: Rodenticide products should be clearly segregated into indoor and outdoor use categories. Outdoor uses of any kind should be limited to specific situations where use is highly controlled and closely monitored. Other countries (e.g., United Kingdom, New Zealand) have recently placed restrictions on the use of brodifacoum for both field and homeowner use. [1, 2, 3, 5]

[36] e.g., California Department of Pesticide Regulation, Pesticide Use Reporting, http://www.cdpr.ca.gov/docs/pur/purmain.htm

EFED Response to Comment 5: This issue will be addressed during the mitigation phase.

Comment 6: The Agency shouldn't draw any conclusions on secondary risks, because studies were of widely differing types, dose regimes, sample sizes, etc. [11, 12]

EFED Response to Comment 6: The rodenticides have been in the reregistration process for more than 10 years to date, and registrants have had ample opportunity to propose any standardized testing for any of the rodenticides. None have done so. Standardized studies for each rodenticide would provide useful comparative information; but, until registrants conduct and submit such studies, EFED must rely on the available data. Some of the available studies were conducted under similar protocols and with the same test species, and some studies (e.g., Mendenhall and Pank 1980)[37] have tested the same test species under the same test protocol to compare the hazards of different rodenticides. Other studies have used different protocols, test species, and sample sizes. What is readily apparent when examining the variety of data available is that some rodenticides (e.g., brodifacoum) exhibited mortality and other adverse effects in many or most test animals in almost every study, despite the differing protocols and/or test species used in the study. When looking at an individual rodenticide, having a variety of studies with a variety of test species is quite useful and relevant for assessing the hazards of that rodenticide.

EFED also emphasizes that potential secondary risks are not based solely on the secondary-hazards studies. As stated in the introduction to the comparative risk assessment, assessments of potential secondary risk are made based on mortality and other adverse effects reported not only in laboratory studies, but also in field studies and operational control programs, incident reports, toxicokinetic data, and residue levels reported in primary consumers.

Comment 7: Syngenta questions why the Agency wants additional toxicity data with predators and scavengers and asks "Are not these the organisms the Agency is trying to protect?" [11]

EFED Response to Comment 7: As noted in EFED's Response to Comment 6, the Agency has attempted to use the available information as much as possible throughout the assessment. For some rodenticides, there may be insufficient information. For brodifacoum, some hazards information exists in the literature, and we have not asked Syngenta or other brodifacoum registrants for additional hazards studies at this time. However, if registrants believe that a standardized study is necessary to compare risks among rodenticides, or that available data are lacking, then additional testing would be needed.

Comment 8: EPA inappropriately infers risk from exposure. [10]

[37] Mendenhall, V.M. and L.F. Pank. 1980. Secondary poisoning of owls by anticoagulant rodenticides. Wildl. Soc. Bull. 8:311-315

EFED Response to Comment 8: Risk is a function of both toxicity and exposure, as we have clearly stated in the introduction of the comparative risk assessment. For primary risks, a risk quotient (RQ) is compared to a Level of Concern (LOC). If an RQ is below the LOC, minimal risk is presumed. For example, a presumption of minimal acute primary risk to birds was made for the first-generation anticoagulants, because a small bird could eat many bait pellets and be at little risk of mortality. In this case, we inferred minimal risk from exposure.

Comment 9: The RRTF states that one peer reviewer found the comparative model to be inappropriate. [10]

EFED Response to Comment 9: One of the three expert peer reviewers raised a concern about use of the comparative analysis model as presented in an earlier draft of the risk assessment. EFED has made extensive changes in response to that reviewer's concerns.[38] We also note that the same reviewer also stated that: "***The bulk of the material in the document addresses the development of the weight of evidence argument. In general this part of the document is well-developed and it is hard to argue with the evident conclusion about each of the nine chemicals. These conclusions are largely implicit in the text since the task of deriving a formal assessment for each chemical is passed over to the decision support analysis. The case about each chemical is thoroughly and logically developed in this part of the document and the document is commendable in showing how the Agency staff have been able to develop the weight of evidence approach as a viable approach to the synthesis of a complex body of evidence***."

Comment 10: EPA suggests in the risk assessment that risk may be inferred by the existence of incidents. This is inappropriate, scientifically indefensible, and bad science. Elsewhere in their comments, the RRTF states that secondary risk is derived solely from hazards tests. [10]

EFED Response to Comment 10: Rodenticides are very highly toxic to mammals, including nontarget species, and some also are very highly toxic to birds, which are nontarget species. That is confirmed by the primary- and secondary-hazards testing that has been conducted and by findings from field, pen, and operational control programs in which nontarget organisms have been killed. Baits are formulated to kill rodents and other mammals (jackrabbits, mongoose, moles, shrews), and registrants have provided no documentation that baits are selective to the target species. Therefore, exposure to rodenticide baits does involve a degree of risk, although the degree varies among the rodenticides. The existence of substantial incident data (more than 300 documented cases) along with liver residues provides important support for the assumption that nontarget birds and mammals are exposed and at risk from the use of at least some rodenticides. Death has been attributed to brodifacoum exposure in some individuals having liver-residue levels as low as 0.007 to 0.077 ppm[39]. These incidents refute the RRTF's

[38] the expert peer reviews are available in the Rodenticide Cluster EDocket, www.epa.gov/oppsrrd1/rodenticidecluster/index.htm

[39] e. g., barn owl (0.007 ppm brodifacoum) and red-tailed hawk (0.077 ppm brodifacoum)

contention that liver-residue levels less than an arbitrary "toxicity threshold" of 0.7 ppm for mortality[40]. The incidents are discussed in more detail in the section entitled "*Incident Data: Birds and Nontarget Mammals*" in the comparative risk assessment.

Comment 11: When homeowners or applicators are using rodenticides according to label directions, they are placing them in inaccessible areas in and around structures or in tamper-resistant bait stations that greatly limits risk and selectivity of these products. Incident data include dissimilar practices and cannot be directly compared. [11]

EFED Response to Comment 11: Documentation of how homeowners are applying bait and complying with label directions is lacking. The RRTF (Kaukeinen et al. 2000, Anonymous 2001 - see footnotes 4 and 11) argues that many of the documented nontarget incidents are due to misuse, in which case applicators are not baiting according to label directions. A major concern is that most outlets selling rodenticide baits over the counter (e.g, grocery stores, hardware stores) do not sell bait stations, and most homeowners would not know where to find and purchase tamper-resistant bait stations even if they were willing to do so. EFED also questions how outdoor applications for rats and mice can be made in areas accessible only to the target species, and product labels provide no advice on how to do so. Even if properly secured, tamper-resistant bait stations are used, they do not prevent small animals from entering the stations and obtaining bait, nor does the use of bait stations preclude secondary exposure of predators and scavengers. The incident data cited in the risk assessment indicate that nontarget animals are being exposed, and the Animal Poison Control Center reports 2334 cases with rodenticides, particularly brodifacoum (1161 cases), between November 2001 and June 2003[41]. Most pet cases involved exposure of dogs. These data seem to indicate that exposure is occurring and raise the question whether the rodenticide baits, as currently used, can continue to be used without resulting in nontarget exposure of pets and wildlife.

Comment 12: How was the weight-of-evidence assessment performed? [19, 21, 23]

- Final Report, Diagnostic Services Section, Southeastern Cooperative Wildlife Disease Study, College of Veterinary Medicine, The University of Georgia, Athens, Georgia (Case No. CC246-03, January 5, 2003) and Golden eagle (0.04 ppm brodifacoum) - Hosea et al. (2001, Forensic investigative techniques to identify impacts (primary and secondary) from three groups of pesticides on raptors in California. Pages 38-51 in J. J. Johnston (ed.), Pesticides and Wildlife. American Chemical Society Symposium Series 771

[40] Anonymous. 2001. Analysis of the supporting data for EPA's EIIS database with respect to rodenticides. Unpubl. report prepared for the Rodenticide Registrants Task Force to EPA by Arcadis Geraghty and Miller, Millersville, MD. 29 pp. and Kaukeinen et al. (2000) [cited in footnote 4 for Comment 3]

[41] S. Hansen (Senior Vice President, Animal Poison Control Center, Urbana, IL) pers. comm. to W. Erickson, EFED

EFED Response to Comment 12: As stated in the introduction of the comparative risk assessment, risk conclusions are based on two analyses of the available data. One is a comparative ranking of the potential risk based on a comparative-analysis model, and the other is a tabular comparative rating of potential risk based on a "lines-of-evidence" approach. Quantitative estimates of risk are used in both; however, the "lines-of evidence" assessment includes qualitative assessments of secondary risk based on mortality and other adverse effects reported in laboratory and field studies, operational control programs, and incident reports, as well as toxicokinetic data and residue levels reported in primary consumers. The potential-risk rankings are in accord with the EPA's Risk Assessment Guidelines, which deem professional judgement or other qualitative evaluation techniques as being appropriate for ranking risks according to categories such as low, medium, and high when exposure and effects data are limited or are not easily expressed in quantitative terms. [see also EFED Response to Comments 1 and 13]

Comment 13: The NYSDEC states that the weight-of-evidence (i.e., lines-of-evidence) methodology used in the risk assessment provides an objective assessment of the various rodenticides. They believe that brodifacoum presents the greatest potential for risk to nontarget birds and mammals, which is consistent with the incident findings of the New York State Wildlife Pathologist[42]. [2]

EFED Response to Comment 13: We agree, and we thank the NYSDEC for providing incident reports for EFED's Ecological Incidents Information System (EIIS). We also note that the California Department of Pesticide Regulation and the California Department of Fish and Game stated in their comments that they agree with most of the conclusions in the comparative risk assessment as well, particularly for those rodenticides used for commensal control. We also thank the CDFG for providing incident reports from California.

Comment 14: EPA wrongly assumes that all rodenticide baits weigh 0.2 g per pellet. [10, 21, 23]

EFED Response to Comment 14: EPA assumes that a typical rat-bait pellets weighs 0.2 g, based on information provided by Syngenta as cited in the refined comparative risk assessment. No other information on pellet or whole-grain size was provided by registrants or other stakeholders during the "errors-only" and "public comment" periods [see also EFED Response to Comment 1]. We did calculate the number of 0.2-g pellets needed to provide an LD50 dose to a bird or nontarget mammal weighing 25 g, 100 g, and 1000 g. However, we realize that some

[42] Stone, W.B., J.C. Okonlewski, and J.R. Stedelin. 1999. Poisoning of wildlife with anticoagulant rodenticides in New York. J. Wildl. Diseases 35:187-193 and

Stone, W.B., J.C. Okonlewski, and J.R. Stedelin. 2003. Anticoagulant rodenticides and raptors: recent findings from New York, 1998-2001. Bull. Environ. Contam. Toxicol. 70:34-40

bait pellets or grains may be smaller or larger than the typical rat-bait pellet, and some are formulated as meal or wax blocks. Therefore, we also calculated the amount of bait that would need to be eaten by a bird or nontarget mammal to provide an LD50 dose, and we calculated what percent of the diet that would comprise. The later calculations are independent of pellet or grain size.

Comment 15: The American Society for Prevention of Cruelty to Animals (ASPCA) Poison Control Center has many incidents for pets exposed to rodenticides, especially brodifacoum. EPA should obtain this information. [5]

EFED Response to Comment 15: EFED is aware that the ASPCA Animal Poison Control Center has reported 2334 cases involving 2685 animals from November 01, 2001 to June 16, 2003 (S. Hansen pers comm. to W. Erickson). The number of cases were 1161 for brodifacoum, 511 for bromadiolone, 218 for zinc phosphide, 206 for diphacinone, 66 for bromethalin, 48 each for difethialone and warfarin, 42 for chlorophacinone, and 34 for cholecalciferol. Although adverse effects to pets and other domestic animals are addressed by OPP's Health Effects Division, we believe that these data augment the wildlife incident data in demonstrating that nontarget animals are being exposed to rodenticide baits.

Comment 16: Label language needs to be more precise regarding where and how rodenticides are placed in order to avoid confusion. The label should indicate potential adverse effects. People using rodenticides around their homes need to be aware of how their local domestic-life and wildlife could be harmed or killed as secondary nontarget species. [7]

EFED Response to Comment 16: We appreciate the comments of the Grassroots Coalition regarding the need to improve label language to warn of potential nontarget risks. Label directions and precautionary measures will be dealt with during the mitigation phase.

Comment 17: The risk assessment does not consider individual products. Product characteristics such as pellet or grain size, color, stabilizers, waxes, and others offer some degree of selectivity. [13, 16, 17, 18, 21, 23]

EFED Response to Comment 17: Reregistration is an assessment of the active ingredient. Various properties of individual products that might reduce risks will be considered when mitigation issues are addressed, providing that registrants have provided appropriate data to support any claims of selectivity. Mitigation issues such as mandatory use of bait stations can also be addressed during this next phase of review.

