



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

03/OPP #3413

27PP

August 30, 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Response to Public Comments on the Preliminary Risk Assessments for the Organophosphate **Terbufos**

FROM: Pam Noyes, Chemical Review Manager
Special Review and Reregistration Division
Office of Pesticide Programs

TO: OPP Public Docket for Terbufos
Docket # **34139**

Introduction

This document addresses public comments received in response to EPA's Notice of Availability (63 FR 43175, August 12, 1998) of preliminary risk assessment[s] for the first nine organophosphate chemicals: azinphos-methyl; bensulide; ethion; fenamiphos; isofenphos; naled; phorate; profenofos; and terbufos. The Notice of Availability of the preliminary ecological risk assessment for terbufos was issued on December 15, 1998 (63 FR 70126). Part I of this document addresses comments received specific to terbufos, and Part II focuses on non-chemical-specific comments. By "non-chemical-specific" we mean that the comment was submitted to the OPP Public Dockets for each of the nine chemicals or for a significant sub-set of the nine. Also, these non-chemical-specific comments generally apply to regulatory or science policy issues that are not unique to any one of the chemicals or risk assessments.

Part I. Terbufos-Specific Comments and Responses

Terbufos-specific comments were received from American Cyanamid Company, Dole Food Corporation, and a property owner from LaFontaine, Indiana.

A. Response to Comments on Preliminary Human Health Risk Assessment

1. Comments from American Cyanamid Company

Comments: American Cyanamid, the registrant, submitted results from several studies, including an acute and subchronic neurotoxicity study in rats, corn and banana field trial studies, dermal toxicity study using the polymer-based granular (20% active ingredient), and two worker

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exposure studies. The company also submitted revised dietary risk assessments, an acute dietary sensitivity analysis, and schedule for submitting ongoing studies.

Response: Considerable data have been submitted by American Cyanamid to refine the human health risk assessment. All studies and risk analyses submitted during and after the comment period are incorporated into the revised human health risk assessment for terbufos. The revised assessment contains further detail on how each of the studies are used in the Agency's risk analysis.

2. Comment from Dole Food Corporation

Comments: Dole Food Corporation had lengthy comments requesting clarification on dietary risks from terbufos residues in bananas because public perceptions put banana growers in a difficult position. Dole requested that EPA clarify the following two points in the final risk assessment: 1) "The chronic dietary risk from terbufos is not of concern because, even at *tolerance levels*, the anticipated exposure would be well below the RfD."; and 2) "Based on the analysis of chronic dietary risk, EPA has no special concern about terbufos levels in bananas."

Dole also expressed concern about broader issues concerning public disclosure of EPA documentation under the OP pilot process, and the impact these disclosures could have on the marketplace. The company stated that the Agency has a responsibility to assure that its public documents are accurate and represent EPA's "best thinking" about public risk, and that much greater quality control is needed in the release of risk assessment documents.

Response: The preliminary chronic dietary risk assessment indicated chronic risks for food alone that were below EPA's level of concern. During the comment period, EPA received banana and corn field trial studies from the registrant. These field trial data, plus older field trial data previously submitted, have been used to revise the dietary risk assessment. The revised chronic assessment indicate risks below EPA's level of concern for food alone.

It is important to note, however, that the chronic dietary risk analysis for food alone is not EPA's only consideration. The Agency must also consider acute risks from foods treated with terbufos, and drinking water contributions to the acute and chronic dietary risk cup (aggregate risk). The Agency also will need to conduct a cumulative risk assessment for all the organophosphates, including terbufos. Based on these considerations, we have worked to refine the risk assessment for terbufos as much as possible, which includes determining the relative contribution of each food item to the risk cup. Although acute and chronic dietary risks are below EPA's level of concern for food alone, when the contribution of individual food items are analyzed in the assessment, bananas appear to be the principal risk contributor to dietary risk for many population subgroups, particularly children.

EPA appreciates Dole's concerns about the impact public disclosure of risk assessment documents can have on the marketplace. The OP pilot review process was developed working

closely with the Tolerance Reassessment Advisory Committee (TRAC), which is represented by a broad range of outside interested parties. In addition, the Agency goes to considerable effort to be as accurate and precise as possible in its risk assessments, including review by senior level management, and clearly identifying, as such, those documents that are describing draft or preliminary information.

B. Response to Comments on the Preliminary Ecological Risk Assessment

1. Comments from American Cyanamid

Comments: American Cyanamid commented on EPA's use of deterministic risk assessments to characterize ecological risk, and on EPA's summary of the aquatic and terrestrial incidents involving terbufos. The company also provided EPA with results from an avian field study that were not considered previously. Finally, several rebuttal documents submitted by American Cyanamid were referenced.

Response: EPA's response to American Cyanamid's comments are outlined fully in the attached memorandum dated August 20, 1999 (D. Farrar to P. Noyes). The Agency reviewed the avian field study (Knapton and Mineau, *Ecotoxicology* 4:138-145) provided by American Cyanamid, and has modified the characterization of terrestrial incidents in the Environmental Fate and Effects Division (EFED) RED chapter. Many of the comments submitted by American Cyanamid are similar to comments from previously submitted rebuttal documents (e.g., the low ecological priority of "farm ponds"). Some minor refinements have been made to the RED chapter, but the Agency continues to have risk concerns about aquatic and terrestrial incidents involving terbufos.

2. Comments from Indiana Property Owner

Comments: A property owner (Martha Philbeck), from LaFontaine, Indiana, submitted a comment recounting a June 1998 aquatic incident involving terbufos that occurred in a two acre pond on her property. She noted a range of observations to the pond community, including kills to fish, amphibians, and ducks. She described investigations by Indiana state and local authorities, and indicated that American Cyanamid tested the water for terbufos on three occasions and that "they [American Cyanamid] had to test it 3 times to get a safe reading". She discusses a variety of negative impacts this has had on her family, including losing a food source and experiencing a degraded quality of life.

Response: To be responsive to the Philbeck's comment and to try to better understand the circumstances under which aquatic incidents involving terbufos could occur, EPA communicated with and was provided materials from the Office of Indiana State Chemists and Seed Commissioners concerning its investigation of the incident on the Philbeck property. The Office also provided EPA with information on investigations of two other fish kills involving terbufos around the same time as the Philbeck incident. The Agency reviewed information submitted by

American Cyanamid under FIFRA 6(a)(2) (Adverse effects reporting requirements), especially as it relates to the role of rainfall. EPA's full response to the Philbeck's comment is contained in the attached memorandum dated August 5, 1999 (D. Farrar to P. Noyes). For reference, the Agency's response to comments from American Cyanamid dated August 20, 1999, provides further information on EPA's position on aquatic incidents involving terbufos.

Part II: Non-Chemical-Specific Comments and Responses

Non-chemical-specific comments were received from: American Crop Protection Association; Idaho Farm Bureau Federation; National Coalition Against the Misuse of Pesticides (NCAMP); National Cotton Council; Learning Disabilities Association; Fish and Wildlife Service, Division of Environmental Contaminants; Texas Agricultural Extension Service; Natural Resources Defense Council (NRDC); the Grocery Manufacturers of America, Michigan Agricultural Cooperative Marketing Association; U.S. Apple Association; Southern Professional Fruit Workers Conference (held at Clemson University); and 16 individuals, 13 of whom identified themselves as pest control operators (PCOs) or otherwise associated with the professional pest control industry.

