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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

December17, 2002

MEMORANDUM

SUBJECT: EFED response to HACCO's errors-only comments on the Agency document "Comparative Risks of Nine Rodenticides to Birds and Nontarget Mammals"

TO: John Pates, Chemical Review Manager
Susan Lewis, Branch Chief

FROM: William Erickson, Biologist
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Environmental Risk Branch III, Environmental Fate and Effects Division

THRU: Stephanie Irene, Acting Chief
Environmental Risk Branch III, Environmental Fate and Effects Division

The Environmental Fate and Effects Division (EFED) has reviewed HACCO's "errors-only" response to the Agency document "Comparative Risks of Nine Rodenticides to Birds and Nontarget Mammals" dated October 3, 2001. HACCO's comments of December 6, 2001 were prepared by J. A. Thompson, Registration Manager, Rodenticides. As stated in the Agency's October 23, 2001 cover letter for the assessment, the registrants' 30-day response should address only mathematical, computational, typographic, or other similar errors. Matters of policy, interpretation, or applicability of data will be addressed after the public comment period in accordance with the Agency's reregistration process for pesticides.

In response to error comments by HACCO, other rodenticide registrants, and the Rodenticide Registrants Task Force, EFED has made necessary computational and/or typographical corrections. However, EFED notes that many comments relate to policy, interpretation, or applicability of data, and those comments will be addressed along with public comments after the 60-day public-comment period.

Re: Preliminary Comparative Ecological Risk Assessment for Rodenticides

Dear Mr. Pates:

I am writing to address several very serious concerns that HACCO, Inc has with EPA's "Preliminary Comparative Ecological Risk Assessment for Nine Rodenticides" (PRA) dated October 3, 2001. The compounds included in the assessment are: brodifacoum, difethethialone, bromadiolone, diphacinone, chlorophacinone, warfarin, zinc phosphide, bromethalin and cholecalciferol. HACCO, Inc. holds active registrations for the following rodenticide active ingredients included in this Assessment: Diphacinone, Brodifacoum, Warfarin and Zinc Phosphide.

We, HACCO, Inc,. are members of the Rodenticide Registrants Task Force (RRTF) and of the Zinc Phosphide Consortium along with many other rodenticide registrants. We have been active in presenting the Agency with added information in regards to rodenticide benefits, usage, toxicity, and relative safety. However, the present version of the PRA contains significant errors and does not incorporate many of the RRTF's comments submitted in response to EPA's October 19, 1999, meeting regarding risks to birds and non-target mammals. HACCO strongly urges that the Agency does not release this PRA to the public. This PRA needs to be revised substantially before it can be released to the public.

HAZARD COMPARISON VERSUS RISK ASSESSMENT

In reading this document, the overall concern is that this PRA is a hazard comparison and not a risk assessment. EPA does not address and characterize exposure. EPA does not address the facts that these active ingredients are used differently and that formulations of these compounds may vary the characterization of exposure. Certain formulations and bait forms may reduce exposure under certain use patterns. The Agency assumes that all exposures are equal in its equations to evaluate risk. In examining field uses, however, the Agency in the PRA gives an example of how a bait form could vary a "risk" through limiting "exposure" when it addresses the desirability of broadcasting a 6 gram pellet to protect birds from primary exposure. As another example of how formulation and form will affect exposure, a broadcast use of grain bait might be preferred where the concern is primary exposure of non target canines. The Agency gave the first example listed above, but the Agency does not characterize exposure components in its equations to evaluate risk. The Agency needs to address exposure to do a "risk" assessment. The Agency needs to broaden the way it looks at rodenticides to include use patterns in the United States, sales volume, formulations and bait forms, identification and behavior of non targets within the vicinity of an application, so that an examination of the actual exposure of non targets can be made. Risk should not be estimated without an adequate characterization of exposure.

> **EFED response:** This has been addressed in the revised document. It is well known that rodenticide baits are formulated to be lethal to rodents and a few other small mammals, and they are not selective to the target species. Although many factors influence which nontarget animals might be exposed to baits, many nontarget organisms are attracted to

and consume grain-based baits. Predators and scavengers also feed on rats and mice or other target species, and they are not likely to avoid feeding on those that have eaten rodenticide bait. Thus, rodenticide baits also pose potential secondary risks. EFED believes that the potential for risks to birds and nontarget mammals is well established for some of these rodenticides.