Comment 18: The available mammalian toxicity data are not sufficient to present a full mortality danger to the various mammalian species. The Agency should require a mammalian acute dietary test. [2, 5]

EFED Response to Comment 18: EFED agrees that additional mammalian-toxicity information would help reduce the uncertainty associated with risk estimation. While EFED can

request a wild mammal toxicity test[43], EFED has not previously required this test for rodenticides. Rodenticides are formulated and proven to be toxic to small mammals, and there is no evidence that they are selective to the target species. However, we will consider the value of a wild-mammal toxicity test when determining what additional data would be useful for reducing uncertainties in the assessment.

We have recently located reports of rat dietary tests conducted at EPA's former toxicology laboratory in Beltsville, MD, where McCann et al.(1981)[44] developed a short-term dietary LC50 test for small mammals. They exposed immature albino Norway rats (Wistar strain) to dry diet offered ad libitum and treated with one of 17 chemicals pesticides, mostly organophosphate and carbamate pesticides. The tests consisted of a 5-day acclimation period, a 5-day exposure period, and a post-treatment observation period lasting at least 9 days. Following submission of the paper for publication, testing continued and included brodifacoum, bromadialone, chlorphacinone, diphacinone, and warfarin. Results of the rodenticide testing were not published, but EFED now has the test reports and has incorporated these data in the risk assessment.

Comment 19: The CDFA notes that uncertainties in the assessment can be addressed by requiring new data where necessary. Such data should include residue data to evaluate secondary exposure, mammalian subchronic toxicity data to evaluate secondary exposure risks to nontarget mammals, and use of avian subacute toxicity or avian reproduction data to evaluate secondary exposure risks to birds. [18]

EFED Response to Comment 19: We agree that additional data would reduce uncertainties in the risk assessment, especially to assess sublethal (e.g., reproductive) effects and to quantify exposure. However, we disagree that avian and mammalian reproduction data can be used to assess secondary risk. Reproduction data are used to assess chronic risk, not secondary risk. The available secondary-hazards data are presented in the comparative risk assessment. Additional data on potential for secondary exposure would help refine the assessment, and we would have incorporated any relevant information if registrants or other stakeholders had made any available. [see also EFED Response to Comment 1]

Comment 20: The Agency should consider factors such as diet and food preferences, proximity of habitat to use areas, home range, etc. in assessing risks. [18]

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[43] 40 CFR §158.490, Wildlife and Aquatic Organisms Data Requirements, Guidelines Reference No.71-3 "Wild mammal toxicity"

[44] McCann, J.A., W. Teeters, D.J. Urban and N. Cook. 1981. A short-term dietary toxicity test on small mammals. Pages 132-142 in D.W. Lamb and E.E. Kenaga (eds): Avian and Mammalian Wildlife Toxicology: Second Conference, ASTM STP 757, American Society for Testing Materials.

EFED Response to Comment 20: The Agency has received no such data from the rodenticide registrants or other stakeholders [see also EFED Response to Comment 1]. As noted in the comparative risk assessment, there are many factors that influence which nontarget animals might be exposed to rodenticide baits. They include the species found in and around treatment areas, species' food habits and foraging behavior, home range, propensity to feed in and near human buildings, bait availability (e.g., quantity, how applied, where applied, when applied), and other such factors. However, there is no doubt that many birds and nontarget mammals are attracted to and will consume grain-based foods. Additionally, many nontarget predators and scavengers feed on rats, mice or other target species. They are not likely to avoid feeding on rats, mice, voles, ground squirrels, or other animals that have eaten bait.

Comment 21: EPA has not utilized the large set of subchronic/chronic mammalian toxicity studies that are available for most, if not all, of the rodenticides. [16, 17, 18]

EFED Response to Comment 21: EFED utilizes the rat two-generation reproduction test[45] to assess chronic risks to mammals. This study is required by OPP's Health Effects Division (HED) to support pesticides with food uses or where use of the product is likely to result in human exposure over a significant portion of the human lifespan. This study is not currently available for any of the rodenticides. HED requires numerous other subchronic/chronic studies (e.g., dermal, inhalation, oncogenicity, neurotoxicity) to assess risks to humans, but these generally are not relevant to assessing risk to mammalian wildlife. For assessing chronic risk to birds, EFED uses avian reproduction studies with the northern bobwhite and mallard[46]. The avian reproduction studies have previously been required by the Agency on a case-by-case basis, but the updated guideline requirements soon to be published will require these studies for all pesticides having outdoor uses. EFED can better assess the potential for adverse reproductive effects when these data become available. [see also EFED Response to Comment 22]

Comment 22: The RRTF disagrees that sublethal doses can have adverse effects. Bell Laboratories, Inc. states that EPA's present infatuation with the concept of 'sub-lethal effects' of anticoagulants is an attempt to find a problem where none exists. [10, 15]

EFED Response to Comment 22: EFED disagrees with these comments. Despite the lack of reproductive data for birds and mammals [see EFED Response to Comment 21], evidence exists that sublethal doses can have adverse effects. For example, poisoning symptoms (e.g., bleeding, delayed blood-coagulation times) have been reported in birds and mammals that survived exposure in some of the secondary-hazard studies discussed in the comparative risk assessment

[45] 40 CFR §158.340, Toxicology Data Requirements, Guidelines Reference No. 83-4 "Reproduction, 2-generation"

[46] 40 CFR §158.490, Wildlife and Aquatic Organisms Data Requirements, Guidelines Reference No. 71-4 "Avian reproduction"

(see secondary-hazards tables for birds and mammals). The Warfarin RED[47] notes that warfarin is a teratogen, and product labels are required to warn "Exposure to warfarin during pregnancy should be avoided. Warfarin may cause harm to the fetus, including possible birth defects." The Rodenticide Cluster RED[48] reports developmental toxicity (e.g., vaginal bleeding, hypotonicity) in rats and rabbits exposed to bromadiolone at about two orders of magnitude less than the LD50 dose. In brodifacoum studies, internal hemorrhage and significantly prolonged prothrombin time of rabbits was reported for those dosed, during gestation, at about two orders of magnitude less than the LD50 dose. A recently published article reported that brodifacoum was detected in two dog pups that died a few hours after birth (Munday and Thompson 2003)[49]. Of 13 pups in a single litter, eight were born dead or died within 48 hours of birth. Three puppies that died shortly after birth were necropsied. Two exhibited hemorrhage in the thoracic and peritoneal cavities, intestinal serosa, and meninges, and brodifacoum was detected in the liver of both puppies. The mother did not have clinical signs of coagulopathy before or subsequent to whelping, and the authors suggest that fetuses may be more susceptible to brodifacoum than are adult animals. EFED believes that reproductive studies are needed to further clarify possible adverse reproductive effects of the nine rodenticides and to assess the possible significance of sublethal doses in primary exposure.

The Avian Effects Dialogue Group (see footnote 2) also discussed the issue of sublethal effects of pesticides on birds. The Group notes that ". . . effects that are sublethal under the controlled environmental conditions of a laboratory might result in decreased survival or reproduction in the field." The Group also discussed several of the factors that may result in sublethal effects becoming lethal under field conditions or which may lead to a reduction in reproductive success. Such factors include physiological parameters, environmental conditions, synergisms with other chemicals, formulation type, and route of exposure.

Comment 23: It is inappropriate to compare different modes of action. [11]

EFED Response to Comment 23: EFED compares the potential nontarget risks of the nine rodenticides. Six of the rodenticides are anticoagulants and three are not. However, all nine rodenticides are registered for control of commensal rats and mice in and around buildings. Therefore, it is appropriate to compare all nine, because they are alternatives for one another for control of commensal rats and mice in and around buildings.

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[47] Warfarin and its Sodium Salt. Reregistration Eligibility Document. 1991. SRRD/OPP/EPA. http://www.epa.gov/pesticides/reregistration/status.htm

[48] Reregistration Eligibility Decision (RED): Rodenticide Cluster. 1998. EPA738-R-98-007. 307 pp. http://www.epa.gov/pesticides/reregistration/status.htm

[49] Munday, J. S. and L. J. Thompson. 2003. Brodifacoum Toxicosis in two neonatal puppies. Vet. Pathol. 40: 216-219

Comment 24: Using rat toxicity data is not appropriate for 1-kg mammals, such as canine or feline, because rodenticides are more toxic to rodents than to other mammals. [11, 13]

EFED Response to Comment 24: There is no scientific basis for that statement. As can be seen from the toxicity tables in the comparative risk assessment, rodenticides are not necessarily more toxic to rats and mice or other rodents than to other mammals. Brodifacoum, for example, is very highly toxic to the rabbit (LD50 = 0.29 mg/kg), possum (LD50 = 0.17 mg/kg), dog (LD50 = 0.25-1.0 mg/kg), and pig (LD50 <2.0 mg/kg), and diphacinone is very highly toxic to the mongoose (LD50 = 0.2 mg/kg) and coyote (LD50 = 0.6 mg/kg). We have followed EFED policy in using rat or mouse toxicity data to extrapolate to a 1-kg mammal and, based on the available toxicity data, believe it is appropriate in the comparative risk assessment.

Comment 25: Information from field studies is irrelevant to use of rodenticides for commensal uses. [11]

EFED Response to Comment 25: Field studies are useful in demonstrating that exposure to rodenticide baits or consumption of target or nontarget animals poisoned from eating bait can have adverse effects to nontarget birds and mammals. More emphasis could be placed on information from commensal studies if registrants were to conduct such studies for each of the nine rodenticides and using focal species that feed on rats and/or mice. One commensal study was undertaken with potential exposure of barn owls to brodifacoum-poisoned rats and mice on farms in New Jersey[50]. That study provided a wealth of information on barn owl biology, but found that the owls fed predominantly on voles, not rats and mice. Other avian and mammalian predators and scavengers, as well as avian and mammalian primary consumers, need to be addressed in commensal settings.

Comment 26: Syngenta questions why EFED cited residues in a possum "when the issue is with birds". [11]

EFED Response to Comment 26: The Agency's issue of residue levels and risks to nontarget animals is not limited to birds but also includes nontarget mammals.

Comment 27: EPA has not used residue data to quantify secondary exposure. [18, 21, 23]

EFED Response to Comment 27: Residue data alone do not quantify exposure. However, the presence of residue in animals that have eaten bait does confirm exposure and potential risk. [see also EFED Response to Comment 1]

[50] Hegdal, P.L. and R. W. Blaskiewicz. 1984. Evaluation of the potential hazard to barn owls of talon (brodifacoum bait) used to control rats and house mice. Environ. Toxicol. Chem. 3:167-179

Comment 28: The greatest risk to nontarget wildlife is from over-the-counter rodenticides available for unregulated homeowner use. [1]

EFED Response to Comment 28: This is an issue that will be addressed during the mitigation phase of reregistration.

Comment 29: The 2000 draft of the comparative risk assessment contains important statements about birds and mammals that are omitted from the version released to the public. [5]

EFED Response to Comment 29: The initial version of the Agency's comparative risk assessment contained information related to possible risk mitigation. OPP management decided that those issues would best be addressed during the mitigation phase of reregistration and not in the risk assessment.

Comment 30: The true impacts of brodifacoum on birds of prey are understated. [6]

EFED Response to Comment 30: As stated in the comparative risk assessment, EFED believes that brodifacoum poses a potentially high risk to birds of prey exposed to primary consumers of brodifacoum bait. The incident data confirm that birds of prey, especially owls (e.g., great horned owl), hawks (e.g., red-tailed hawk), and eagles (e.g., golden eagle), are being exposed to brodifacoum, and the toxicity data demonstrate that brodifacoum is very highly toxic to birds. Thus, preliminary information on both exposure and hazard indicate potential risk to birds of prey, as do the available incident data.

Comment 31: The RRTF disputes long-term bioaccumulation, because binding sites in the liver are limited. [10]

EFED Response to Comment 31: The RRTF has not provided any documentation to support this assertion. Moreover, as we note in the *"Incident Data: Birds and Nontarget Mammals*" section of the comparative risk assessment, retention and accumulation of anticoagulants is not limited to the liver but occurs in other organs and tissues as well. Concentrations in the liver are often, but not always, higher than in other tissues. However, because the liver comprises only about 4 to 7% of the weight of a rat or mouse (Newton et al. 1990[51], Howald et al. 1999[52]), most residue actually may accumulate in other parts of the carcass. For example, Newton et al. (1990) reported a much higher mean residue concentration in liver (2.13 $\pm$ 0.33 ppm) than in the remainder of the carcass (0.36 $\pm$ 0.05 ppm) of 10 mice fed brodifacoum bait. However, the mean total amount of residue in the carcass (without the liver) was 11.85 $\pm$ 1.54 ppm versus only 3.51

[51] Newton, I., I. Wyllie, and P. Freestone. 1990. Rodenticides in British barn owls. Environmental Pollution 68:101-117

[52] Howald, G.R., P. Mineau, J.E. Elliott, and K.M. Cheng. 1999. Brodifacoum poisoning of avian scavengers during rat control on a seabird colony. Ecotoxicol. 8:431-447

± 0.66 ppm in the liver. The section of the comparative risk assessment entitled *"Comparative Toxicokinetics: Absorption, Metabolism and Excretion of Anticoagulants"* also discusses some of the residue levels detected in various organs and tissues of exposed animals.