Because there are several recurring issues in the comments that were submitted, we have chosen to divide our responses into two sub-sections. In order to avoid repetition, sub-section A deals with comments that are closely related and were repeated in more than one of the submissions, and with comments that are testimonial in nature. Sub-section B responds to those comments that are unique to each submission and refers the reader to the appropriate common responses in sub-section A.

A. EPA Responses to Recurring Issues in the Non-Chemical-Specific Comments

1. Comments Related to Common Mechanism of Toxicity

Comments: The Idaho Farm Bureau Federation felt that the criteria defining all organophosphate pesticides as having a common mechanism of toxicity are too broad, and that EPA should develop appropriate criteria for common mechanism. Other commentors, the NRDC and NCAMP, questioned why EPA has not considered a common mechanism of toxicity in these first nine OP risk assessments.

Response: With respect to developing criteria, EPA is required under FQPA to consider available information on the effects of cumulative exposure to the pesticide and other substances with common mechanisms of toxicity. EPA believes that the organophosphate pesticides should be considered to operate via at least one common mechanism of toxicity--cholinesterase inhibition, unless and until the Agency receives data demonstrating otherwise.

In the Federal Register of August 6, 1998 (63 FR 42031 (FRL-5797-9)), EPA issued a notice announcing the availability of the proposed EPA pesticide policy guidance document

entitled "Guidance for Identifying Pesticide Chemicals That Have a Common Mechanism of Toxicity for Use in Assessing the Cumulative Toxic Effects of Pesticides." The guidance document describes the approach that EPA proposes to use for identifying and categorizing pesticide chemicals that have a common mechanism of toxicity for purposes of assessing the cumulative toxic effects of such pesticides. The 60-day comment period ended October 8, 1998. The revised guidance was issued in February, 1999. In developing this document, the Agency solicited advice from the FIFRA Scientific Advisory Panel (SAP) in February 1997; a year later (March 1998), OPP reported its progress to the SAP.

With respect to the comments that EPA has not considered common mechanism in these first nine assessments, the Agency acknowledges that it has not yet performed a cumulative risk assessment, because the methodology for conducting such assessments is still being developed. Since there are currently no standard methods for doing cumulative risk assessment, EPA is pursuing an open, peer-reviewed process to develop approaches to cumulative risk assessment. The Agency is also nearing completion of the revision of the Chemical Mixtures Risk Assessment Guidelines, which present methods for combining risks from multiple chemicals. In addition, the International Life Sciences Institute (ILSI) is independently exploring appropriate methods and developing a framework for performing a cumulative risk assessment. ILSI held a workshop on this subject in September 1998, and will issue a report. The Agency will continue its ongoing efforts in this area along with examining the ILSI work and other sources of information in preparation for release of an Agency draft guidance document. This guidance document is currently scheduled for the late Summer or early Fall of 1999 with a 60-day comment period.

Until a method is available, EPA intends to complete risk assessments for individual OPs and proceed with the public process for development of risk mitigation strategies.

2. Comments Related to Additional Data, Data-Call-Ins, and Default Assumptions

Comments: The Idaho Farm Bureau Federation, thirteen individual comments from PCO's, and the National Cotton Council encouraged EPA to use its data call-in (DCI) authority to obtain the data necessary to conduct realistic risk assessments. The Cotton Council noted that comments in the Public Docket from the registrants indicated that, in some cases, data had been submitted, but have not been reviewed or considered in the preliminary risk assessments. A common theme was that EPA should use actual data, particularly usage data, and avoid default assumptions in its assessments.

Response: In phase four of reregistration, EPA exercised its data call-in authority to require studies to upgrade chemical data bases to current scientific standards. Most of the OPs were subject to reregistration DCIs and registrants have been allowed ample time to submit those studies. EPA makes its reregistration and tolerance reassessment decisions on the best data that are available. Where data are incomplete EPA may compensate by using an additional

uncertainty factor or making a reasonable health-protective assumption. This has long been EPA practice, and is reinforced by FQPA's emphasis on the importance of the use of uncertainty factors where data are incomplete.

It should be noted, however, that the OP risk assessments in the docket are "preliminary," and that many of these first nine assessments were completed prior to receipt of all required data. During the public comment and response period, EPA has continued its evaluations of available data, e.g., Monte Carlo analyses, for these first nine chemicals, and these evaluations have been incorporated into the revised risk assessments. In general, if additional, pertinent data are submitted prior to or during the comment periods, EPA will take these data into account in its final assessments and risk management options.

For a discussion of the sources of use and usage data and how EPA employs these data in its assessments, the reader is referred to a science policy paper entitled, "The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management." An FR Notice announcing the availability of this paper for a 60-day public comment period was published July 14, 1999. The draft document is available on EPA's web page : <http://www.epa.gov/oppfead1/trac/science>.

3. Comments Related to Inconsistencies in the Risk Assessments

Comments: NCAMP and others noted that the assessments for the nine OPs are inconsistent in format, level of refinement, assumptions used, and methods. For example, acute dietary risk is expressed in some assessments as a percentage of the reference dose (RfD), in others it is characterized by a margin of exposure. Drinking water risks are estimated in some assessments and not in others. It is not clear what risks are being aggregated and why.

Response: EPA acknowledges inconsistencies in the preliminary assessments for the first nine OPs. In many cases, the assessments were begun many months ago and have not been constantly updated to reflect new formats and methods. In the revised risk assessments we have made an effort to ensure consistency in the assumptions and the levels of refinement that are applied, given the data available for each chemical. For example, for drinking water, we have calculated acute and chronic DWLOCs for all chemicals and compared them to the levels estimated to be found in water. In the revised assessments, all acute dietary risks are now expressed as a percentage of the acute population adjusted dose (aPAD). (The aPAD is the reference dose including the FQPA safety factor. If the FQPA safety factor has been removed, the aRfD and the aPAD are the same.) We have attempted to identify major risk contributors (i.e., commodities or use patterns that contribute most to the risk), and have refined the residue estimates to the extent possible with existing data, including use of USDA Pesticide Data Program (PDP) and FDA monitoring data in some cases. In an attempt to make the risk assessments easier to understand and compare, EPA has prepared risk summary and overview documents for each OP. These risk overview documents have been prepared in a standard, logical format and are intended to assist the reader by identifying key features and findings of the risk assessments, as well as highlighting any assumptions and refinements that have been used.

4. Comments Related to Application of the FQPA 10X Safety Factor

Comments: The Learning Disabilities Association and the NRDC commented that EPA failed to demonstrate the existence of reliable data for most OPs to justify departure from the use of the FQPA 10X safety factor.

Response: OPP has developed criteria for retaining, reducing, and removing the ten-fold safety factor provided for in the FQPA to account for special susceptibility of infants and children to the effects of pesticide exposures. These criteria involve a weight-of-evidence consideration of both the nature and severity of effects observed in young animals, as well as the adequacy of the data base for the chemical. OPP's rationale for these criteria has been reviewed at various stages of development by the SAP. OPP has completed a draft Standard Operating Procedure (SOP) that provides procedural guidance at the working level for making recommendations for retaining or modifying the 10-fold factor.

In addition, an Intra-Agency workgroup is looking at general considerations regarding the FQPA safety factor decisions such as: establishing procedures for consistency and documentation; ensuring the adequacy of the data set for decision-making; and establishing criteria for retaining or modifying the FQPA factor.

The Agency's policy for applying the FQPA 10-fold safety factor is currently one of the science policy issues being prepared for public comment. Both the SOP and the Intra-Agency workgroup draft guidance document were discussed at the May, 1999 SAP meeting. An FR Notice announcing the availability of these documents for a 60-day public comment period was published July 8, 1999.

