October 12, 1999

MEMORANDUM

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

FROM: Beth Edwards, Chemical Review Manager
Special Review and Reregistration Division
Office of Pesticide Programs

TO: OPP Public Docket for Fenthion
Docket # 34145

Introduction

This document addresses public comments that were received in response to EPA's Notice of Availability (63 FR 48213, September 9, 1998) of preliminary risk assessment[s] for the seven organophosphate chemicals: cadusafos, dimethoate, ethoprop, fenthion, sulfotepp, temephos and tribuphos. Part I of this document addresses comments specific to fenthion, 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 seven chemicals or for a significant sub-set of the seven. Also, these non-chemical-specific comments generally apply to regulatory or science policy issues that are not unique to any one of the risk assessments.

Part I: Fenthion Specific Comments and Responses

A. Response to Comments on the HED Chapter

1. Comments were received from Bayer Corporation Agriculture Division on November 9, 1998 regarding the HED Chapter. These comments, and the Agency's response, are summarized below.

Comment: Bayer addressed the issue of the Agency's inclusion of potential exposure scenarios from granular products in the fenthion risk assessment even though no granular products are currently marketed. Bayer stated that while there are active registrations for a granular fenthion

mosquito larvicide product held by Amvac, no fenthion product has been sold by another registrant for use in a mosquito control product since prior to the issuance of the Registration Standard. Bayer has asked that these exposure scenarios be removed from the risk assessment.

Response: A recent survey of mosquito pesticide use (1998 survey of Mosquito Control Districts in the U.S. by the American Mosquito Control Association for the use year 1996) shows that these products have been used in the Pacific Northwest as recent as 1996. At this time, the Agency will continue to assess the risk from this use of fenthion. In addition, the Department of Health & Human Services (DHHS) has stressed the importance of this use internationally.

Comment: Bayer stated that the Agency reached an agreement for cancellation of Rid-A-Bird in December 1997 and that this information was left out of the HED chapter.

Response: The Agency reached an agreement with Rid-A-Bird, Inc. on November 5, 1997 to voluntarily cancel Rid-A-Bird Perch 1100 Solution and published a Memorandum of Agreement in the Federal Register on March 27, 1998 (63 FR 14924). This aspect of the regulatory history of fenthion will be discussed in the upcoming RED for fenthion.

Comment: Bayer stated that no flagging operators involving human bodies are involved in aerial adulticiding operations. Bayer committed to submit an application for amended registration for Baytex Liquid Concentrate, EPA Reg. No. 3125-194 and asked that these exposure scenarios be removed from the risk assessment.

Response: There are currently no restrictions on the technical label or the liquid concentrate that prohibit the use of human flaggers. To date the application for amended registration referred to above has not been received. Accordingly, this exposure scenario will not be deleted from the risk assessment.

Comment: Bayer believes that the Agency is using the wrong average application rate for fenthion in Lee County, Florida. The Agency is using an average application rate of 0.056 lb ai/acre in the risk assessment. Bayer maintains that the correct average application rate for fenthion in Lee County, Florida is 0.029 lbs ai/acre.

Response: Data that document the actual quantities of fenthion used for mosquito control in various Florida counties (1993-1995) (*Florida Coordinating Council on Mosquito Control's* "White Paper") were used to determine average application rates. The average aerial application was calculated to be 0.056 lb ai/acre and the average ground was 0.016 lb ai/acre. These average rates were considered in conjunction with the label maximum rates for these methods in order to provide for a more informed risk management decision. The maximum application rates for each method are 0.1 lb ai/acre for aerial and 0.03 lb ai/acre for ground. Note that for regulatory purposes, the maximum rate is used.

2819

B. Response to Comments on the Environmental Fate and Effects Preliminary Risk Assessment

1. Comments were received from Bayer Corporation Agriculture Division on November 9, 1998 regarding the EFED Preliminary Risk Assessment. These comments, and the Agency's response, are summarized below.