Comment 32: Regarding diphacinone, the RRTF and HACCO, Inc. note that residue data in ground squirrels (EPA MRID nos 435346-01 and -02) were not included in the risk assessment, and the "wrong" rat LD50 is used. Also, they believe that EFED should accept a secondary-hazards test with the rat (Bullard et al. 1976[53]) to fulfill a data requirement (70-A-SS) for a secondary-poisoning test with a mammalian predator or scavenger. [10, 14]

EFED Response to Comment 32: Based on the EPA MRID numbers provided by the registrant, EFED has obtained copies of the efficacy field tests in which residues were determined in ground squirrels. We have included those data in the refined risk assessment. Regarding the rat LD50, the existence of a "core" study does not mean that the results from other scientifically sound studies, albeit ones which deviated in minor ways from Agency guidelines, should be ignored. In a preliminary risk assessment, the Agency typically uses the toxicity values for the most sensitive organisms tested in scientifically sound studies in the assessment of risk. A refined assessment will attempt to address the magnitude and likelihood of the risk based on a distribution of available data, if sufficient data exist to make such an analysis.

The Rodenticide Cluster RED issued in July, 1998, required secondary toxicity studies with a mammalian predator and an avian predator to support reregistration of 0.005% ai and 0.01% ai diphacinone baits. More than five years have passed without diphacinone registrants providing the required data. The Bullard et al. (1976) study does not fulfill this data requirement for several reasons. Because the rat is a target species for all diphacinone products with commensal uses, it isn't considered to be of ecological or regulatory relevance for fulfilling a data requirement for a nontarget species. Moreover, the rats were fed only liver tissue from cattle sublethally dosed with diphenadione. Cattle are not a target species, they were only sublethally dosed, and only liver tissue was fed to the rats. At this time, a more appropriate question is why haven't diphacinone registrants addressed the outstanding data requirements rather than attempting to cite inadequate and inappropriate data.

Comment 33: Syngenta asks why the Agency assumes that incidents with avian and mammalian predators and scavengers are the result of secondary exposure. "The incident data is principally based upon carcass autopsies and thus cannot determine the route of exposure. It is unknown." [11]

EFED Response to Comment 33: For predator and scavengers, EFED simply states that poisoning was likely due to secondary exposure based on the species involved and their food habits. We acknowledge that tertiary exposure likely occurs as well. However, it seems highly

[53] Bullard, R.W., R.D. Thompson, and G. Holgvin. 1976: Diphenadione (diphacinone) residue in tissue of cattle. J. Agric. Food Chem. 24:261–263.

unlikely that species such as the great horned owl, red-tailed hawk, golden eagle, or weasels would consume bait, and registrants have provided no information that primary exposure is important for these species. Nevertheless, we realize that some omnivores may eat bait as well as poisoned animals, and the actual routes of exposure may be unknown for some species. For example, we do know that dogs will consume rodenticide baits[54] [see also EFED Response to Comment 15], and it is feasible that wild canids (e.g., coyote, kit fox, red fox) may do so in addition to capturing and feeding on dead and dying rodents and nontarget birds and mammals that have eaten bait.

Comment 34. Syngenta claims that dog LD50 values are incomplete for brodifacoum, and that the Agency has been given other publications with more robust LD50 values than the 0.25 to 1 mg/kg value cited in the comparative assessment. They state that the definitive dog LD50 of 3.56 mg/kg was established in New Zealand (M.E.R. Godfrey, 1981, New Zealand J. Expt. Agriculture 9:147-149). [11]

EFED Response to Comment 34: EFED has utilized the toxicity data submitted by registrants to support the registration of brodifacoum. Those data are submitted to OPP's Health Effects Division (HED) and are provided in HED's "Tox Oneliners' database. For brodifacoum, the database contains only one acute-oral toxicity study with the dog, and EFED has cited that value in the comparative risk assessment. The database does contain results of a dog study from New Zealand in 1981 (EPA MRID No. 251781), but that was an antidote study in which the dosed dogs also were treated with vitamin K. To use an LD50 derived from an antidote study would be misleading and inappropriate.

Comment 35: Zinc phosphide liberates phosphine, not phosgene as stated in two instances in the risk assessment. [15]

EFED Response to Comment 35: This has been corrected in the refined risk assessment.

Comment 36: Data in Diaz and Whitacre (1976)[55] indicate that elimination of diphacinone in the rat is rapid and similar to chlorophacinone. These data were not included in Table 37 or in EPA's analysis, which relied only on elimination data for blood and liver. [10]

EFED Response to Comment 36: These data are discussed in the risk assessment. The tabulated data are half-lives and retention times (days). Those values are not obtainable from Diaz and Whitacre (1976); as stated in the risk assessment, nearly a third of the dose administered was not recovered in the study, which limits its usefulness.

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[54] e. g., Marsh, R.E. 1985. Are anticoagulant rodenticides a problem for household pets? Pest Control 53(8):20-22,24 and 53(9):26-28,31

[55] Diaz, L.I. and D.M. Whitacre. 1976. Excretion and retention of ^{14}C-diphacinone in rats. Unpubl. report, submitted by Velsicol Chemical Corporation. 8 pp

Comment 37: The risk assessment states that difethialone is expected to pose similar risks to brodifacoum due to their very similar chemical structures. It does not, however, make this conclusion for diphacinone and chlorophacinone, which also differ by only one atom in their structures. Rather, in some areas, it reaches relatively different conclusions about these two compounds. How can these dissimilar conclusions be justified? [15]

EFED response to Comment 37: This comment is somewhat misleading. The risk assessment actually says the conclusions of comparable risks for brodifacoum and difethialone are assumed based not only on very similar chemical structures but also on nearly identical acute-toxicity profiles and physical/chemical properties (see "*Attachment A: Chemical Structures and Selected Physical/Chemical Properties of the Rodenticides*" and the toxicity tables in the comparative risk assessment). In contrast, although chlorophacinone and diphacinone have similar chemical structures, they differ to a greater extent in their toxicity and physical/chemical structures. Additionally, some secondary-hazards data are available for both chlorophacinone and diphacinone, whereas secondary-hazards data have not been submitted for difethialone.

A more relevant question is why hasn't LiphaTech, Inc. submitted secondary-hazards data for difethialone. EFED is aware that a paper involving difethialone secondary-hazards information for birds and mammals was presented at a symposium[56], although the performing laboratory (National Wildlife Research Center) declined to provide any additional details on the study when they were contacted. Subsequently, at a meeting with OPP in September of 2001, LiphaTech, Inc. stated that they had contracted the study and would submit it for review. They have not done so, even though submission of adverse-effects data is required under FIFRA 6a(2) reporting.

Comment 38: APHIS and TZPC question why EFED hasn't used use information they provided to an EFED reviewer at a meeting in 1996. [16, 17]

EFED response to Comment 38: EFED welcomed any relevant use data for zinc phosphide and the other rodenticides. We are not aware of the information referred to, which apparently was use information from the early to mid-1990s, and there is no such information in EFED's zinc phosphide chemical file. However, we do question whether use data from more than 10 years ago would be relevant at this time. APHIS and the ZPC had ample opportunity to provide up-to-date usage data during the comment periods. [see also EFED Response to Comment 3]

ATTACHMENT 2

[56] Goldade, D.A., P.J. Savarie, J.C. Hurley, S.A. Gaddis, and J.J. Johnson. 2001. Design of a laboratory secondary hazard study. Pages 146-156 in J. J. Johnston (ed.), Pesticides and Wildlife. American Chemical Society Symposium Series 771

Field and Other Outdoor Uses of Zinc Phosphide, Diphacinone, and Chlorophacinone for Control of Rodents and Other Mammalian Pests

Note: The tabulated information is based on a review of registered product labels current as of May 2005. Several labels were not available for review; thus, the information may not be complete. However, EFED believes that the majority of uses and target species have been captured in this table. Due to the variety of target species and use sites, the tables are arranged differently for zinc phosphide and diphacinone and chlorophacinone, but each table provides information on use sites, target species, application methods, application rates and intervals if specified on product labels, and whether prebaiting is required for zinc phosphide uses. Only the common names of target species are presented in the tables; the scientific names are listed after the last table.

Zinc Phosphide:

Many zinc phosphide baits are formulated as 2% ai (20,000 ppm) grain (corn, oats, wheat, barley, rye, millet, milo) baits or grain-based pellets. Other baits include 3.25 % ai meat-based baits (ground meat, canned dog or cat food, or dry meat-based pet food), 3.25% ai sunflower-seed baits, and 1% ai baits made with fruit (grapes, mulberry, apricots, figs, apples, pears), nuts (unspecified types), vegetables (carrots, sweet potato, potato, cabbage), or fresh vegetation (alfalfa, dandelions, beet tops). A 1% ai grain bait is registered for use only in California. Prebaiting with untreated bait for 2-3 days prior to bait application is recommended, but not required, for some uses as noted in the table.

Zinc Phosphide registered field/outdoor uses				
Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
Around Buildings:				
White-footed mouse Voles [also includes commensal rats and mice]	Hand Baiting and/or Bait Stations; Baits include: · Meats (ground meat, canned or dry dog or cat food) · Gains (wheat, oats, barley, rye, milo, or millet) · Fruits (grapes, mulberry, apricots, figs, apples, pears) · Sunflower seeds · Nuts · Vegetables (carrots, sweet potato, cabbage, potato) · Greens (alfalfa, dandelions, beet tops)	not specified	unlimited	no
Orchards (dormant season only) and/or Groves:				
White-footed mouse Voles Ground squirrels (CA only)	Aerial or Ground Broadcast Machine Baiting Bait Stations Hand Baiting note: includes sunflower-seed baits	6-10 3-6 not specified 2-3 or not specified	unlimited	no
Ground squirrels	Ground Broadcast Hand Baiting note: includes fruit and vegetable baits	6 not specified	≥30-day int. unlimited	yes
Woodrats	Hand Baiting	not specified	unlimited	no
Cotton rat Voles Ground squirrels	Hand Baiting (CA only)	not specified	unlimited	yes

Zinc Phosphide registered field/outdoor uses				
Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
Commensal rats	Hand Baiting (CA only)	not specified	every 3 mo.	yes
Vineyards:				
White-footed mouse Voles	Aerial or Ground Broadcast Trail Builder (mechanical) Hand Baiting note: includes fruit and sunflower-seed baits	6-10 2-3 3-5	unlimited	no
Ground squirrels	Ground Broadcast Hand Baiting note: includes fruit and vegetable baits	6 not specified	$\geq$30-day int.	yes
Voles Native mice	Ground Broadcast	6-10	unlimited	no
Ground squirrels	Ground Broadcast Hand Baiting (CA only)	6-10	unlimited	yes
Ground squirrels Voles Cotton rat	Hand Baiting (CA only)	not specified	unlimited	yes
Commensal rats	Hand Baiting	not specified	every 3 mo.	yes
Rangeland (including adjacent timber areas in MT and WY only):				
Ground squirrels	Hand Baiting	not specified	unlimited	yes
Ground squirrels	Aerial or Ground Broadcast Hand Baiting (CA only)	6-10 not specified	1 1	yes
Voles	Aerial or Ground Broadcast (CA only)	6	1	yes

Zinc Phosphide registered field/outdoor uses				
Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
Voles White-footed mouse	Aerial or Ground Broadcast Trail Builder Hand Baiting	6-10 not specified not specified	unlimited	no
	Trail Builder (mechanical) Hand Baiting	2-3 3-5	unlimited	no
Woodrats Kangaroo rats	Hand Baiting	not specified	unlimited	no
Woodchuck Marmot Black-tailed jackrabbit	Hand baiting	not specified	unlimited	yes
Moles Pocket gophers	Burrow Builder (mechanical)	2-3	unlimited	no
Commensal rats	Hand Baiting (CA only)	not specified	every 3 mo.	yes
Rangeland and Pastures in ND, SD, NE, KS, OK, TX, NM, AZ, CO, MT, UT, NV, and WY:				
Prairie dogs	Hand Baiting note: treatments can be made only from July to February	not specified	1	yes
Ground squirrels	Aerial or Ground Broadcast (MT only) Hand Baiting (MT and WY only)	$\leq$6	unlimited	yes
Reforestation areas and/or Forest areas:				
Voles White-footed mouse	Aerial or Ground Broadcast Trail Builder (mechanical) Hand Baiting	6-10 2-3 or ns 3-5 or ns	unlimited	no
Pocket gophers	Burrow Builder (mechanical) Hand Baiting	1-3 not specified	unlimited	no
Noncrop Rights-of-way:				