The question of what constitutes a reliable data base for making decisions related to the FQPA safety factor is being thoroughly reviewed. Once that review process is completed, EPA may need to revisit its assessments and decide how best to incorporate the revised procedures into its ongoing decision making process.

5. Comments Related to Highly Exposed Populations

Comments: Both NCAMP and NRDC noted that EPA failed to consider the increased potential for pesticide exposure to "sentinel" populations, such as farm worker children.

Response: NRDC has petitioned the Agency to designate farm children as a major identifiable subgroup under the FQPA. The Agency is currently evaluating the scientific and legal issues raised in that petition. Specifically related to the preliminary risk assessments for the first nine OPs, EPA acknowledges that exposures to farm worker children were not evaluated separately, i.e., as a distinct population sub-group. However, based on the limited data currently available to characterize actual pesticide exposure to children of agricultural workers, such as a 1997 biomonitoring study by Loewenherz, Fenske and others (Environ. Health Perspect. 105:1344-

1353), we believe that the exposure estimates developed by EPA using the Agency's Residential Exposure SOPs and other available information are reasonably inclusive of the exposures likely to be experienced by this sub-group.

EPA is concerned about the disproportionate exposure of farm children to pesticides and has several ongoing projects designed to both assess and reduce these exposures. Some of EPA's major efforts in this area are described below.

EPA's major external research program, Science to Achieve Results (STAR) program allocated funds in fiscal year 1996 for three years of research on the most urgent issues regarding exposure of children to pesticides. The studies are looking at major types of exposure (touching, eating, crawling, etc.) and at seasonal and locational differences, including agricultural settings. This research will support regulations and public education efforts that are more fully protective of children, for example through revised use restrictions and labeling requirements, and improved training and public information materials. Under the STAR program, the University of Arizona is assessing exposure of the children of seasonal and migrant laborers to agricultural pesticides. In addition, the University of Washington is assessing, on a comprehensive seasonal basis, children's exposures to organophosphate pesticides.

EPA's National Center for Environmental Research and Quality Assurance of the Office of Research and Development is funding a grant with the University of California at Berkeley for a five-year study, that began in August 1998, to quantify the exposure of children in agricultural areas of California to pesticides. The project will integrate biological research with community-based intervention efforts. The study will determine the impacts of pesticide exposure on children's growth and development. The University will also work with the farm worker community to investigate approaches for reducing these exposures.

Finally, based on recommendations from the Children's Health Protection Advisory Committee (CHPAC), EPA has committed to conduct a national assessment of implementation and enforcement of the Worker Protection Standard, including its effectiveness in addressing the safety needs of women and children as agricultural workers.

6. Comments Related to the Role of OPs in Integrated Pest Management (IPM)

Comments: The Michigan Agricultural Cooperative Marketing Association, the Grocery Manufacturers of America and the Southeastern Professional Fruit Workers Conference noted that the loss of OPs would reduce the effectiveness of entire IPM programs. The loss of any tool in the IPM arsenal can result in greater overall use of pesticides and the return to prophylactic use of pesticides. IPM should be explicitly addressed in the risk assessment process.

Response: EPA recognizes the importance of some OPs in IPM and resistance management programs. We intend to consider these factors, as appropriate, in our risk management decisions.

Specifically, under FQPA, EPA cannot use the biological or economic importance of a chemical as a factor in determining allowable dietary risk. However, if risk management is necessary, these factors would be considered in determining which chemical uses are most critical and should be retained.

7. Testimonial Comments

Comments: Two individuals provided comments that were testimonial in nature, that is, they expressed opinions but provided little or no specific information for the Agency to respond to. One person offered the view that OP's are "nerve gas" and all use should be banned. Another offered his support for the continued availability and use of phorate, terbufos, chlorpyrifos, methyl parathion, fonofos, carbaryl, carbofuran, and bromacil (only first 5 are OPs; only terbufos and phorate were among the first nine OPs.) The commentator noted that yields on his farm would be reduced without these products, but provided no documentation to quantify the yield loss.

Response: EPA recognizes the diversity of views exhibited by these comments.

B. EPA's Response to Submitter - Specific Comments

1. Comments from Private Citizens

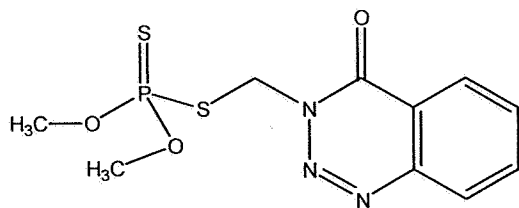
Comment: One commentator urged EPA to account for "enantiomer" toxicity in reassessing tolerances for the OPs. Enantiomers are mirror image molecules produced in the manufacture of organophosphate active ingredients. Specifically, the commentator raises concern over the possibility that specific enantiomers of these substances could be produced during manufacture, and that these enantiomers may be more toxic than other enantiomers that may be present. Hence, the risks posed by these substances could be greater than the risks anticipated by EPA. The commentator would like to know specifically how EPA took into account the possibility of specific enantiomers and their toxicity during its risk assessment of the nine organophosphorus compounds and what procedures ensure that the current toxicity testing of active ingredients will reveal any potential problem with enantiomer contamination.

The commentator also referred to incidents "in Pakistan or Afghanistan and in the SW United States" related to the toxic effects of enantiomers of organophosphorus compounds in which "hundreds of people were killed."

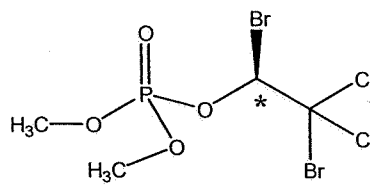
The American Crop Protection Association (ACPA) submitted a comment to the docket which responded that normal toxicity testing for registration will test all of the enantiomers together. They also said that of the nine OPs only naled has a chiral center (a carbon atom bonded to four different groups), none of the others can possibly have enantiomers.

Response: Enantiomers of a given substance are isomers whose mirror images are not superimposable. While enantiomers of a given substance have identical physicochemical properties (except in the direction in which they rotate a plane of polarized light), they may vary in toxicity and, therefore, pose different risks to human health or the environment. In a given manufacturing process it is possible for more than one specific enantiomer of the product substance to form. It is also possible that one enantiomer may be produced more readily than another enantiomer, and may predominate in the commercial product. Even if an enantiomer is formed in low concentration relative to another enantiomer during synthesis of a commercial product, it may still contribute significantly to the overall risk of the product if its toxicity is greater than the toxicity of the other enantiomer. EPA's Office of Pesticide Programs (OPP) routinely evaluates the manufacturing processes used to synthesize pesticides as part of its process to evaluate the risks posed by pesticides. The primary purpose of evaluating a manufacturing process of a given pesticide is to ascertain the composition of the technical product with regard to overall risk to human health and the environment. The evaluation includes an analysis and consideration of the feedstocks, reagents, catalysts, solvents and any other substances used in the process; reaction conditions; pesticide yield; byproducts, and any other substances that are known, or could reasonably be anticipated to form under the reaction conditions of the process. OPP also considers any impurities in the reactants or other substances used in the synthesis that may contaminate the technical product and contribute to overall risk.