Comment: Bayer believes that the Preliminary EFED Risk Assessment is incorrect when it states that "acceptable data have not been submitted for degradates." Bayer states that there are data evaluating the toxicity of fenthion sulfone and sulfoxide to bluegill and freshwater trout that demonstrate that neither the sulfone or sulfoxide are toxic to bluegill or trout and at concentrations up to the maximum tested (100 mg/L).

Response: These studies were evaluated by EFED and considered to be invalid, and therefore unacceptable. This will not result in a change to the EFED chapter.

Comment: Bayer has requested a meeting with the Agency, once the risk assessments have been completed, to discuss additional data requirements to support the continued registration of fenthion for adult mosquito control.

Response: For EFED, the additional requirements are 3 acute shrimp studies, one for a formulation, one for the sulfoxide degradate, and one for the sulfone degradate. Note that even if the above mentioned fish studies with the degradates were acceptable, it would not negate the need for testing of those degradates with shrimp since shrimp are far more sensitive than fish to parent fenthion.

C. Other Comments

1. Other comments from Bayer Corporation, Agriculture Division dated November 9, 1998.

Comment: One of the objectives in the use of fenthion in adult mosquito control is potential disease vector control. Thus, the public health benefits of fenthion need to be considered in the assessment of the eligibility of fenthion for reregistration of the mosquito control use. Information has previously been provided to the Agency on the need expressed by Florida mosquito control districts for the continued useof fenthion due to the development of resistance to alternatives for some species and the physical and chemical properties advantages over other alternatives. If further infmation is needed by the Agency regarding fenthion and potential alternatives, the Agency may wish to hold a meeting with the mosquito control district officials to discuss these issues.

Response: The Agency is also very concerned about the public health aspects of mosquito control. The Agency will consider this very carefully should any risk mitigation for mosquito

control uses be necessary.

2. Comments were received from several mosquito control districts in Florida (Collier Mosquito Control District, Indian River Mosquito Control District, Lee County Mosquito Control District, and East Volusia Mosquito Control District) regarding the benefits of fenthion as a mosquito adulticide. These comments are summarized below.

Comment: Several mosquito control districts in Florida (Collier Mosquito state that they are dependent upon this product as a tool to control mosquito vectors for the following reasons: 1) nuisance mosquitoes and disease carrying mosquitoes are effectively controlled by fenthion; 2) many mosquitoes are resistant to other pesticides; 3) fenthion can be used in ground adulticiding operations without irritation to the public; 4) aircraft operations are efficacious (i.e., payload vs. application rate); 5) fenthion is compatible with metallic materials, unlike other pesticides which attack metal; 6) cost per acre are reasonable; and 7) fenthion stores well.

Many offices employ an Integrated Pest Management (IPM) approach to mosquito control which includes rotating among several adulticides to try and avoid mosquitoes developing resistance to any one of them. Baytex, which is currently labeled for use as a mosquito adulticide in the State of Florida, is one of only a handful of chemicals which can serve as part of this rotation.

In addition, as public health officials, they state that it is their duty to protect the citizens of their communities from vectors. Fenthion has been a tool which they have relied upon for a number of years.

Response: The Agency understands the importance of this chemical as a mosquito adulticide and will consider the information given above carefully should any risk mitigation for mosquito control uses be necessary.

Part II: Non-Chemical-Specific Comments and Responses

Non-chemical-specific comments were received from: Idaho Farm Bureau Federation; National Cotton Council; Natural Resources Defense Council (NRDC); American Farm Bureau Federation; Fish and Wildlife Service, Division of Environmental Contaminants; Southern Professional Fruit Workers Conference (held at Clemson University); and 14 individuals, 13 of whom identified themselves as pest control operators (PCOs) or otherwise associated with the professional pest control industry. The other individual commentor, John Abbotts, provided no organizational affiliation.

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

4/8/19

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: Several commentors, including the NRDC and Private Citizen Abbotts, questioned why EPA has not considered a common mechanism of toxicity in these OP risk assessments.