Zinc Phosphide registered field/outdoor uses				
Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
Ground squirrels	Hand Baiting	not specified	unlimited	yes
Voles	Aerial or Ground Broadcast	6-10	unlimited	yes
Voles	Ground Broadcast	≤6	1	yes
Ground squirrels	Ground Broadcast Hand Baiting note: includes fruit and vegetable baits	6	≥30-day int.	yes
Woodrats Kangaroo rats Ground squirrels Voles Cotton rat	Hand Baiting	not specified	unlimited	no
Commensal rats	Hand Baiting (CA only)	not specified	every 3 mo.	yes
Pocket gophers	Burrow Builder (mechanical) Hand Baiting	1-3 not specified	unlimited	no
Sugarcane Fields:				
Commensal rats Native rats	Aerial or Ground Broadcast	5	4	yes
Noncrop areas:				
Voles White-footed mouse	Ground Broadcast Trail Builder (mechanical) Hand Baiting	6-10 2-3 3-5	unlimited	yes
Woodchuck Marmot Black-tailed jackrabbit Kangaroo rats Ground squirrels	Hand baiting	not specified	unlimited	yes

Zinc Phosphide registered field/outdoor uses				
Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
Voles Moles				
Ground squirrels	Aerial or Ground Broadcast (MT only)	≤6	unlimited	yes
Pocket gophers	Burrow Builder (mechanical) Hand Baiting	2-3 not specified	unlimited	no
Sugar beets (CA only):				
Voles	Aerial or Ground Broadcast note: aerial allowed only for overwintered beets	5-10	2 (30 day int.)	yes
Macadamia Nut Orchards and Noncrop Sites Adjacent to Orchards (HI):				
Commensal rats	Aerial or Ground Broadcast Bait Stations Burrow Treatment	5 not specified not specified	4	no
Pastures:				
Voles White-footed mouse	Aerial or Ground Broadcast Trail Builder (mechanical) Hand Baiting	6-10 2-3 3-5	unlimited	no
Ground squirrels	Ground Broadcast Hand Baiting	6 not specified	≥30-day int.	yes
Woodchuck Marmot Black-tailed jackrabbit Woodrats Ground squirrels	Hand baiting	not specified	unlimited	yes
Tree farms:				
Woodrats Kangaroo rats	Hand Baiting	not specified	unlimited	no

Zinc Phosphide registered field/outdoor uses				
Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
Nurseries, and/or Ornamentals, Highway medians, Plantings of nonbearing fruit trees, Conifer/Christmas trees:				
Voles Ground squirrels	Hand Baiting	not specified	unlimited	yes
Voles	Ground Broadcast Hand Baiting	6-10 2-3	unlimited	no
Voles White-footed mouse	Aerial or Ground Broadcast Trail Builder (mechanical) Hand Baiting	6-10 2-3 3-5	unlimited	no
Ground squirrels	Ground Broadcast Hand Baiting	6 not specified	$\geq$30-day int. unlimited	yes
Voles White-footed mouse	Ground Broadcast Trail Builder (mechanical) Hand Baiting	6-10 2-3 3-5	unlimited	yes
Commensal rats	Hand Baiting (CA only)	not specified	every 3 mo.	yes
Pocket gophers	Burrow Builder (mechanical) Hand Baiting	2-3 not specified	unlimited	no
Ground squirrels Voles Cotton rat Norway rat Roof rat	Hand Baiting	not specified	unlimited	yes
Berry production (blueberry, blackberry, gooseberry, boysenberry, raspberry, strawberry):				
Voles White-footed mouse	Ground Broadcast Trail Builder (mechanical) Hand baiting	6-10 3-4 3-5	unlimited	no
Croplands:				
Pocket gophers	Burrow Builder (mechanical) Hand Baiting	1-3 not specified	unlimited	no

Zinc Phosphide registered field/outdoor uses				
Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
Moles Pocket gophers	Hand Baiting	not specified	unlimited	no
Ground squirrels	Hand Baiting (MT only)	≤6	unlimited	yes
***Corn Fields (no-till and minimum -tillage operations in OH only)**:*				
Voles House mouse	Aerial or Ground Broadcast Planter Application	6-10 4-6	1-2 1	no
Alfalfa and/or Timothy Hay Fields:				
Meadow voles	Aerial or Ground Broadcast (after cuttings) (CA only)	6-10	2 (30-day int.)	yes
Meadow vole	Bait Stations	not specified	unlimited	no
Pocket gophers	Burrow Builder (mechanical) Hand baiting	2-3 not specified	unlimited	no
Ground squirrels	Hand Baiting (MT only)	≤6	unlimited	yes
Uncultivated Agricultural Areas (CA only):				
Voles	Aerial or Ground Broadcast	6-10	unlimited	yes
Commensal rats	Hand Baiting	not specified	unlimited	yes
Waterways (streams, lakes, canals, ponds, bayous), Croplands, Turf:				
Muskrat Nutria	Baiting on anchored rafts (4' x 4' or 6" x 6")	not specified	≥30-day int.	yes
Rights-of-way:				
Voles White-footed mouse	Ground Broadcast Trail Builder (mechanical) Hand Baiting	3-10 2-3 3-5	unlimited	yes
Ground squirrels	Ground Broadcast	6	≥30-day int.	yes

Zinc Phosphide registered field/outdoor uses				
Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
	Hand Baiting			
Ground squirrels Woodrats Voles Cotton rat	Hand Baiting (CA only)	not specified	unlimited	yes
Voles	Aerial or Ground Broadcast (CA only)	6-10	unlimited	yes
Commensal rats	Hand Baiting (CA only)	not specified	every 3 mo. or not spec.	yes
Along fence rows:				
Ground squirrels	Ground Broadcast Hand Baiting	6 not specified	≥30-day int.	yes
Crop rights-of-way and/or Noncrop borders :				
Ground squirrels	Ground Broadcast Hand Baiting	6 not specified	≥30-day int.	yes
Voles	Aerial or Ground Broadcast (CA only)	6-10	unlimited	yes
Commensal rats	Hand Baiting (CA only)	not specified	every 3 mo.	yes
Recreational Areas (e.g., campgrounds):				
Voles	Aerial or Ground Broadcast (CA only)	6-10	unlimited	yes
Commensal rats	Hand Baiting (late spring and summer only)	not specified	unlimited	yes
Areas inhabited by Cotton Rats and "Field Mice":				
Cotton rat Voles White-footed	Ground Broadcast Hand Baiting	6-10 2-3	unlimited	no

Zinc Phosphide registered field/outdoor uses				
Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
mouse				
Rural Noncrop Sites Surrounding Residential and Resort Areas (HI only):				
Roof rat Polynesian rat House mouse	Aerial or Ground Broadcast	5	4	no
Lawns, Golf Courses, Others (e.g., parks, turf and grass fields):				
Moles Pocket gophers	Burrow Builder (mechanical) Hand Baiting	1-3 not specified	unlimited	no
Voles White-footed mouse	Ground Broadcast Trail Builder (mechanical) Hand Baiting	6-10 2-3 3-5	unlimited	yes
Ground squirrels	Ground Broadcast Hand Baiting note: includes fruit and vegetable baits	6 not specified	≥30-day int.	yes
Cotton rat Voles Ground squirrels	Hand Baiting (CA only)	not specified	unlimited	yes
Grasses Grown for Seed (OR only):				
Voles Deer mouse House mouse Ground squirrels	Ground Broadcast Hand Baiting note: limitations exist on timing and extent of area that can be treated at any one time	6-10 2-3	4 (per treated area)	no
Cottonwood/Hybrid Poplar Plantations (OR only) and Adjacent Noncrop Areas (WA only):				
Voles	Aerial or Ground Broadcast	5-10	unlimited	no
Sugar Maple Orchards (VT only):				

Zinc Phosphide registered field/outdoor uses				
Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre-bait?
Red squirrel Chipmunk Deer mouse	Bait Stations (November 1 to May 31 only)	1.5	7	yes

Diphacinone:

Most diphacinone baits are 50 ppm ai grain-based pellets or treated grains, but California also has 100 ppm ai baits for some uses as indicated in the table below. As of May 2005, 46 Special Local Needs (SLNs) registrations exist for 25 states and the Virgin Islands. Seven national registration (section 3's) products include the "wet areas" labeling for field control of commensal rats and mice.

Diphacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
National registrations (§3's):			
All	Wet or damp areas, such as: Riverbanks Gullies Irrigation ditches Garbage dumps Landfills	Rats: Norway Roof House mouse	50 ppm grain-based "cakes" or blocks (including some peanut-flavored products); for rats, apply 4-16 ounces at 15- to 30-ft intervals; for mice, apply 1-oz. pieces at 8- to 12-ft intervals; for rats and mice, maintain an uninterrupted supply of fresh bait for at least 10-15 days or until signs of activity cease
All	Wet or damp areas, including: Riverbanks Gullies Irrigation ditches Railroad tracks In and around rat holes Along fences Garbage dumps Landfills	Rats: Norway Roof House mouse	50 ppm food bait; for rats, apply 2-8 bait packs per bait placement and maintain uninterrupted supply of bait for at least 10 days; for mice, open bait pack and apply 1/4-1/2 oz. bait at 8- to 12-ft intervals and maintain uninterrupted supply of bait for at least 15 days

Diphacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
All except as noted	River banks Irrigation ditches Gullies Railroad tracks Fences Sanitary landfills	Rats: Norway Roof House mouse	a 'restricted-use' 50 ppm food bait; for rats apply 4-16 oz. bait at 15- to 30-ft intervals and maintain an uninterrupted supply of bait for at least 10 days or until signs of activity cease; for mice, apply 1/4 to ½ oz. of bait at 8- to 12-ft intervals and maintain an uninterrupted supply of bait for at least 15 days or until signs of activity cease; outdoor placements other than around buildings must be made in tamper-resistant bait stations or deeply into rat burrows
	Fruit tree orchards (bearing and nonbearing, including apples, pears, peaches, nectarines) in the following states: CT, GA, ID, MA, MI, MO, MT, NC, NH, OH, OR, PA, SC, UT, VA, VT, WA, WV Nut orchards (pecans, almonds, walnuts, filberts/hazelnuts) in the following states: ID, OH, MT, OR, WA Christmas tree farms, Commercial nurseries, and Tree plantations in the following states: GA, MI, MO, NC, SC, WA	Voles: Meadow Pine	50 ppm 'restricted use' bait applied after fall harvest; broadcast bait uniformly at 20 lb bait/acre for pine voles and 10 lb bait/acre for meadow voles with commercially-made seed or fertilizer spreader or (except in CT, GA, MA, MO, NC, NH, SC) by aerial application; alternatively, handbaiting can be done at 10 lb bait/acre by placing bait in active holes, trails, or runways at each tree site; for all methods, a second application can be made after 1-2 months
All	Rangeland Forest areas Grain fields Alfalfa crops Vegetable crops	Pocket gophers: Valley Northern Mazama Townsend's	50 ppm grain bait applied manually into underground gopher burrows

Diphacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
	Golf courses Parks Nurseries Around homes	Giant Sierra Plains	
All	Levees Ditch banks Around farm buildings Fence lines Orchards Crop areas Noncrop areas	California ground squirrel	50 ppm oat bait applied in bait stations 20- to 100-feet apart; use 2-4 lb bait per station and maintain an uninterrupted supply of bait for at least 30 days or until all signs of feeding have stopped
All	Lawns Turf Golf courses Other non-food grassy areas	Moles: Eastern Star-nosed Hairy-tailed Coast Broad-footed Townsend	50 ppm gel bait injected into active burrow systems through probe or shovel hole; make 6 ½ oz. placements per burrow system
State registrations (Special Local Need, §24c's):			
AK	Alaska Maritime National Wildlife Refuge islands	Rats: Norway Black	50 ppm fish-flavored grain bait applied in bait stations or placed in burrow openings; use restricted to Certified Applicators or persons under their direct supervision
AZ	Levee and ditch banks Fence lines Around farm buildings Orchards Other crop areas Other noncrop areas	California ground squirrel	50 ppm grain/nut bait applied in bait stations (2-4 lb bait per station) spaced at 20- to 100-ft. intervals; maintain an uninterrupted supply of bait for at least 15 days or until all signs of feeding cease; use restricted to Certified Applicators or persons under their direct supervision
CA	Levee and ditch banks Fence lines Around farm buildings Orchards	California ground squirrel	50 ppm grain/nut bait applied in bait stations (2-4 lb bait per station) spaced at 20- to 100-ft. intervals; maintain an uninterrupted supply of bait for at least

Diphacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
	Other crop areas Other noncrop areas		15 days or until all signs of feeding cease; use restricted to Certified Applicators or persons under their direct supervision
	Vineyards Orchards Groves Rangelands Noncrop borders Fallow lands Fence rows Rights-of-way adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities Campgrounds Recreational areas Horticultural nurseries Plantations of forest trees Around livestock pens	Ground squirrels: California Belding's	***100 ppm bait:*** ground (mechanical spreader) or aerial broadcast bait at 10 lb bait/acre; make a second application after 4 days ***50 ppm bait:*** apply in bait stations (1-5 lb per station) spaced at 20- to 100-ft intervals and replenish as needed; or, scatter bait near active burrows and runways, making a second application after 4 days but applying no more than 10 lb bait/acre per treatment
	Campgrounds Recreational areas Noncrop borders Fallow lands Fence rows Rights-of-way adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities Horticultural nurseries Plantations of forest trees	Golden-mantled ground squirrels Chipmunks	50 ppm bait applied at 4-16 oz. per station in bait stations spaced at 20- to 50-ft intervals and replenished as needed
	Vineyards Orchards Groves	Pocket gophers	100 ppm bait applied directly into underground gopher tunnels

Diphacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
	Rangelands Forage crops Grain and edible seed crops Oil crops Fiber crops Fruits Vegetables Noncrop areas Fallow lands Rights-of-way adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities Campgrounds Recreational areas Horticultural nurseries		
	Crop areas Noncrop areas		50 ppm food bait applied by hand or mechanical 'burrow builder' into underground burrow sustems; use restricted to Certified Applicators or persons under their direct supervision
	Vineyards Orchards Groves Rangelands Fruit-tree plantations Noncrop borders Fallow lands Rights-of-way adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities Campgrounds Recreational areas Horticultural nurseries Plantations of forest	Deer mice	***100 ppm bait:*** ground (mechanical spreader) or aerial broadcast bait at 2-6 lb bait/acre; make a second application after 4 days ***50 ppm bait:*** scatter bait near burrow openings or where activity detected; make a second application after 4 days; do not apply more than 6 lb bait/acre per treatment

Diphacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
	trees Reforestation areas		
	Unspecified sites	Ground squirrels: California Belding's	100 ppm bait scattered by hand near active burrows or runways; retreat every other day for 3 to 4 applications
	Vineyards Orchards Groves Rangelands Noncrop borders Fallow lands Fence rows Rights-of-way adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities Campgrounds Recreational areas Horticultural nurseries Plantations of forest trees	Voles: California Montane	***100 ppm bait:*** ground (mechanical spreader) or aerial broadcast bait at 6-10 lb bait/acre; make a second application after 4 days ***50 ppm bait:*** scatter bait near burrow openings or where activity detected; make a second application after 4 days; do not apply more than 10 lb bait/acre per treatment
	In and around cabins Citrus tree plantations Conifer plantations	Woodrats	50 ppm bait applied in bait stations
	None specified	Woodrats Roof rat	50 ppm bait block placed in trees near damage areas
	Natural and man-made waterways and wetlands adjacent to agricultural crops, rangelands, noncrop borders, uncultivated agricultural areas, and rishts-of-way	Muskrat	50 ppm bait applied in floating bait stations on anchored rafts; replenish bait as needed
	Ditches Waterways	Muskrat	50 ppm bait block placed near burrows, runways, or where activity seen

Diphacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
	Infested ditch banks Lumber and rubbish piles	Norway rat Roof rat House mouse	50 ppm bait block placed in areas where they feed, drink, or frequent
	Borders of agricultural crops Rangelands Fallow lands Fence rows Rights-of-way adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities Campgrounds Recreational areas Horticultural nurseries Plantations of forest trees Airports	Jackrabbit	50 ppm bait applied in covered self-dispensing feeders or enclosed nursery flats near runways or resting or feeding areas; replenish bait as needed
CT	Fruit-tree orchards	Voles: Meadow Pine	50 ppm pelleted bait ground-broadcast at 10 and 20 lb per infested acre for meadow voles and pine voles, respectively; or, hand-baited at 10 lb/acre in active burrows or runways; may reapply once after 1-2 months by either method
FL	Ditch banks Levees Fence rows Tall grass Other noncrop areas adjacent to fields	Rats: Norway Roof Cotton Florida water rat Mice	50 ppm fish-flavored pelleted bait applied in bait boxes no more than 20 to 30 feet apart
HI	Forests Offshore islands Other noncrop outdoor areas	Mongoose Rats: Norway Roof	50 ppm fish- or molasses/peanut butter flavored bait blocks applied in bait stations; 2 of 5 products are for use only by Certified Applicators or

Diphacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
	Macadamia nut orchards	Polynesian House mouse	persons under their direct supervision
ID	Field perimeters of small-grain crops Orchards (tree fruits and nuts)	Voles	50 ppm pelleted bait applied in bait stations around grain crops; for orchards, broadcast 10 lb per acre by air or ground or apply in tunnels; a second application can be made after 20-40 days
	Levees ditch banks Around farm buildings Fence lines Orchards Other crop and noncrop areas	Ground squirrels: California Columbian Townsend Washington	50 ppm food bait applied in bait stations at 20- to 100-foot intervals
MA	Orchards (tree fruits)	Voles: Meadow Pine	50 ppm pelleted bait applied at 10 lb bait/acre by ground broadcast for meadow voles and by in-tunnel application for pine voles; for either species, a second application can be made after 20-40 days
MI	Orchards (tree fruits) Christmas tree plantations	Meadow vole	50 ppm fish-flavored pelleted bait broadcast by air or ground or hand-baited at 10 lb bait per acre; a second application can be made after 1-2 months
MO	Orchards Christmas tree plantations Commercial nurseries Tree plantations	Voles: Meadow Pine Prairie	50 ppm fish-flavored bait ground broadcast at 20 lb bait/acre for pine voles and 10 lb bait/acre for meadow and prairie voles or handbaited at 10 lb bait/acre; may reapply once after 1-2 months by either method
MT	Levees Ditch banks Fencelines Orchards	Ground squirrels	50 ppm fish-flavored bait; apply 2-4 lb bait per bait station with stations placed at 20- to 100-foot intervals; bait stations may be maintained on a

Diphacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
	Other crop areas Other noncrop areas Around farm buildings		permanent basis to prevent reinfestation
NC	Orchards Christmas tree farms Commercial nurseries Tree plantations	Voles: Meadow Pine	50 ppm pelleted bait ground broadcast at 20 lb bait/acre for pine voles and 10 lb bait/acre for meadow voles or handbaited at 10 lb bait/acre; may reapply once after 1-2 months by either method
NH	Tree fruits	Voles: Meadow Pine	50 ppm pelleted bait applied at 10 lb bait/acre by ground broadcast for meadow voles and by in-tunnel application for pine voles; for either species, a second application can be made after 20-40 days
NV	Levees Ditch banks Around farm buildings Fence lines Orchards Other crop areas Other noncrop areas	California ground squirrel	50 ppm fish-flavored bait or grain/nut bait applied in bait stations (2-4 lb bait per station) spaced at 20- to 100-foot intervals; maintain baiting for at least 15-30 days or until activity ceases
OH	Orchards (tree fruits)	Voles: Meadow Pine	50 ppm fish-flavored bait ground broadcast at 20 lb bait/acre for pine voles and 10 lb bait/acre for meadow voles or handbaited at 10 lb bait/acre; may reapply once after 1-2 months by either method
OR	Orchards (tree fruits and nuts)	Voles	50 ppm pelleted bait applied at 10 lb bait/acre by aerial or ground broadcast for surface-foraging voles and by in-tunnel application for subsurface root-feeding voles; for either method, a second application can be made after 20-40 days
	Levees	Ground squirrels:	50 ppm grain/nut bait applied in bait

Diphacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
	Ditch banks Around farm buildings Fence lines Golf course Nurseries Orchards Other crop and noncrop areas Residential yards and gardens	California Townsends	stations (2-4 lb bait per station) spaced at 20- to 100-foot intervals; maintain an uninterrupted bait supply for up to 15 days or until feeding activity ceases
PA	Orchards (apples, pears, peaches, nectarines)	Voles: Meadow Pine	50 ppm bait applied by aerial or ground broadcast or handbaited at 10 lb bait/acre; second application allowed after 1-2 months
SC	Orchards Christmas tree farms Commercial nurseries Tree plantations	Voles: Meadow Pine	50 ppm bait ground broadcast at 20 lb bait/acre for pine voles and 10 lb bait/acre for meadow voles or handbaited at 10 lb bait/acre; may reapply once after 1-2 months by either method
UT	Orchards	Voles	50 ppm pelleted bait
VA	Orchards (apples, pears, peaches, nectarines)	Voles: Meadow Pine	50 ppm bait applied by aerial or ground broadcast or handbaited at 10 lb bait/acre; second application allowed after 1-2 months
VT	Orchards (tree fruits)	Voles: Meadow Pine	50 ppm fish-flavored pelleted bait applied at 10 lb bait/acre by aerial or ground broadcast for meadow voles and by in-tunnel, handbait, or bait-station application for pine voles; for either method, a second application can be made after 20-40 days
WA	Small grains for seed production	Meadow vole	50 ppm bait for aerial or ground broadcast at 10 lb bait/acre; 3 applications allowed at 20- to 40-day intervals

Diphacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
	Orchards (tree fruits and nuts)	Meadow vole	50 ppm bait for aerial or ground broadcast at up to 20 lb bait/acre per application; 2 applications allowed at 20- to 40-day intervals
	Levees Ditch banks Around farm buildings Fence lines Orchards Other crop and noncrop areas	Ground squirrels: California Columbian Townsend Washington	50 ppm fish-flavored bait applied in bait stations at 20- to 100-foot intervals
WV	Orchards (tree fruits)	Voles: Meadow Pine	50 ppm fish-flavored pelleted bait applied at 10 lb bait/acre by aerial or ground broadcast for meadow voles and by in-tunnel, handbait, or bait-station application for pine voles; for all methods, a second application can be made after 20-40 days
WY	Levees Ditch banks Around farm buildings Fence lines Orchards Other crop and noncrop areas	Ground squirrels	50 ppm fish-flavored bait applied in bait stations at 20- to 100-foot intervals
Virgin Islands	Forests Offshore islands Noncrop outdoor areas	Mongoose Rats: Norway Roof Polynesian House mouse	50 ppm molasses/peanut butter flavored bait blocks applied in bait stations (4-16 ounces bait per station) at 75- to 150-foot intervals; product is for use by or in cooperation with government conservation agencies only

Chlorophacinone:

Most chlorophacinone baits are 50 ppm ai grain-based pellets or treated grains, but California also has 100 ppm ai baits for some uses as indicated in the table below. As of May 2005, there are 21 SLNs in 18 states.

Chlorophacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
National registrations (§3's):			
All	Lawns Golf courses Other turf areas	Moles: Eastern Star-nosed *Scapanus* spp.	100 ppm food bait applied manually in moles' deep tunnels or subsurface runways; several treatments may be necessary
All	Lawns Golf courses Rangeland Alfalfa fields Noncrop areas	Pocket gophers	50 ppm food bait manually inserted into underground burrow systems in 2-3 locations per burrow system; maintain a constant supply of bait for as long as gopher activity occurs
State registrations (Special Local Need, §24c's):			
CA	Vineyards (dormant season) Orchards and Groves (dormant season) Rangelands Noncrop borders Fallow fields Fence rows Rights-of-way (adjacent to canal banks, ditch banks, highways, levees, railroad lines, utilities) Campgrounds Recreational areas Horticultural nurseries Plantations of forest trees In and around livestock buildings (e.g., cattle barns, poultry houses) Livestock pens	Ground squirrels: California Belding's	***100 ppm grain bait:*** broadcast bait by ground (mechanical spreader) or air at rate of 10 lb bait/acre; make a second application after 4 days ***50 ppm grain bait:*** all sites: apply 1-5 lb bait per bait station, with stations spaced at 20- to 100-ft intervals near active burrows and runways; replenish bait as needed for up to 4 weeks ***note:*** according to OPP/RD, these directions allow 605 lb or more of bait per acre per treatment orchards and groves: as above or scatter 0.1-lb bait over 40-50 sq. feet near active burrows and runways; make a second application after 4 days; do not exceed 10 lb bait/acre per treatment
		Deer mice	***100 ppm grain bait:***

Chlorophacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
			broadcast bait by ground (mechanical spreader) or air at rate of 2-6 lb bait/acre; make a second application after 4 days ***50 ppm grain bait:*** scatter 1 tsp. bait (1/12 ounce) over a 30-sq-ft area near burrow openings or where activity detected; make a second application after 4 days; do not exceed 6 lb bait.acre per treatment
		Voles: California Montane	***100 ppm grain bait:*** broadcast bait by ground (mechanical spreader) or air at rate of 6-10 lb bait/acre; make a second application after 4 days ***50 ppm grain bait:*** scatter 1-2 tbsp. bait (1/4-1/2 ounce) near active burrow openings or in runways; make a second application after 4 days; do not exceed 10 lb bait.acre per treatment
	Campgrounds Recreational areas Noncrop borders Fallow lands Fence rows Rights-of-way (adjacent to canal banks, ditch banks, highways, levees, railroad lines, utilities) Horticultural nurseries Plantations of forest trees	Golden-mantled ground squirrel Chipmunks	50 ppm grain bait applied in bait stations at 20- to 50-ft intervals near active burrows and runways; replenish bait as needed for up to 4 weeks
	Artichoke fields	California vole	100 ppm artichoke-bract baits scattered near burrow openings and runways; 2

Chlorophacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
			additional applications are allowed at 21-day intervals
	Natural and man-made waterways and wetlands adjacent to agricultural crops, rangelands, noncrop borders, uncultivated agricultural areas, and rights-of-way	Muskrat	1-5 lb bait per covered or enclosed bait station secured to small raft anchored or secured to bottom or bank; replenish bait as needed
	Borders of agricultural crops Rangelands Fallow areas Fence rows Rights-of-way (adjacent to canal banks, ditch banks, highways, levees, railroad lines, utilities) Horticultural nurseries Plantations of forest trees Campgrounds Recreational areas	Black-tailed jackrabbit	apply bait in self-dispensing feeders or enclosed nursery flats near runways or nesting or feeding areas; replenish bait as needed
	Orchards Groves Vineyards Forage crops Grain and edible seed crops Oil crops Fiber crops Fruits Vegetables Rangeland Noncrop areas Fallow lands Campgrounds	Pocket gophers	100 ppm grain bait applied directly into underground tunnels

Chlorophacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
	Recreational areas Horticultural nurseries Rights-of-way adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities		
ID	Forest plantations	Meadow vole	Apply bait in spots for 5-7 consecutive days but not to exceed 10 lb bait/acre; a second application is allowed
	Orchards	Voles: Meadow Mountain	Ground broadcast bait at 10 lb bait/acre or handbait in active burrows or runways; a second application is allowed after 1-2 months
KS	Rangeland Noncrop areas	Prairie dog	50 ppm bait applied at least six inches down prairie dog burrows; applied between October 1 and March 15
MD	Orchards	Meadow vole	Aerial or ground broadcast at 10 lb bait/acre; a second application is allowed after 1-2 months
		Pine vole	Handbait at up to 10 lb bait/acre in active holes or runs; a second application is allowed after 1-2 months
MI	Orchards	Voles: Meadow Pine	Ground broadcast bait (50 ppm) at 10 and 20 lb bait/acre for meadow and pine voles, respectively, or handbait in active burrows and runways at 10 lb bait/acre; a second application is allowed after 1-2 months for either method
MO	Orchards	Voles: Meadow Pine	Handbait at up to 10 lb bait/acre in active holes or runs; a second application is allowed after 1-2 months
MT	Noncrop areas Rangeland	Ground squirrels: Columbian	Scatter 50 ppm oat bait on bare ground by burrows; apply second application

Chlorophacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
	Pasture Alfalfa Wheat Oats Barley	Richardson's	after 4 days
NC	Orchards Commercial nurseries Christmas tree farms Tree plantations	Voles: Meadow Pine	Ground broadcast bait (50 ppm) at 10 and 20 lb bait/acre for meadow and pine voles, respectively, or handbait in active burrows and runways at 10 lb bait/acre; a second application is allowed after 1-2 months for either method
NV	Levees Ditch banks Fence lines Around farm buildings Orchards Other crop and noncrop areas	Ground squirrels	Apply 2-4 lb of 50 ppm grain/nut bait in bait stations placed at 20- to 100-foot intervals
NY	Orchards	Voles: Meadow Pine	Handbait at up to 10 lb bait/acre in active holes or runs; a second application is allowed after 1-2 months
OH	Orchards Ornamentals Forestry nurseries	Voles: Meadow Pine	Ground broadcast bait (50 ppm) at 10 and 20 lb bait/acre for meadow and pine voles, respectively, or handbait in active burrows and runways at 10 lb bait/acre; a second application is allowed after 1-2 months for either method
OR	Orchards	Voles: Meadow Pine	Ground broadcast bait (50 ppm) at 10 and 20 lb bait/acre for meadow and pine voles, respectively, or handbait in active burrows and runways at 10 lb bait/acre; a second application is allowed after 1-2 months for either method

Chlorophacinone registered field/outdoor uses			
State	Use sites	Target spp.	Bait/Application methods
PA	Orchards	Voles: Meadow Pine	Ground broadcast bait (50 ppm) at 10 and 20 lb bait/acre for meadow and pine voles, respectively, or handbait in active burrows and runways at 10 lb bait/acre; a second application is allowed after 1-2 months for either method
SC	Orchards	Voles: Meadow Pine	Handbait at up to 10 lb bait/acre in active holes or runs; a second application is allowed after 1-2 months
VA	Orchards	Voles: Meadow Pine	Handbait at up to 10 lb bait/acre in active holes or runs; a second application is allowed after 1-2 months
		Meadow vole	Ground broadcast at 10 lb bait/acre; a second application is allowed after 1-2 months
VT	Orchards	Voles: Meadow Pine	Handbait at up to 10 lb bait/acre in active holes or runs; a second application is allowed after 1-2 months
WA	Orchards (apple, apricot, cherry, nectarine, peach, pear, prune, plum)	Voles	Aerial or ground broadcast at 10 lb bait/acre; a second application is allowed after 1-2 months
WV	Orchards	Meadow vole	Aerial or ground broadcast at 10 lb bait/acre; a second application is allowed after 1-2 months
		Pine vole	Handbait at up to 10 lb bait/acre in active holes or runs; a second application is allowed after 1-2 months

Target Species for Registered Field/Outdoor Uses

Rodents:

Commensal rats and mice:
Norway rat (*Rattus norvegicus*)
Roof rat (*R. rattus*)
Polynesian rat (*R. exulans*)
House mouse (*Mus musculus*)

Ground squirrels:
California ground squirrel (*Spermophilis beecheyi*)
Belding's ground squirrel (*S. beldingi*)
Columbian ground squirrel (*S. columbianus*)
Franklin's ground squirrel (*S. franklini*)
Golden-mantled ground squirrel (*S. lateralis*)
Rock squirrel (*Spermophilus variegatus*)
Townsend's ground squirrel (*S. townsendii*)
Richardson's ground squirrel (*S. richardsoni*)
Round-tailed ground squirrel (*S. tereticaudus*)
Thirteen-lined ground squirrel (*S. tridecemlineatus*)
Unita ground squirrel (*S. armatus*)
Idaho ground squirrel (*S. brunneus*)
Wyoming ground squirrel (*S. elegans*)
Washington ground squirrel (*S. washingtoni*)
Antelope ground squirrel (*Ammospermophilus leucurus*)

Prairie dogs:
White-tailed prairie dog (*Cynomys leucurus*)
Black-tailed prairie dog (*C. ludovicianus*)
Gunnison's prairie dog (*C. gunnisoni*)

Marmots:
Yellow-bellied marmot (*Marmota flaviventris*)
Woodchuck (*M. monax*)

Voles:
Meadow vole (*Microtus pennsylvanicus*)
Pine vole (*M. pinetorum*)
Prairie vole (*M. ochrogaster*)
Mountain vole (*M. montanus*)
California vole (*M. californicus*)
Townsend's vole (*M. townsendii*)
Oregon vole (?)

Woodrats:
Easter woodrat (*Neotoma floridana*)
Southern plains woodrat (*N. micropus*)

Whitethroat woodrat (*N. albiqula*)
Desert woodrat (*N. lepida*)
Mexican woodrat (*N. mexicana*)
Dusky-footed woodrat (*N. fuscipes*)
Bushytail woodrat (*N. cinerea*)

Kangaroo rats:
Ord's kangaroo rat (*Dipodomys ordii*)
Merriam's kangaroo rat (*D. merriami*)
Banner-tailed kangaroo rat (*D. spectabilis*)

Pocket gophers:
Botta's (Valley) pocket gopher (*Thomomys bottae*)
Camas pocket gopher (*T. bulbivorus*)
Wyoming pocket gopher (*T. clusius*)
Idaho pocket gopher (*T. idahoensis*)
Mountain (Sierra) pocket gopher (*T. monticola*)
Northern pocket gopher (*T. talpoides*)
Townsend's pocket gopher (*T. townsendii*)
Mazama pocket gopher (*T. mazama*)
Giant pocket gopher (*T. bulbivorus*)
Southern pocket gopher (*T. umbrinus*)
Desert pocket gopher (*Geomys arenarius*)
Plains pocket gopher (*G. bursarius*)
Texas pocket gopher (*G. personatus*)
Southeastern pocket gopher (*G. pinetis*)
Yellow-faced pocket gopher (*Pappogeomys castanops*)

Native mice and rats:
White-footed mouse *(Peromyscus leucopus*)
Deer mouse (*P. manniculatus*)
Oldfield mouse (*P. polionotus*)
Jumping mice (*Zapus spp.*)
Cotton rat (*Sigmodon hispidus*)
Rice rat (*Oryzomys palustris*)
Florida water rat (*Neofiber alleni*)

Others:
Muskrat (*Ondatra zibethicus*)
Nutria (*Myocastor coypus*)
Red squirrel (*Tamiasciurus hudsonicus*)
Eastern chipmunk (*Tamias striatus*)

Lagomorphs:

Black-tailed jackrabbit (*Lepus californicus*)

Insectivores:

Eastern mole (*Scalopus aquaticus*)
Broad-footed mole (*Scapanus latimanus*)
Coast mole (*S. orarius*)
Townsend's mole (*S. townsendii*)
Star-nosed mole (*Condylura cristata*)
Hairy-tailed mole *(Parascalops breweri*)

Carnivores:

Mongoose (*Herpestes auropunctatus*)

ATTACHMENT 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

September 7, 2004

Memorandum

Subject: EFED Response to USDA/APHIS' "Partner Review Comments: Preliminary Analysis of of Rodenticide Bait Use and Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: A Comparative Approach (June 9, 2004)"

To: Laura Parsons, Team Leader
Kelly White
Reregistration Branch 1
Special Review and Reregistration Division

From: William Erickson, Biologist
Environmental Risk Branch 2
Environmental Fate and Effects Division

Through: Tom Bailey, Branch Chief

Environmental Risk Branch 2
Environmental Fate and Effects Division

Attached are EFED's comments on APHIS' review of the comparative rodenticide risk assessment dated June 9, 2004. We have inserted EFED's response after each APHIS comment that pertains to the comparative risk assessment (comment 6 relates to BEAD's benefits assessment). Some of these issues were addressed in EFED's response to registrants' comments during the 30-day "errors-only" comment period in 2001 and comments submitted during the 120-day "public-comments" period from January to May of 2003. The present submission also includes a copy of APHIS' comments from March 31, 2003, and they request that comments 2, 4, 5, 6, 7, 8, and 9 be addressed. EFED addressed those comments in our July 17, 2004 "*Response to Public Comments on EFED's Risk Assessment: "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach", dated December 19, 2002*", and we reiterate our response to those comments as well. We have also attached a table of many zinc phosphide use sites, methods of application, application rates and number of applications permitted, although many product labels do not provide that information. A list of the names of more than 70 target species also is included. [included in Attachment 2]

APHIS' comments and EFED's response to those comments are provided below. The full text of APHIS' comments are in the EDocket.

APHIS comments dated August 4, 2004:

1) APHIS would like to reiterate a serious concern regarding the both the previous and the current drafts of the document we reviewed. This document is not, as stated, "an assessment of potential risk". This draft successfully addresses the hazard aspect of risk. However, the exposure component of risk is not adequately considered. No attempt has been made to address the exposure scenarios that necessarily include application methods, timing, rates, etc. This, therefore, is not a risk assessment. Presumably EPA's overall goal is to mitigate potential risk to non-target birds and mammals. Hazard or toxicity of a chemical is constant. It is only by addressing exposure that risk can be mitigated. Thus exposure cannot be ignored.

EFED Response to Comment 1: EFED is surprised that APHIS continues to insist that there is no exposure of zinc phosphide baits to birds and nontarget mammals. Baits can be formulated with whole grains (wheat, barley, oats, corn, milo, millets), grain-based pellets, fruits (grapes, mulberry, apples, pears, apricots, figs), nuts, sunflower seeds, vegetables (carrots, sweet potato, potato, cabbage), fresh vegetation (alfalfa, dandelions, beet tops), and meat-based products (ground meat, canned or dry meat-based cat or dog foods). Many of these foods are likely to be highly attractive to granivorous, frugivorous, omnivorous, and even carnivorous birds and mammals. Zinc phosphide is registered for controlling more than 70 mammalian species, mostly a variety of rodents, but also lagomorphs (jackrabbits) and insectivores (moles). Zinc phosphide baits are applied (often by multiple aerial, ground-machine (e.g., cyclone spreader), or hand broadcasts) to a wide variety of treatment sites, ranging from in and around buildings to rangeland and pastures, rights-of-way, orchards and groves, vineyards, uncultivated areas,

croplands, waterways, lawns and golf courses, nurseries, ornamentals, forestry, and numerous other sites. A list of treatment sites, application methods, bait formulations, and target species is attached. It should be noted that for many uses, both for commensal and field uses, product labels do not specify either an application rate (lb/acre) nor put any limitations on the number of applications that can be made, other than a few uses with seasonal restrictions. Repeat applications are likely to increase the likelihood of exposure of nontarget organisms.