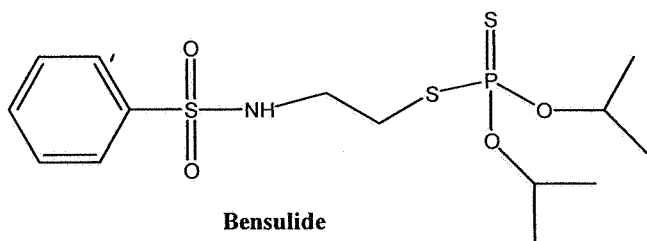
The structures of the nine organophosphorous substances are shown below. Naled has a chiral carbon atom (indicated with an asterisk), and fenamiphos, isofenphos and profenofos have chiral phosphorus atoms. Hence, two enantiomers are possible for naled, fenamiphos, isofenphos and profenofos. The other substances shown do not have chiral atoms and, therefore, it is not possible for them to exist as enantiomers. The Agency does not know the relative ratios of the specific enantiomers in the technical products of naled, fenamiphos, isofenphos and profenofos. However, the mammalian toxicity studies submitted by the registrants correspond to the technical products as manufactured, and reflect the actual toxicity of the technical products. The same is also true for the ecotoxicity studies submitted to the Agency. Therefore, even if one of the two enantiomers of any of the substances is substantially more toxic than the other enantiomer, and is present in the technical product, its toxicity would be expressed in the mammalian and ecotoxicity data submitted to the Agency and used in OPP's risk assessment of the technical product.



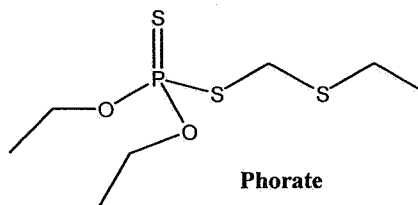
Azinphos-methyl



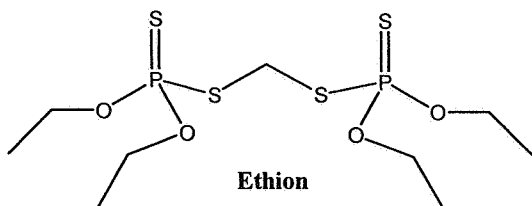
Naled



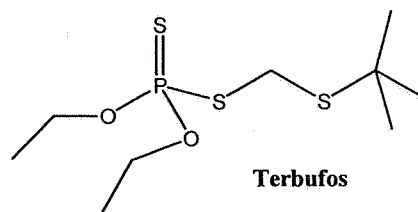
Bensulide



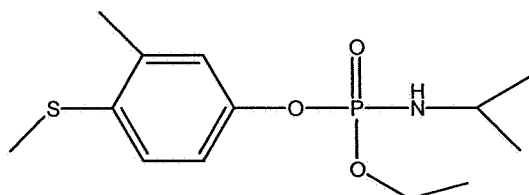
Phorate



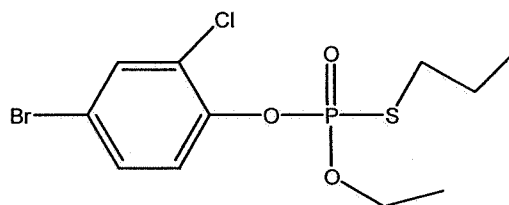
Ethion



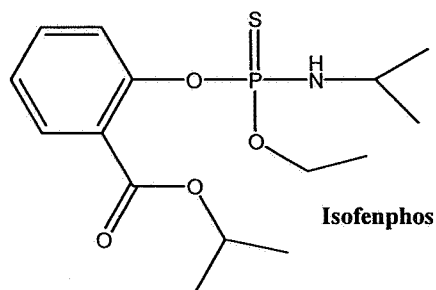
Terbufos



Fenamiphos



Profenophos



Isofenphos

OPP also considers environmental fate during its risk assessment of a given pesticide. Environmental fate laboratory studies are typically conducted with a pure sample of the pesticide, radiolabelled at least at one site of the molecule. Separation of specific enantiomers of a pure sample prior to the environmental testing is not required, and usually not performed. The Agency recognizes, however, that a specific enantiomer of a substance could convert to another enantiomer under actual environmental conditions. Environmental photolysis, for example, may lead to interconversion of one enantiomer to another. OPP evaluates geometrical, configurational and/or conformational isomer interconversions, but only for those chemicals known to show specific isomer bioactivity. That is, one or more of the isomers are the only ones associated with pesticidal activity over the other isomers.

For naled, fenamiphos, isofenphos or profenofos, OPP does not have optical rotation data on any of the pure active ingredients to rule out or confirm the prevalence of one enantiomer over the other, or to conclude that the active ingredient exists as an equimolar (racemic) mixture. The environmental fate studies submitted for these substances were not intended to follow the fate of individual enantiomers in regard to enantiomeric interconversions. Hence, OPP does not know to what extent, if at all, the individual enantiomers of naled, fenamiphos, isofenphos or profenofos interconvert in the environment. In addition, data are lacking regarding the mammalian toxicity and ecotoxicity of the individual enantiomers of these substances. Because of these data gaps, there is no basis from which OPP can consider in its risk assessments of these substances the possibility of, and extent to which the specific enantiomers of these substances may interconvert in the environment and the impact that such interconversions may have on human health and the environment.

It should be noted that EPA has recently published a Federal Register notice requesting public comment on how the Agency should handle registration of pesticide active ingredients (AIs) that are composed of chemical isomers. Among other issues, the notice solicits comment on whether or not an AI originally registered at a particular proportion of isomers should be subsequently registered as a new AI when purified for one or more chemically active isomers. The notice was published in the Federal Register on April 28, 1999, Volume 64, Number 81, Pages 22863-22865. Comments, identified by the docket control number "OPP-00580", must be received by June 28, 1999. EPA will consider comments received in developing a policy on registration of isomeric active ingredients.

As to the commentor's reference to large numbers of deaths resulting from OPs, EPA has no record of pesticide poisoning incidents of the magnitude described. One incident was reported in Pakistan among malaria workers. In this instance there was an abrupt shift from DDT to malathion use for mosquito control. One of the malathion batches was contaminated with the more toxic isomalathion, resulting in numerous exposures and possibly five deaths.

Anyone with specific knowledge of harmful incidents related to OP use or OP contamination with enantiomers is encouraged to submit them to EPA, so they can be considered in our risk assessments. Incident information is most useful if it contains sufficient detail to

determine the circumstances of exposures, e.g., was it an accident or misuse, what symptoms were observed, how severe and long lasting were the symptoms, etc.

2. Comments from Growers, Commodity and Marketing Groups

Comment: The Idaho Farm Bureau Federation felt that the criteria defining all OPs as having a common mechanism of toxicity are too broad. EPA should take time to develop appropriate criteria for common mechanism, gather actual data rather than rely on conservative default assumptions, and communicate decisions to all stakeholders. The Federation supports Vice President Gore's directive to have an open and transparent process, a reasonable transition to alternative products, and the use of sound science. They believe that sound science dictates not allowing decisions to be driven by a statutory time frame. The Federation offers assistance with usage questions.

Response: EPA is committed to the principles outlined by Vice President Gore. It is primarily for that reason that the Tolerance Reassessment Advisory Committee (TRAC) was formed and the pilot process for increased public participation in pesticide decisions was developed. However, EPA must balance the goal of providing for greater transparency and participation in development of science policy with its mission to ensure the safety of the food supply and the health of consumers--especially children, workers, and the environment. In order to accomplish our mission through timely decision making, EPA has established an ambitious schedule for completion of individual OP risk assessments and development of risk management options. It should also be noted that FQPA does establish a statutory deadline to complete the reassessment of existing tolerances by 2006, and the Agency is making every effort to comply with that deadline.

See also responses to II.A.1 and II.A.2 above.