The risk assessment is based on the available data. Registrants have not submitted the data that would be needed to assess the probability of exposure. These data have been outlined in a section on *Uncertainty and Data Needs* in the revised assessment. 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)[1]; 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 here.

Risk conclusions are presented in tabular and graphical form based on two analyses of the available data. The first is a comparative ranking of the potential risk based on a comparative-analysis model, and the second is a tabular comparative rating of potential risk based on a qualitative "weight-of-evidence" assessment. Quantitative estimates of risk are used in both; however, the "weight-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 EPA's risk-assessment guidelines[2], where professional judgement or other qualitative evaluation techniques may be used to rank risks using categories such as low, medium, and high when exposure and effects data are limited or are not easily expressed in quantitative terms.

COST/BENEFITS OF USING RODENTICIDES

Since FIFRA is a cost/benefit statute, EPA should address the benefits of using rodenticides in this document. EPA summarized in its Rodenticide Cluster RED of July, 1998, the benefits of rodenticides specifically to include 1) health benefits - prevention of disease transmission, 2)

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

[2] See Guidelines for Ecological Risk Assessment (EPA/630/R-95/002F, 1998) at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12460

prevention of property damage and 3) prevention of rodent attacks on humans. I would like to add the benefit of rodenticides in restoring threatened and endangered species to island ecological systems.

In regards to item 1), the CDC presented a report at the Rodenticide Stakeholder's working group, June, 1999, that rodents directly cause hantavirus pulmonary syndrome, leptospirosis, rat-bite fever, salmonellosis, yersinia pseudotuberculosis, lymphocytic choriomeningitis, trichinosis and toxoplasmosis. Rodents indirectly (through harboring hosts such as fleas and mites) cause plague, rickettsialpox, Colorado tick fever, Rocky Mountain spotted fever, Lyme's disease, relapsing fever, babesiosis, western equine encephalitis, California encephalitis, murine typhus, human granulocytic ehrlichiosis and cutaneous leishmaniasis.

Concerning item 2) rodents are estimated to consume or contaminate with urine or droppings $1 billion of food in the U.S. annually. As noted in the above mentioned RED, rodents damage structures by gnawing on integral parts and contaminating them with bodily excretions. Rodents are also believed to account for 50% of fires of unknown origin by gnawing on electrical wiring. This was discussed by Dr. Robert Corrigan at a meeting of the above mentioned Rodenticide Stakeholder's Working Group

In regards to item 3) per the above mentioned RED, the number of cases of rats biting humans is estimated to be 14,000 per year. The CDC collected data showed that between 1986 and 1994, 809 non-work related rat bites were reported to the New York City Department of Health. Two percent of rat bites require hospitalization and 95% require treatment.

Finally, I would like to mention that Rodenticides are used in the restoration of natural ecosystems. Uninhabited islands in the United States have used brodifacoum to control rats. Hawaii is currently using diphacinone in its ecosystem restoration program. Non indigenous rodents (often rats) threaten indigenous birds and plants. Rodenticides have been used and plans are being made to use them in the future to protect threatened indigenous birds and plants.

> **EFED response:** The Agency will be considering benefits later in the reregistration process, and the document has been modified to clarify that this is EFED's assessment of potential risks.

OTHER ERROR CORRECTIONS

In conclusion, I would like to add that HACCO has given its page by page review to the RRTF for inclusion with the RRTF's comments and believes that itemization in this correspondence would be unnecessary repetition. However, we do want to emphasize, once again, that diphacinone's acute oral toxicity for rats should be listed as 7.0 mg/Kg. This is the number that should be used in EPA's equations for ecological effects. It shows a bias on the Agency's part to continue to list and to always use in its equations the rat acute oral LD50 of 2.5 and 2.1 mg/Kg, the results of an unacceptable study. The Agency notified the registrants that this study was unacceptable. Our letter from EPA on the unacceptability of this study is dated February 6, 1992.

In the letter, it was stated that if the Agency's question could not be answered, the Agency required that a replacement study be done. The accepted replacement study found the combined acute oral LD50 in rats to be 7.0 mg/Kg.

> **EFED response:** HACCO provides no supporting documentation that this study is "unacceptable". The study is categorized as "supplementary" in the EPA/OPP Health Effects Division's toxicity database; data from supplementary studies are used in OPP risk assessments.

IN SUMMARY

We urge EPA not to issue publicly this erroneous and incomplete document as EPA's current statement of its Ecological Risk Assessment of Rodenticides, but rather to review our comments and the comments soon to be submitted by the RRTF and to make revisions accordingly.