The issue of quantifying exposure is addressed in the revised comparative risk assessment and in EFED's *Reponse to Public Comments* dated July 17, 2004 and is worth repeating here:

> EFED's risk assessment is in accord with the Agency's Guidelines for Ecological Risk Assessment [Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F, April 1998, Final. 171 pp. http://www.epa.gov/ncea/ecorsk.htm]. Registrants are correct in noting that the Guidelines state that "*Ecological risk assessment is a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors*"(PART A, page 1, paragraph 1). However, the Guidelines go on to state that "*Descriptions of the likelihood of adverse effects may range from qualitative judgments to quantitative probabilities. Although risk assessments may include quantitative risk estimates, quantitation of risks is not always possible. It is better to convey conclusions (and associated uncertainties) qualitatively than to ignore them because they are not easily understood or estimated*" (PART A, page 1, paragraph 3). Refining the exposure assessment to establish a quantitative measure of likelihood of exposure and effects would require a much more extensive data set than registrants have submitted for their rodenticides and for the nontarget species potentially at risk. The Agency provided the preliminary risk assessment to rodenticide registrants in October, 2001 and posted it in the EDocket on EPA's website for public comments from January 29 to May 30, 2003. No additional data or relevant information to refine the exposure assessment has been provided by the registrants or other stakeholders. The necessary data have been outlined in a section on *"Uncertainty and Data Needs*" in the refined assessment. Nevertheless, despite the lack of quantifiable data, the existence of substantial incident data along with liver-residue analysis confirms that birds and nontarget mammals are being exposed and adversely affected by applications of rodenticide baits. The fact that numerous species of birds and mammals, including predators and scavengers, have been found exposed to these baits indicates that both primary and secondary exposures are occurring.
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> EFED's risk conclusions are based on analyses of the available data by a "lines-of-evidence" approach and comparative-analysis modeling. Quantitative estimates of risk are used in both; however, the "lines-of evidence" assessment includes qualitative assessments of secondary risk based on mortality and other adverse effects reported in laboratory and field studies, operational control programs, and incident reports, as well as toxicokinetic data and residue levels reported in primary consumers. This approach is in concert with the Guidelines, which clearly state that professional judgement or other qualitative evaluation techniques are appropriate for ranking risks using categories such as low, medium, and high when exposure and effects data are limited or are not easily expressed in quantitative terms. A "lines-of-

evidence" approach also has been advocated by the Avian Effects Dialogue Group for helping to interpret the variety of information collected during field studies [see Rymph, B. (ed.). 1994. Assessing Pesticide Impacts on Birds: Final Report of the Avian Effects Dialogue Group, 1988-1993. RESOLVE Center for Environmental Dispute Resolution, Washington, DC. 156 pp]. Regarding the lines-of-evidence analysis, one of the expert external peer reviewers stated that "*The bulk of the material in the document addresses the development of the weight of evidence argument. In general this part of the document is well-developed and it is hard to argue with the evident conclusion about each of the nine chemicals. These conclusions are largely implicit in the text since the task of deriving a formal assessment for each chemical is passed over to the decision support analysis. The case about each chemical is thoroughly and logically developed in this part of the document and the document is commendable in showing how the Agency staff have been able to develop the weight of evidence approach as a viable approach to the synthesis of a complex body of evidence*." The three expert peer reviews are available in the Rodenticide Cluster EDocket, www.epa.gov/oppsrrd1/rodenticidecluster/index.htm]

EFED also notes that the methodology used is similar to that used in the Agency's "*Comparative Analysis of Acute Risk From Granular Pesticides*" (EPA 1992) and "*A Comparative Analysis of Ecological Risks from Pesticides and Their Use: Background, Methodology, Case Study*" (EPA 1998); both were reviewed by a FIFRA Scientific Review Panel. Concerning the latter analysis, the Panel noted the many scientific uncertainties in the method, yet agreed that it was a useful screening tool that provides a rough estimate of relative risk. The Panel made a number of helpful suggestions to improve the utility of the method, most of which are included in the risk assessment.

2) EPA's Section 7 consultation with the U.S. Fish and Wildlife Service (FWS) is a beneficial addition. The FWS has not only identified those threatened and endangered species that may be impacted, but also included recommendations for mitigation of potential adverse effects. The mitigation measures are in the form of buffer zones that prevent or reduce possible exposure.

EFED Response to Comment 2: OPP's Endangered Species Protection Program will be addressing endangered species issues and, if necessary, reinitiating consultation with the U. S. Fish and Wildlife Service for the nine rodenticides addressed in their 1993 Biological Opinion [USFWS Biological Opinion: Effects of 16 Vertebrate Control Agents On Threatened and Endangered Species. March, 1993. 168 pp.]

3) The inclusion of all available incident data is appropriate for a discussion of risk. However, EPA has not adequately discussed the new data provided by the American Society for the Prevention of Cruelty to Animals (ASPCA) Poison Control Center. The text assumes the poisonings are a result of rodenticide application. Does the ASPCA track the mechanism of

exposure in their database? The incidents may be due to exposure during normal labeled use, poisoning from accidental ingestion of stored rodenticides, or from the too common problem of intentional and illegal poisoning of dogs and other canines. We suggest EPA review their agency enforcement data to evaluate the severity of illegal canine poisoning using pesticides. EPA appears again to be ignoring the exposure aspect of risk. If the exposure data are not available, which is often the case in other poison control center databases, EPA needs to acknowledge the lack of data.

EFED Response to Comment 3: EFED does not conduct risk assessments for pets and domestic animals. Those issues are addressed by OPP's Health Effects Division, and they likely would be willing accept any relevant data that APHIS could provide. ASPCA did provide EFED with the number of incidents reported in their database during an 18-month period. Mostly these were incidents with dogs. Because there is a substantial cost in obtaining the individual incident reports, EFED could not obtain them, nor has any registrant provided them to EFED. However, the fact that there were more than 2300 incidents reported for rodenticides indicates that dogs and other pets are being exposed to rodenticide baits. Whether this exposure is due to intentional or inadvertent misuse or improper storage is unclear, but a combination of these means of exposure seems likely. Possibly label warnings and application directions are not adequate to prevent exposure. That is an issue that can be addressed during the mitigation phase.

We do note that at least one of APHIS' zinc phosphide products (EPA Registration No. 56228-6 - Zinc Phosphide Concentrate "*For the control of voles, house mice, white-footed mice, norway rats, roof rats, polynesian rats, rice rats, Florida water rats, cotton rats, pocket gophers, muskrats, nutria, prairie dogs, wood rats, ground squirrels, marmots and woodchucks, and black-tailed jackrabbits . . .*") states that "*Dogs, cats and other nontarget animals may actively search for bait, especially when meat-based baits are used*." Thus, it would seem inappropriate to imply that all exposure of dogs is due to intentional misuse or improper storage of baits. We also note other warnings on the labels of zinc phosphide baits. For example, EPA Reg. No. 56228-6 is a Restricted Use Pesticide "*Due to hazards to nontarget species*", which implies that nontarget animals might be exposed to baits. This and other labels also state that "*This product is toxic to wildlife and fish. Birds and other wildlife feeding in treated areas may be killed*." Labels also have a section entitled "*Endangered Species Considerations*" that requires applicators to determine if endangered species are present in the treatment area. We assume that this warning relates to bait application in the field, not solely to misuse or storage situations. That APHIS includes such warnings and precautions on their product labels indicates that they are indeed aware that there is a potential risk to nontarget organisms.

4) The current comparative risk model can provide some useful information. However, there are several characteristics of zinc phosphide which demonstrate that assumptions in the model need to be adjusted:

a) The model may not be as useful for comparison of pesticides having different mechanisms of action, particularly if that mechanism influences the quantity of active ingredient consumed, which translates to different levels of exposure. Zinc phosphide, once ingested, produces phosphine gas (the toxic agent) in the stomach. This mechanism is rapid (hours) compared to anti-coagulants (days). Generally rodents will continue to consume anti-coagulants for several days, whereas rodents will quickly stop consuming bait treated with zinc phosphide in part due to rapid onset of toxicosis. In addition, zinc phosphide has a disagreeable taste leading to bait shyness. In either case, the relatively high concentration of a rodenticide in bait is not equivalent to exposure, because animals do not consume equal amounts of bait. These differences in exposure are not incorporated into the model.

EFED Response to Comment 4a: EFED agrees that the amount of bait eaten over a several-day period does have consequences for risk. For example, second-generation anticoagulants can provide a lethal dose to a primary consumer in a single feeding, but death is delayed and the animal may continue feeding and accumulating residue for several or more days. In contrast, zinc phosphide kills quickly. Because residues do not accumulate to any significant extent in consumers of zinc phosphide bait, EFED made a presumption of minimal secondary risks to avian and mammalian predators and scavengers. That presumption is supported by studies in which poisoned rodents have been fed to avian and mammalian predators and/or scavengers and observed for adverse effects. However, for primary consumers, the issue is not the total quantity of bait that might be eaten but rather if the amount of bait that might be eaten will provide a lethal dose or have other adverse effects (e.g., reproductive). Zinc phosphide grain baits are formulated mostly at 2% ai (1% for fruits, nuts, vegetables and 3% for meats), versus the 0.005% ai baits for the second-generation anticoagulants. Because they are formulated at such higher concentrations of active ingredient, very little bait needs to be eaten to provide an LD50 dose. As tabulated in the comparative risk assessment (see Table 28 in the revised assessment), a 25-g bird needs to eat only about 0.02 g of a 2% ai zinc phosphide bait to ingest an LD50 dose, and that accounts for only about 0.3% of the amount of food it will eat in a day. Because a bird is likely to eat a pellet or treated grain whole, rather than chewing it, it will ingest multiple LD50 doses. A small mammal might chew only a piece of a pellet or grain, but a 25-g nontarget mammal needs to eat only about 0.03 g of bait to ingest an LD50 dose (see Table 31). Even if bait shyness is a factor, an animal is likely to consume multiple LD50 doses before avoiding any additional bait. As already noted, zinc phosphide baits are targeted for control of more than 70 mammalian species, and APHIS has provided no data demonstrating that baits are selective to these target species and won't be eaten by nontarget species. [see also EDED Response to Comment 4c]

b) Another indication that the model may need an adjustment is that the model results are inconsistent with EPA's own incident data for zinc phosphide. The EIIS data suggest that birds may be at far greater risk than mammals, as indicated by the relative number of

animals in each class reported in the database. But the model predicts the exact opposite. There are many times more incidents and numbers of birds than mammals in the data. As with the ASPCA data (as it is reported in the risk document), the EIIS data may not reflect exposure. In addition, reporting may be incomplete and not indicative of actual incidents. For example, small mammals may be in burrows and not visible. However, the observation that the model and the incident data do not support each other should raise questions.

EFED Response to Comment 4b: There are no inconsistencies between the incident database and EFED's risk conclusions, but we agree with APHIS that the incidents do indicate that birds that eat zinc phosphide baits are at risk. The incident database is not comprehensive and contains only incidents that have been reported to the Agency (see section entitled "*Incident Data: Birds and Nontarget Mammals*" in the comparative risk assessment). The fact that there are more bird incidents than mammal incidents is not surprising. Larger birds such as geese, ducks, and wild turkeys are much more likely to be found, analyzed, and reported to local, state, or federal authorities than are small mammals. As APHIS notes, small mammals may die in burrows (or other hiding places such as crevices and dense vegetation) where they would be inconspicuous and easily overlooked. The fact that they are not represented in the incident database is not surprising, but it does not mean they are not at risk. We remind APHIS that zinc phosphide is a rodenticide and is registered for lethal control of more than 70 mammalian species.

c) There is also inconsistency between the model results for zinc phosphide and EPA's own concern regarding the efficacy of the USDA registered products. EPA has conducted label reviews of 2% zinc phosphide bait products. In the most recent review (April 5, 2004) EPA expressed concern about mediocre performance. Bait shyness by rodents is an issue with zinc phosphide. Again, this relates to exposure. If the exposure is relatively low, the corresponding risk is low. And again, the model predicts high risk to mammals.

EFED Response to Comment 4c: We are surprised that APHIS seems to be arguing that their products are not efficacious. Agency efficacy-testing guidelines require that 70% control must be achieved in field tests and 90% mortality obtained in laboratory tests. Many zinc phosphide products have met those standards and are currently registered. However, it is inappropriate to compare efficacy against target species to risks to nontarget species. Efficacy would be mediocre if only 60% or 65% of the target species were killed in a field trial. Yet, 60 or 65% mortality of one or more nontarget species could be devastating to that species.