Comment: The National Cotton Council notes that registrant comments in the dockets indicate relevant data were not considered in the assessments. Publishing risk assessments that are incomplete and thus inaccurate does not enhance the process, exemplify sound science, or inspire confidence in the growers that EPA will make good decisions. The Council is concerned that exposures from gin trash as a feed additive are grossly overestimated. No cotton uses should be canceled based solely on unacceptable risk resulting from gin byproducts using current EPA assumptions. (Note: OPs with cotton uses include azinphos-methyl, phorate, profenofos, naled, dicotophos, and DEF (tribufos). The Council is working with the Agency to "adjust" these assumptions.

Response: EPA representatives recently (10/13/98) met with a delegation from National Cotton Council (NCC) in response to their request to discuss cotton gin byproducts (CGB) and its proportion in livestock feeds. In addition to members of the NCC, representatives of cotton ginners associations (Texas Cotton Ginners Association, Southeastern Cotton Ginners

Association, and the California Cotton Ginners Association) were present. These experts are familiar with CGB, its volume of production in the USA, and its use as animal feed.

EPA discussed how a risk assessment is performed, i.e., how CGB are factored into the beef and dairy cattle diets and how potential transfer of residues to meat and milk could therefore affect a person's daily dietary intake of pesticide residues. Table 1 of OPPTS Test Guidelines Series 860 currently lists CGB as a raw agricultural commodity as comprising up to 20% of the diet of beef and dairy cattle.

Representatives of the ginners associations agreed that in some parts of the country CGB are fed at up to 10% of the diet to beef cattle when the cattle first enter the feed lot. CGB are then reduced to approximately 3% in the finishing rations. Based on this information, the NCC has asked EPA to reconsider how CGB are currently listed in Table 1.

EPA asked the NCC to provide detailed information concerning the disposition and use of CGB. The NCC has submitted, and EPA has approved, a protocol for obtaining such information.

See also response to II.A.2 above.

Comment: The Michigan Agricultural Cooperative Marketing Association notes that phorate fits well into growers established IPM plans to minimize pest resistance. Its loss would reduce effectiveness of the entire IPM program. Azinphos-methyl is essential to blueberries and tart cherries-- Michigan is a leading producer of these commodities in the US. No quantitative loss estimates were are given. The Association encourages EPA or USDA to obtain from growers on a national level the necessary use data which will satisfy the crop-pest-pesticide requirements so that proper FQPA decisions can be made.

The Association notes that the Michigan Department of Agriculture is completing a research project designed to evaluate the impacts of various production and handling practices on pesticide residues on food. The project was funded by EPA Region 5 and will test samples at the farm gate and at various stages during processing to quantify residue reductions. The Association urges EPA not to make any determinations--interim or final--until science policy issues are resolved; they acknowledge the magnitude of the task facing EPA in implementing FQPA and offer assistance.

Response: EPA has contacted Michigan State University to determine the scope and timing of the research that was described in this comment. The project is currently focusing on apples, peaches, blueberries, cucumbers, squash and potatoes, but other commodities are planned. The analysis of field data is scheduled for completion in 1999. Until these data are submitted and reviewed, we cannot comment on how they will impact current assessments. However, EPA notes that this type of data, i.e., linking actual application rates and practices with residue reduction from various processing techniques, could be very useful in determining pesticide-crop

specific processing factors for refining residue estimates. If these data are received in a timely manner, they can be considered in EPA's ongoing assessments.

See also response II.A.6 above.

Comment: US Apple Association has worked with the Agency to develop data that could refine residue estimates and has submitted such data to the Agency. However, it is impossible to ascertain from the preliminary risk assessment in the docket, what data were used in the azinphos-methyl apple assessment.

Response: This comment primarily relates to azinphos-methyl; however, a general discussion of how EPA employs use and usage data may be helpful. EPA has various sources for these data including USDA, California EPA, National Center for Food and Agriculture Policy, grower groups, as well as proprietary sources. These data tend to be more robust for major crops such as corn and cotton, and less so for minor crops. It is for these minor crops that usage data from growers can be most useful. In general, EPA incorporates use and usage data in a number of ways to assess dietary risk. Initial refinement involves incorporating the percentage of the crop that is actually treated (%CT). Further refinements involve applying processing factors, and calculating residue decline and residue degradation where data are available to quantify these residue reductions. Additionally, an apple cooking study on baby food could reduce the estimated dietary risk. Also, single serving data on apples could reduce or increase the estimated dietary risk.

Growers and others frequently point out that the actual or typical application rates and frequencies are lower than labeled rates and that actual PHIs are longer than those specified on the product labels, and that these typical values should be used in EPA's risk assessments. This information is useful to the Agency only if it is accompanied by data to quantify residue reductions from longer PHIs, lower application rates, etc. Further, in order for the Agency to be able to rely on lower application rates and longer PHIs in its risk management decisions, product labels may need to be revised to reflect these refinements.

In its refined risk assessments, EPA has tried to show clearly which refinements have been applied to each crop. For example, for azinphos-methyl the revised risk assessment has an appendix table of crop by crop descriptions of specific data used in the revised analysis. This table clearly indicates that the Agency used USDA Pesticide Data Program (PDP) and FDA monitoring data for 80% of foods treated.

Comment: The Grocery Manufacturers of America emphasized four general points: 1) the importance of sound scientific principles; 2) the importance of using all available data to the maximum extent feasible; 3) ensuring the availability of chemicals required for IPM programs; and 4) validate all models and methods before use for regulatory purposes.

EPA should use both monitoring data and processing studies wherever possible, including PDP, and FDA data and actual use practices rather than theoretical maximums and assumptions.

Response: Until now, EPA has used PDP monitoring data in acute dietary assessments only for blended commodities, such as apple sauce and tomato paste. EPA has not used PDP data for single serving commodities, such as a single fresh apple or a baked potato, because PDP data are derived from composite samples, and do not represent the highest concentrations that could be found in individual single servings. It is these potentially high residues that are of concern for acute dietary risk assessments. However, recently EPA has developed a statistical method to determine the range of residue values comprising composited samples for certain commodities. This method has been applied to several of the acute dietary assessments for the first 9 OPs, including azinphos-methyl. It is currently undergoing additional peer review.

See also responses to II.A.2, II.A.3, and II.A.6 above.

3. Comments from Environmental and Consumer Groups

Comment: The National Coalition Against the Misuse of Pesticides (NCAMP) questions why EPA has made only nine assessments available to the public and why the Agency has ignored common mechanism. NCAMP compared methodology across all nine assessments and found inconsistencies in methods, different ways of combining risks, different assumptions, data sources used, and formats.

For example, in the Human Health Assessments NCAMP feels that real world exposures such as drift, routine misuse, exposure to multiple chemicals, and exposures to children of farm workers were ignored. Similarly, for Ecological Risk Assessments, multiple routes of exposure should be considered, e.g. direct application, runoff, drift, bioaccumulation, etc. Direct and indirect (food chain) effects should also be considered.

For all assessments, not all inerts, contaminants, metabolites and degradation products were considered. EPA ignored sources such as NCAMP, other non-profits and Agencies, and open literature for incident and other information. EPA's assessments fail the criteria of transparency; EPA should produce a guide to all OP risk assessments summarizing hazard, exposures and why risks have not been combined.