Response: 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 a 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), 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 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 recently submitted a report to the Agency outlining its findings. 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 late summer/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 and Default Assumptions

Comments: The American Farm Bureau Federation, The National Cotton Council and Private Citizen Abbotts encouraged EPA to obtain the data necessary to conduct realistic risk assessments. A common theme was that EPA should use actual data, particularly usage data, and avoid default assumptions in its assessments. Private Citizen Abbotts encouraged EPA to cancel all registrations, rather than make assumptions, when required data are missing.

Response: In phase four of reregistration, EPA exercised its data call-in authority to require studies to upgrade chemical databases 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 an additional safety factor where data are incomplete.

It should be noted, however, that the OP risk assessments that were in the docket at the time this comment was submitted were "preliminary," and that many of the first assessments were completed prior to receipt of all data. During the public comment and response period, EPA has continued its evaluations of available data, e.g., Monte Carlo analyses and other data, for these seven chemicals, and these evaluations have been incorporated into the refined 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 revised assessments.

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 at: http://www.epa.gov/oppfead1/trac/science.

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

Comments: 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. They also requested that EPA offer an explanation as to why the additional safety factor should not be retained for all OPs that are not supported by a developmental neurotoxicity study.

Response: OPP has developed criteria for retaining, reducing, and removing the additional 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 Scientific Advisory Panel (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 available 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 was published on July 8, 1999. The deadline for comments has been extended to October 7, 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 SOPs and decide how best to incorporate the revised procedures into its ongoing decision making process.

It should be noted the EPA has recently (September 10, 1999) issued a Data Call-In (DCI) notice for all OP pesticides with food uses to fill any existing data gaps for acute, subchronic and developmental neurotoxicity data. This first notice will be followed shortly by other similar DCIs for these same data for other classes of chemicals known to be neurotoxic.

4. Comments Related to Highly Exposed Populations

Comments: 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 assessment for the first 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.

7819

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 ways children can be exposed (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 in the agricultural setting.

5. Comments Related to Relying on Sound Science

Comments: The National Cotton Council, American Farm Bureau Federation and Private Citizen Abbotts all supported EPA's reliance on sound science to make regulatory decisions. The National Cotton Council encouraged the Agency to finalize the nine science policy issues identified during the Tolerance Reassessment Advisory Committee (TRAC) before making regulatory decisions.

Response: EPA is committed to the principles outlined by Vice President Gore to have an open and transparent process, a reasonable transition to alternative products, and the use of sound science. It is primarily for that reason that the 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

8819

decision making, EPA has established an ambitious schedule for completion of individual OP risk assessments and development of risk mitigation 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.

6. Comments Related to a Transparent Process

Comments: The National Cotton Council, American Farm Bureau Federation, Natural Resources Defense Council (NRDC) and Private Citizen Abbotts applauded EPA's efforts to make a transparent process for the reregistration of the organophosphate pesticides. NRDC felt that further efforts were needed to ensure that all risk assessment methods used to establish tolerances (e.g. Monte Carlo methods and underlying assumptions) were transparent. Private Citizen Abbotts noted that the formats for risk assessments were not always consistent, that the "bottom line" risk could not always be determined, and that a table summarizing risks for all OPs would help in making risk management decisions.

Response: EPA agrees that a transparent process is essential to public participation and sound decision making. The Tolerance Reassessment Advisory Committee (TRAC) was established to ensure that the process for the reregistration of the organophosphate pesticides was transparent and open to all. EPA intends to continue its dialogue with the various constituents throughout the reregistration process.

EPA acknowledges inconsistencies in the assessments for the first 16 OPs. In many cases, the assessments were begun many months ago and have not been constantly updated to reflect new formats. 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 for each chemical. 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, highlighting any assumptions and refinements that have been used, and discussing ways of further refining the risk assessments.