5) USDA/APHIS provided a number of comments on the December 19, 2002 draft in a letter to EPA dated March 31, 2003. The majority of these comments have not yet been addressed.

A copy of the March 31, 2003 letter is attached for your reference. Please direct your attention to comments numbered 2, 4, 5, 6, 7, 8 and 9.

EFED Response to Comment 5: EFED has responded to those comments that relate to EFED issues. OPP management determined that the Responses to Public Comments would be issued when the revised comparative risk assessment and BEAD's benefits assessment are issued. APHIS' comments have been addressed in that response. However, we will respond to APHIS' comments 2, 4, 5, 6, 7, 8, and 9 as requested (see below).

Synopsis of APHIS comments from March 31, 2003:

Comment 2: APHIS agrees that technical materials can be toxic to birds and mammals but argues that end-use products offer some degree of selectivity due their unique formulations and application directions. "*End-use products are formulated with many different carriers, strengths and can be applied under a wide range of use patterns and methods (Broadcast, underground, bait stations, indoors, outdoors, etc.). These factors afford some level of selectivity for primary risk. These factors should be considered and assessed prior to imposing mitigation measures*." APHIS goes on to state that "*The development of zinc phosphide into effective products included the use of many different grains, stickers, flavors, stabilizers, dyes, etc. Today, manufacturers have settled on a few formulations. These formulations have been selected because of the high degree of acceptance by target species, but also because they present less hazard to nontarget species than other formulations.*" APHIS adds that a submission by Eisemann et al. (1999) entitled "*A literature review (1942-1998): Efficacy of zinc phosphide for controlling Norway rats, roof rats, house mice, Peromyscus sp., prairie dog, and ground squirrels*" (MRID No. 449066-01) has been submitted to the Agency, and it included a hard copy of 103 manuscripts that reinforces the point that site-specific risk assessments should be performed prior to imposing any mitigation measures.

EFED Response to Comment 2: APHIS has provided no information that anything in product formulations deters nontarget species or is highly specific to the target species. The label for Zinc Phosphide Concentrate (EPA Registration No. 56228-6) provides mixing instructions for a variety of baits. Meat-based baits are made solely with a meat base (ground meat, canned dog or cat food, or dry meat-based pet food) mixed with zinc phosphide concentrate. Sunflower-seed baits are made by mixing sunflower seeds, zinc phosphide concentrate, and mineral oil. Fruit and vegetable baits are made by mixing a fruit (grapes, mulberry, apricots, figs, apples, pears), nut (unspecified), vegetable (carrots, sweet potato, potato, cabbage), or vegetation (alfalfa, dandelions, beet tops) with zinc phosphide concentrate and vegetable oil. Granted, not all nontarget species will eat meat or vegetables, but they are likely to be attractive to many species. Adding vegetable oil might actually enhance their attractiveness to some nontarget species.

Regarding application methods, EFED recognizes that there are many application methods (see EFED attachment). Some methods, such as underground baiting for pocket gophers and moles, likely does minimize exposure of surface-feeding birds and mammals. However, the suggestion that broadcasting bait by aircraft, ground-driven machines, or by hand is selective to the target species is not supported by any data and seems highly improbable; in fact, broadcasting seems a highly unselective method of applying bait. Many of the aerial broadcast application rates are higher than those for ground broadcast (machine or by hand) or when hand baited. That higher rate would seem to suggest that aerial broadcast may, in fact, be less selective.

APHIS is inconsistent in comments about the efficacy of zinc phosphide baits. In the comment above APHIS states that "*These formulations have been selected because of the high degree of acceptance by target species*", yet in their comments of June 9, 2004 state that "*EPA has conducted label reviews of 2% zinc phosphide bait products. In the most recent review (April 5, 2004) EPA expressed concern about mediocre performance*." How does a high degree of acceptance by target species lead to mediocre performance?

APHIS' submission submitted under MRID No. 449066-01 is an efficacy submission. Efficacy studies are reviewed by OPP's Registration Division. Such studies conducted with the target species, under Agency efficacy testing guidelines, and they are not adverse-effects studies. That efficacy submission referred to contains 103 documents encompassing more than 1600 pages. If APHIS believes that there is any relevant information for assessing nontarget risks, the appropriate documents should be cited and brought to EFED's attention.

Comment 4: APHIS believes that pen studies conducted by Ramey et al. (1994) and Ramey et al. (1998) are not discussed in enough detail in the comparative risk assessment.

EFED Response to Comment 4: The Ramey et al. (1994) study conducted in alfalfa enclosures does demonstrate that pheasants may eat zinc phosphide bait and that they may be killed if they do so. Quail also were present but did not eat bait. The fact that the quail presumably found alternative food suggests that pheasants could have done so as well and were not forced to eat the bait. The study does clearly indicate that birds can be killed if they eat zinc phosphide bait. That doesn't mean that every bird in every zinc phosphide treatment site will eat bait and die, but it does suggest that under some situations some birds may eat bait and be at risk. Whether nontarget animals eat bait in any particular situation likely depends on many factors, including food preferences and the availability of alternative foods. Bait may be more readily eaten if natural foods are scarce and that can vary annually, geographically, seasonally, and even weekly and daily. Can one argue that because the quail didn't eat bait in the alfalfa enclosure that they will never do so under any circumstance? On the other hand, because pheasants ate bait and died in the enclosures does not mean that every pheasant on every zinc phosphide treatment area will eat bait and die. However, it does suggest that some

birds will eat bait and are at risk if they do so.

The Ramey et al. (1998) study was conducted with pheasants in alfalfa fields in the Sacramento Valley of California. Zinc phosphide was applied between alfalfa cuttings, at which time pheasants were not utilizing the fields. Therefore, pheasants were not exposed. Based on that study, EPA registered this use of zinc phosphide. But does this mean there is no risk to zinc phosphide? The study did not address geographical differences in pheasant behavior and diets, nor did it address any possible annual differences at the study sites. Pheasants in the highland alfalfa-growing areas in California might behave differently, and so might those in Minnesota alfalfa fields. The study also did not address risks to other species that might have been exposed. The researchers did conduct transects across treated fields. However, searches were done using ATVs, and small birds and nontarget mammal carcasses, especially those inside burrows or dying off the fields, might have been overlooked. Therefore, while this was a well conducted study on the risks of pheasants in treated alfalfa fields in central California, there are many uncertainties in extrapolating these results to other areas and possibly even other years.

Comment 5: APHIS questions why EFED hasn't used zinc phosphide use information they provided to an EFED reviewer at a meeting in 1996.

EFED Response to Comment 5: EFED welcomes any relevant use data for zinc phosphide and the other rodenticides. The Agency provided the preliminary risk assessment to rodenticide registrants in October, 2001 and posted it in the EDocket on EPA's website for public comments from January 29 to May 30, 2003. No additional data or relevant information to refine the exposure assessment has been provided by the registrants or other stakeholders. We are not aware of the information APHIS said was provided in a handout at a meeting in 1996 - it is not in EFED's file for zinc phosphide nor does the zinc phosphide chemical reviewer have any recollection of receiving that information. However, we have tabulated current zinc phosphide uses, target species, and application methods (see attachment and responses to previous comments). This information is current, whereas information from the early 1990's may be outdated for some uses. Regarding production data, EPA does obtain data on the amount of each product produced annually. However, many zinc phosphide products have many use sites and target species on individual product labels (e.g., APHIS product 56228-6). Production data provide no information on when, where, or how the product was used and thus provide little relevant information for assessing exposure and risk.

Some of those same problems apply to the Pesticide Use Reporting by the California Department of Pesticide Regulation (http://www.cdpr.ca.gov/docs/pur/purmain.htm). The annual reporting only provides the amount of rodenticide applied per crop without providing any information of the target pest, seasonal use, application method (e.g., broadcast versus bait station), or other such relevant factors. Moreover, homeowners and non-certified applicators

do not report pesticide use, and noncrop uses are poorly represented or lumped together.

Comment 6: Very few incidents have been reported during the past 60 years of zinc phosphide use. The Agency should compare the number of incidents with the use information discussed under Comment 5.

EFED Response to Comment 6: The fact that few incidents have been reported could be due to a variety of reasons. One is that few incidents occur. However, it could also be that incidents occur but are not detected or reported. That most reported incidents for rodenticides involve anticoagulants is not surprising, because anticoagulants are stored in body tissues and can be detected by analyzing liver tissue. Confirmation of zinc phosphide poisoning is much more difficult, because the phosphine gas is liberated and not stored in the body. It is generally detected by the presence of dyed bait in the crop, stomach, or alimentary canal. The presence of an acetylene odor also is diagnostic of zinc phosphide toxicity but can be detected only if intact carcasses are sent to an examining laboratory soon after death (Michigan Wildlife Diseases Manual: Zinc Phosphide www.dnr.state.mi.us/wildlife/division/RoseLake). Neither the incident information nor the use information is adequate to make a comparison of the number of incidents per application or any other such criteria. EFED has addressed this issue in the "*Target species, use sites, and rodenticide usage*" section of the revised comparative risk assessment and in EFED's July 17, 2004 "*Response to Public Comments on EFED's Risk Assessment: "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach", dated December 19, 2002*".

Comment 7: The value of carcass searches during efficacy field studies has been undervalued. Data collected during systematic onsite searches is stronger than that collected by accidental discovery.

EFED Response to Comment 7: As noted in EFED's Response to Comment 2, efficacy studies are designed to address effectiveness of the bait and application method in controlling the target species. Efficacy tests are not designed to assess risks to nontarget species, and they rarely do so other than occassionally searching for carcasses along transects on treatment plots. However, in terms of the impact of a bait on nontarget organisms, simply walking transects across treated areas can be misleading. As APHIS astutely pointed out in Comment 4b, "*For example, small mammals may be in burrows and not visible*.", and small birds may fly offsite before dying. A good effects study needs to assess nontarget population levels before and after control by means such as mark-recapture or radio telemetry. APHIS argues in Comment 1 that exposure has not adequately been assessed, but how does walking transects adequately address exposure? It doesn't and can be misleading. For example, the search efficiency of the individuals doing the transect searches must be determined but ususally isn't,

nor are those individuals inside burrows accounted for. EFED has provided guidance for conducting field trials to assess nontarget exposure (Fite et al. 1988: *Guidance Document for Conducting Terrestrial Field Studies*, EPA 540/09-88-109), including design considerations, addressing search efficiency, and methods appropriate for assessing nontarget impacts. We also encourage APHIS to discuss study protocols with EFED prior to initiating a field study.

Comment 8: Prior to requiring avian production data, APHIS suggests that EFED examine chronic data collected by other OPP divisions. APHIS also cites four chronic or subchronic rat studies that were submitted to the Agency.

EFED Response to Comment 8: EFED will look at those studies to determine if there are any relevant information for mammals. EFED typically utilizes the rat two-generation reproduction test (40 CFR §158.340, Toxicology Data Requirements, Guidelines Reference No. 83-4 "Reproduction, 2-generation") to assess chronic risks to mammals. This study is required by OPP's Health Effects Division (HED) to support pesticides with food uses or where use of the product is likely to result in human exposure over a significant portion of the human lifespan. This study is not currently available for zinc phosphide or for any of the other rodenticides. Most other subchronic/chronic studies (e.g., neurotoxicity, dermal, inhalation, oncogenicity) required by HED are not relevant to assessing risk to nontarget mammals from food baits. For birds, EFED uses avian reproduction studies with the northern bobwhite and mallard (40 CFR §158.490, Wildlife and Aquatic Organisms Data Requirements, Guidelines Reference No. 71-4 "Avian reproduction"). The avian reproduction studies have previously been required by the Agency on a case-by-case basis, but the updated guideline requirements soon to be published will require these studies for all pesticides having outdoor uses. EFED can better assess the potential for adverse reproductive effects when these data become available.

Comment 9: APHIS states that rodents are hesitant to accept zinc phosphide treated grains. Baiting efficacy is greatly improved when treated sites are first prebaited with untreated grain. Aversive properties can be assumed to extend to other mammals and should be considered.

EFED Response to Comment 9: The argument that bait aversion can be reduced by prebaiting, at least for some species, may be correct and is not disputed by EFED. However, we note that nontarget mammals also would be prebaited and thus more likely to accept bait as well. Product labels recommend prebaiting for some species but not others (see attachment), suggesting that zinc phosphide treated grains may not be aversive to some species. What about birds? What about baits other than grains (meat-based baits, nuts, sunflower seeds, fruits, vegetables, vegetation)? The fact that there are at least 70 mammalian species listed as target species for zinc phosphide baits indicates that many mammals will eat bait. Moreover,

as previously discussed, very little bait needs to be eaten to provide an LD50 dose to a small mammal or small bird.