Response: EPA considers, on a routine basis, a number of the factors that NCAMP lists as omissions in our risk assessments. Some of these considerations are standard procedures and as such, are not mentioned in every risk assessment. For example, both technical active ingredients and end-use products are tested for comparative toxicity and composition. If inerts, contaminants, degradates or metabolites of toxicological concern are identified, we can require additional data, both toxicity and environmental fate data, if necessary, on those substances. EPA's Inert Ingredients Policy identified inerts of most concern, required testing and labeling for certain classes of inerts, and has resulted in a shift from more to less toxic inerts in pesticide products.

When studies are brought to the Agency's attention, EPA can and has used information from the open literature for its risk assessments. For example, EPA's "Hazard Assessment of the Organophosphates" (July 1998) mentions literature studies as part of the weight-of-evidence considerations for acephate, chlorpyrifos, malathion, and methamidophos.

EPA routinely considers incident information in its risk assessments. The Agency maintains data bases of incidents related to human poisoning from pesticides, contamination of water resources, and wildlife exposures and die-offs due to pesticide exposure. We work with states, particularly California, other government agencies, and private organizations, such as Poison Control Centers to obtain accurate and up-to-date information related to pesticide exposure incidents of all kinds. We encourage NCAMP, through this public comment process, to actually provide EPA with any information that they may have relevant to the risk assessment of the OPs, rather than simply noting the existence of such information.

See also responses to II.A.3. and II.A.5 above.

Comment: The Learning Disabilities Association (LDA) notes that none of the first nine organophosphate chemical risk assessments retained the FQPA 10X factor. In the Report of the FQPA Safety Factor Committee, EPA found no evidence of enhanced susceptibility for 33 of 40 OPs. LDA seriously questions this conclusion based on two factors. First, is the inadequacy of the developmental neurotoxicity database. This is the only study that looks at functional effects like learning and memory. If EPA does not have developmental neurotoxicity data, how can we be sure there are no functional effects. Second is EPA's tendency to disregard offspring toxicity as "secondary" to maternal toxicity. LDA believes that even if developmental effects occur at higher doses than maternal, the maternal effects could be transient, and the effects in offspring might be permanent.

LDA requests EPA to defer final decisions on the FQPA 10X safety factor for all OPs until the expert panel recommendations for what constitutes an appropriate toxicity and exposure data base for making 10X determinations are available in late December.

Response: EPA's process for reviewing current procedures related to the 10-fold FQPA safety factor are described in detail above in section II.A.4. The Agency is currently beginning the public participation process to develop risk mitigation for the first nine OPs. Developing and implementing interim mitigation for these chemicals now does not preclude additional mitigation and/or data requirements in the future in response to new or revised policies and guidance. With few exceptions, the Agency's decisions related to the OPs cannot be considered final until a cumulative assessment has been conducted.

See also response to II.A.4 above.

Comment: The Natural Resources Defense Council (NRDC) submitted a copy of their report, "Putting Children First," and provided comments on four broad issues: 1) EPA fails to demonstrate the existence of reliable data for most OPs to justify departure from the use of FQPA

10X safety factor; 2) preliminary assessments do not provide reasonable certainty of no harm, e.g. EPA did not consider "sentinel" population of farmworker children; 3) EPA must conduct a cumulative assessment; and 4) often, e.g., for azinphos-methyl, occupational risks are unacceptable even with maximum mitigation. These should be eliminated expeditiously.

Response: EPA intends to complete risk assessments for individual OPs, taking into account any comments received during the public comment period. For the first nine OPs, the public comment period closed on the preliminary risk assessments in October, 1998. According to the plan developed by the TRAC, EPA will revise the risk assessments, respond to comments on the preliminary risk assessments, hold a Technical Briefing, and work with USDA and stakeholders to solicit risk management ideas.

See also responses to II.A.1, II.A.4, and II.A.5 above.

4. Comments from Other Federal Agencies

Comment: The Fish and Wildlife Service, Division of Environmental Contaminants, pointed out that all nine of the OPs have Final Biological Opinions (1989) for Endangered Species. FWS recommends that EPA implement, at a minimum, via label modifications and county bulletins, the applicable Reasonable and Prudent Alternative measures identified in 1989 Biological Opinions. EPA should also implement the risk reduction and mitigative measures identified in the OP ecological risk assessment documents to reduce hazards to non-target organisms.

Response: EPA is in the process of developing county-specific bulletins that specify measures to protect endangered and threatened species. Although bulletins have not yet been developed for all counties where they will be needed, EPA has included the pesticide use provisions from the 1989 Biological Opinion (as well as other opinions) or equivalent protective measures in the over 300 bulletins that have been completed and distributed.

The mitigation measures suggested in the preliminary ecological risk assessments, along with other measures that may be put forward during the comment period, will be considered in developing risk management strategies for these nine OPs.

5. Comments from Universities and Extension Services

Comment: The Texas Agricultural Extension Service provided a preliminary economic assessment of the withdrawal of certain FQPA target pesticides on prominent vegetable crops (onions, melons, carrots, crucifers and peppers) in the Rio Grande Valley of Texas. The report examines changes in yield and estimated economic losses in farm revenue, from the loss of various chemicals and combinations of chemicals including the OPs, bensulide, diazinon, dimethoate, disulfoton, chlorpyrifos. The assessment includes several other non-OP pesticides.

Response: This information has been provided to our Biological and Economic Analysis Division and to the Chemical Review Managers for the listed chemicals for use in developing risk mitigation options. Under the provisions of FQPA, EPA can not use benefits information as a rationale for exceeding acceptable dietary risk levels. However, such information could be useful in considering risks and developing transition strategies, if such strategies become necessary.

Comment: The Southeastern Professional Fruit Workers Conference, the annual meeting of applied fruit scientists (held at Clemson University in October, 1998) provided their evaluation of the OPs (and other pesticides) that are crucial in resistance management and IPM programs for crops in their area.. The group identifies opportunities for mitigation (primarily reductions in numbers of applications and increased PHIs). *(Note: This comment was submitted after the dockets for the first nine OPs closed. However, because it pertains to some of the first nine, we have chosen to address it in the first response document.)*

Response: This information has been provided to our Biological and Economic Analysis Division and to each of the Chemical Review Managers for the chemicals named in the analysis. This type of information is useful to the Agency in determining the feasibility of mitigation such as reduced frequency and timing of pesticide applications, and in considering risk trade-offs, where appropriate.

SUB BEAN: D258896
PC Code: 105001



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

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

FROM: David Farrar, Statistician, Terbufos RED task leader *David Farrar 8/20/99*
James Breithaupt, Agronomist *James Breithaupt 8/20/99*
Environmental Fate and Effects Division (7507C)

THRU: Pat Jennings, Acting Branch Chief *Pat Jennings 8/20/99*
Environmental Risk Branch II
Environmental Fate and Effects Division (7507C)

TO: Pam Noyes, Chemical Review Manager
Special Review and Reregistration Division

SUBJECT: Terbufos: Responses to Comments from American Cyanamid Co.
submitted Feb. 16, 1999; Updated characterization of Terbufos aquatic incidents

DP BARCODE: D253363 (D258896)

DATE: Aug. 20, 1999

The purpose of this communication is to respond to comments submitted by American Cyanamid Co. on Feb. 16, 1999. Concurrently but in a separate communication EFED is providing a RED chapter revised to address comments from Cyanamid, as well as other comments and information received recently by EFED.

Issues raised by Cyanamid include the significance of 'farm pond' incidents (in practice, usually fish kills), the interpretation of terrestrial risk quotients, and availability of an avian field study not considered in the draft chapter (11/4/98) that Cyanamid reviewed. In responding to Cyanamid's comments on aquatic incidents, we find it useful to synthesize EFED's previous communications on issues related to aquatic incidents.

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Characterization of Terbufos aquatic incidents. Previous communications from EFED related to aquatic incidents include a 4/11/99 memo discussing the significance of reported incidents. After the 4/11/99 communication EFED responded to material submitted to the docket by Martha Philbeck, whose pond was damaged by Terbufos applied on neighboring property, as were ponds owned by two neighbors of the Philbecks. Each of these communications has been placed in the Terbufos document.

The 4/11/99 communication includes the following points related to Terbufos incidents:

- For each reported incident there was some evidence to associate the incident with use on corn. Eighty percent of incidents occurred in five corn belt states (IA, IN, IL, NE, OH).
- Terbufos ranks fourth among all pesticides in number of incidents reported to the Agency, and first for incidents related to use on corn;
- EFED believes that incidents involving farm ponds are significant for reasons that include (1) the value of managed fish in the farm ponds; (2) the value of natural populations that farm ponds support (e.g., with breeding habitat, food, or water); and (3) the value of farm pond incidents as indicators of impacts on other surface water. Each of these points is discussed in detail in the 4/11/99 memo.
- Incidents reported annually ranged from 1 in 1996 to 18 in 1990. The average rate of incidents is 8 per year. The numbers of incidents per year are tabulated in the 4/11/99 memo, as well as in the recently revised RED chapter.
- The number fish killed in particular incidents ranged up to 90,000.
- All application methods for corn (band, t-band, and in furrow) caused incidents.
- Both 15G and 20CR formulations caused incidents.
- Large grassy buffer strips (350-1000 feet) did not prevent incidents in some cases.
- Incidents generally occurred from 2 days to 3 weeks after application.

Cyanamid maintains that the record of aquatic incidents demonstrates that a special series of events must occur in order for an incident to occur. However, the documentation provided is not adequate to support a position that the circumstances surrounding aquatic incidents are so peculiar that they will occur with negligible frequency. This applies in particular to the role of heavy rainfall, as discussed in greater detail below. Statements that incidents occur on highly erodible soils or soil with high runoff potential also have not been adequately documented.

Cyanamid performs calculations which attempt to quantify the rate of incidents relative to the number of acres treated with Terbufos. EFED does not agree that these types of calculation are meaningful. This type of approach treats the reported incidents as if they account completely for the adverse aquatic effects that actually occur in the field. EFED treats the reported incidents as a "sample" of the actual adverse effects due to a pesticide: *Reported* farm pond incidents are a sample of *actual* farm pond incidents. In addition to farm pond incidents (reported or otherwise), we expect that adverse effects occur in surface water other than farm ponds, but are detected and reported less frequently than incidents in farm ponds.

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(The EFED team wishes to acknowledge the assistance of David Brassard of the Biological and Economic Analysis Division, who developed a summary of the Terbufos incidents that is still the basis of EFED's characterization, while detailing in EFED.)

The "Philbeck," "Bright," and "Anders" incidents (Indiana). Subsequent to EFED's 4/11/99 discussion, EFED and other OPP staff reviewed additional information on 3 incidents in Indiana, on the property of the Philbecks and on property of two neighbors of the Philbecks (the Anders and the Brights). These incidents appear to have been reported to the Agency by Cyanamid under FIFRA 6(a)(2) (Adverse Effects Reporting Requirements). These incidents provide additional useful perspectives on incidents caused by Terbufos.

The incidents occurred in June 1998 and have been attributed to T-band applications of Counter 20CR by the same applicator during May 1998. These incidents were investigated by the state of Indiana and no indications of misuse could be identified. For the Philbeck incident, tests conducted by Cyanamid found residues of Terbufos metabolites (Terbufos sulfone and Terbufos sulfoxide) in tests conducted on July 9 and August 5. Residues could not be detected in a test on August 25. For the incidents on the Anders property and the Bright property, only parent Terbufos was tested for by the state. Parent Terbufos was not detected. However, it is known that parent Terbufos degrades rapidly to form the sulfoxide and sulfone metabolites, which are more mobile and persistent than parent Terbufos. Therefore the lack of detections for parent Terbufos does not provide useful information on the role of Terbufos in aquatic incidents. Detection of Terbufos metabolites but not parent Terbufos in the Philbeck pond provides further support for that conclusion.

The incidents illustrate how ecological damage caused by Terbufos can affect the quality of life of individuals. The Philbeck pond was a 2 acre body with large fish. Martha Philbeck reports "We have lost a much used food source, we lost recreational facilities for a whole summer. What if the neighbor kids would have gone swimming like they usually do and would have had serious problems ... ?" These incidents also illustrate that, due to the high persistence and mobility of Terbufos residues, ponds may be affected other than on the property of the farmers who actually use the pesticide. The Bright property is not located immediately adjacent to the property where Terbufos was applied, further confirming that in some situations buffers will not prevent incidents. The residue sampling for the Philbeck pond indicates that surface water contamination may occur for weeks following application.

The role of rainfall in causing aquatic incidents. Cyanamid maintains that the record of aquatic incidents demonstrates that a special series of events must occur in order for an incident to occur. However, the level of documentation required to support such a position is not available to the Agency, if such documentation exists. This applies in particular to the role of heavy rainfall. Cyanamid reports, for the majority of FIFRA 6(a)(2) submissions on the fish kills, that "heavy rainfall" preceded the incident. Cyanamid usually indicates a minimum rainfall volume (in inches). Cyanamid does not ordinarily report a time period in which the volume fell. Documentation of these values (e.g., daily records from rain gauges) are not reported by Cyanamid to substantiate the rainfall volumes claimed, and in fact no basis has been provided for the values stated. Therefore, although EFED has previously made use of the rainfall volumes

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indicated in Cyanamid in 6(a)(2) reports, at this time we conclude that these rainfall volumes are of questionable value for interpreting Terbufos aquatic incidents.

Indeed, it appears that for the recent incidents in Indiana discussed above, the information available at this time fails to support the descriptions given by Cyanamid. Cyanamid reported in August 1998 an incident in LaFontaine Indiana. Although Cyanamid's report does not identify the owners of the pond, we believe the incident is the Philbeck incident based on details of the description. Cyanamid states that "dead fish were noticed following heavy rainfall of >2 inches." Cyanamid's FIFRA 6(a)(2) report dated September 1998 on the Bright incident states "dead fish noticed following rainfall in excess of 5 inches." The state of Indiana (Office of the Indiana State Chemist and Seed Commissioner) obtained rainfall records from the Indiana Climate Page for two stations located about 30 miles west and northeast of the locations of the incidents. For the station receiving higher rainfall, found in the state report for the Philbeck incident, rainfall approached 2 inches for the entire week preceding the Philbeck incident, without exceeding half an inch on any day of that week. The information available to the Agency allows that incidents may be associated with normal springtime rainfall.

For the current RED chapter, EFED has removed references to rainfall volumes except where associated with a time interval. In place of rainfall volumes, the chapter states only that heavy rainfall was reported to precede the event.

Limitations of risk quotients (particularly terrestrial). Cyanamid presents a scatterplot (developed by the Office of Research and Development) showing no apparent correlation between RQs and mortality in field studies, for 24 field studies and for RQs within a range 1 to 1000. The EFED Terbufos team has not confirmed the data used in the scatterplot. However we do not view the result as unexpected. The graph does not actually relate directly to the primary use of RQs (determination of concern versus no concern) because the chemicals are only those for which RQ concern levels are exceeded. (Of course, field studies would ordinarily be conducted only where concern levels are exceeded.)

We concur with Cyanamid that it is desirable to develop procedures to quantify variability in exposure. However, we suspect that more refined risk assessment procedures will continue to predict poorly the level of mortality in field studies, because of irreducible variability in field conditions, the limited quantity of data collected in field studies, and other limitations of field studies.

We suggest that for Terbufos the dialogue on the limitations of risk quotients has little relevance. EFED suggests that discussion of mitigation strategy would naturally focus on reducing the frequency of aquatic incidents and/or other measures of mitigation effectiveness for adverse aquatic effects. If convincing measures can be put into place for the aquatic effects, it is possible that a significant reduction in terrestrial risk would result simultaneously (depending on the measures adopted). For Terbufos, the terrestrial RQs suggested a concern, and the field information suggests that indeed Terbufos sometimes kills birds in the field.

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Avian field studies by Knapton and Mineau. In previous communications, Cyanamid has called the Agency's attention to an important terrestrial field study (by Knapton and Mineau) which had not been incorporated in previous drafts of the RED chapter. Cyanamid has transmitted a copy of the paper by Knapton and Mineau (Ecotoxicology 4:138-145). Based on that study, EFED has removed a statement from the RED chapter stating that terrestrial field studies have consistently demonstrated acute hazard to birds. However, it is important that the limited sensitivity of field studies be kept in mind, as discussed in greater detail in the revised RED chapter.

Additional comments from American Cyanamid.

- 1) With regard to fate/transport properties of Terbufos sulfone and Terbufos sulfoxide, Cyanamid has submitted information on hydrolysis and aerobic aquatic metabolism which has been used by EFED to revise the EECs.
- 2) With regard to the relative attractiveness of different Terbufos formulations to birds (15G versus 20G) the RED chapter as recently revised does not contain hypotheses on that issue.
- 3) Cyanamid takes exception to EFED's description of a terrestrial incident in which Terbufos killed 20 hawks as "particularly severe." However, the arguments given by Cyanamid relate to the frequency (or uniqueness) of the incident rather than to severity. EFED considers the report submitted by Cyanamid (Bennett et al.) to be useful. The report was reviewed by an avian biologist in EFED as well as by the RED team, and material from the report has been incorporated into the RED chapter.

cc Tom Steeger
Edward Fite
James Felkel

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

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

FROM: David Farrar, Statistician, Terbufos RED task leader *David Farrar*
James Breithaupt, Agronomist *James Breithaupt*
Environmental Fate and Effects Division (7507C)

THRU: *Pat Jennings*
Pat Jennings, Acting Branch Chief *8-5-99*
Environmental Risk Branch II
Environmental Fate and Effects Division (7507C)

TO: Pam Noyes, Chemical Review Manager
Special Review and Reregistration Division

SUBJECT: Terbufos: Response to material submitted for the docket by Martha Philbeck,
and related material.

DP BARCODE: D257287, *PC Code: 105001*

DATE: Aug. 5, 1999

The purpose of this communication is to comment on material submitted for the terbufos docket, by Martha Philbeck of LoFountain Indiana, concerning an aquatic incident in a 2 acre pond on her property in 1998. In addition to comments received from Philbeck (multiple items received in 1999), we have reviewed the following related material indicated by SRRD:

- 6(a)2 reports submitted by the registrant (American Cyanamid);
- Material from an investigation of the incident by Kevin Neal, Pesticide Investigator in the Office of the Indiana State Chemist and Seed Commissioner.
- communications received by Philbeck from Am. Cyanamid and from Kevin Neal.

In addition to material on the incident on the Philbeck property, EFED has reviewed material on incidents that occurred on property of neighbors of the Philbecks, which the affected

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parties have attributed to terbufos use by a single applicator. Here we focus on the incident on the Philbeck property, which resulted in submission of comments to the terbufos docket. We have some indications that these incidents may be subject to litigation.

According to M. Philbeck, dead fish were noted in the pond on June 13, 1998. After learning that Counter had been applied on the property of a neighbor, Philbeck contacted Cyanamid. Cyanamid tested for terbufos residues on July 9, Aug. 5, and Aug. 25. Residues were found on the first 2 sample dates. The Cyanamid 6(a)2 report indicates a detection limit of 1 ppb. Pet ducklings placed in the pond by a neighbor died with frothy salivation, indicating organophosphate poisoning. Therefore the report of the incident in the RED chapter will include ducks as a species affected.

Communications from Cyanamid to Philbeck indicate that the compounds detected were terbufos metabolites rather than parent terbufos. The Cyanamid 6(a)2 reports identify the detected chemicals as terbufos sulfone and terbufos sulfoxide. Based on the mobility and persistence of the degradates compared to parent terbufos, EFED believes that it is actually more likely to detect the degradates. Although EFED does not have toxicity information for terbufos sulfone and terbufos sulfoxide at this time, limited information based on other organophosphate sulfones and sulfoxides in EFED's toxicity one-liner database supports that these type of compounds may be toxic to aquatic animals.

In all the material we have reviewed, the most probable source of the pesticide is identified as use by a specific applicator on the property of a neighbor (the Brinson farm). A report prepared by Kevin Neal states that "the Philbeck pond is located to the south and west of the field ... where, according to a Pesticide Investigation Inquiry (PII) completed and signed by [applicator], an application of Counter Insecticide was made on 5/19/98." That PII (dated 10/20/98) indicates T-band application of 456 lb Counter CR at 6 lb/acre (presumably formulated product). For a 20% formulation, that rate would correspond to 1.2 lb active ingredient/acre.

Based on the finding of terbufos residues, and the overall plausibility of the description, EFED concludes that there is adequate evidence to conclude that the incident was caused by terbufos. We have received no evidence of misuse for the incident. The Neal report concludes that "after reviewing the label for Counter insecticide reference the use directions of this product it was determined that none of the restrictions had been violated." Also, the Agency has received no evidence that the incident occurred under environmental conditions or other circumstances that are expected to occur infrequently. The Cyanamid 6(a)2 report states that "dead fish were noticed following heavy rainfall of >2 inches." However, as with other 6(a)2 reports, Cyanamid does not state the duration of time to which the rainfall applies. The Neal report provides estimates of rainfall for the period preceding the incident, from the Indiana Climate Page. According to those data, the total rainfall for the week up to June 13 approaches 2 inches, with no more than 0.51 inches falling on any one day of that week.

The comments from Philbeck illustrate some of the ways that pesticide incidents may affect individuals. Philbeck reports "My husband retired to enjoy the fishing in the pond and we had 25 years of growth in the fish. He cannot live long enough for them to get that big again."

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"We have lost a much used food source, we lost recreational facilities for a whole summer. What if the neighbor kids would have gone swimming like they usually do and would have had serious problems ... ? My dogs are water dogs and was told to keep them from the water" "We could not let anything near the water." Philbeck indicates disappointment with the protection applied by "government agencies" and wonders "What can be done to prevent this from happening again?"

In this incident, a balanced pond community with a history of sustained yield was severely impacted. While complete recovery, including presence of some large fish and an appropriate balance of predator and prey species, might not require 25 years, complete recovery with a few years could be difficult and expensive. Philbeck provides a range of observations on the biological community associated with the pond after the incident, such as algae and snakes, suggesting undesirable indirect effects. A range of indirect effects is conceivable, but EFED cannot make use of the specific observations suggesting indirect effects, without corroborative evidence supporting that the specific effects are expected to result from pesticide contamination.

cc David Brassard
Tom Steeger

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