7. Comments Related to Transitioning to Safer Alternatives

Comments: American Farm Bureau Federation expressed concern that EPA administer FQPA in a practical and realistic way by allowing sufficient transition time for users to adapt to new or alternative products and practices. In his comments, Private Citizen Abbotts advocated linking approval of safer chemicals with cancellation of corresponding "older, riskier alternatives."

Response: EPA's Registration Division has established a priority plan intended to encourage and expedite the registration of reduced risk pesticides and, particularly, alternatives to the OPs. However, this priority plan is not "linked" to cancellation of specific "older, riskier, alternatives." To do so would likely slow down both processes. In some cases, there may already be preferable

alternatives, and thus no need to wait for a new reduced risk registration. Conversely, when a safer chemical is registered, it may take several years of use on actual field crops before its ability to completely replace another chemical is known and recognized.

With regard to the American Farm Bureau's concern, EPA is working closely with USDA and grower groups in developing risk mitigation and transition strategies.

B. EPA's Response to Submitter - Specific Comments

1. Comments from Private Citizens

Comment: Private Citizen John Abbotts submitted a detailed 15-page letter outlining his views on the Agency's preliminary risk assessments and made several suggestions for process improvements. In addition to the comments addressed above, Mr. Abbotts indicated that some of the risks presented in the preliminary assessments were substantive enough to trigger immediate regulatory action by the EPA.

Private Citizen Abbotts also advocated that the EPA quickly process all deletions of particular uses requested by registrants. He particularly cited a letter where the registrant for dimethoate, Cheminova, requested cancellation of all dimethoate residential uses. Similarly, Mr. Abbotts requested that the EPA revoke all tolerances for which there are no registered uses. .

Private Citizen Abbotts expressed concern that the EPA was allowing other pesticides, such as cadusafos, to remain on the market, even though the risk assessment used residues of ½ the Limit of Detection (LOD) and percent crop treated data rather than tolerance level residues and 100% crop treated. He felt that the risks were unacceptable using 100% crop treated and tolerance level residues. Mr. Abbotts also suggested that EPA establish import tolerances based on toxicological data so that consumption at tolerance level would result in acceptable dietary risk.

Private Citizen Abbotts also made several suggestions for implementing a risk-reduction strategy to begin reducing the cumulative risks posed by organophosphates. These suggestions included requiring each registrant to reduce the cumulative risk from all of their registered organophosphate products to acceptable levels, requiring registrants to work together to reduce the risk on each commodity to a level consistent with the commodity's proportion of the diet, or creating market-based incentives for reducing the risks to organophosphates.

In his letter, Mr. Abbotts also maintains that the Agency should examine cumulative occupational risk.

Response: EPA disagrees that the risks outlined in the assessments for these seven chemicals are significant enough to require immediate regulatory action. All of these assessments are

preliminary in nature and thus the stated risks likely overestimate the actual risk posed by the use of the chemical. Before demanding risk mitigation measures that may adversely affect the safety of the U.S. food supply, EPA has a duty to ensure that the risk assessment is as refined, and thus realistic, as possible.

EPA agrees with Mr. Abbotts assertion that use deletions should be processed quickly. However, registrants frequently propose to delete uses to mitigate risks without actually submitting amendments to remove those uses from their labels. In addition, other registrants may have registered products with the same uses and be unwilling to remove them from their labels. Unless all registrants of a particular chemical request to delete these uses from their labels, these uses will remain part of the risk assessment. Finally, the Agency is committed to vetting proposed deletions with the grower community and other members of the public before taking any regulatory action. The TRAC (Tolerance Reassessment Advisory Committee) has been specifically established to promote this kind of dialogue among the public, grower groups, industry and EPA.

FQPA establishes a statutory deadline to complete the reassessment of existing tolerances by 2006. The Agency is making every effort to comply with that deadline. As part of this goal, EPA has taken actions to revoke all tolerances for which there are no registered uses and that are not supported for import purposes. See 65 FR 5907 published February 5, 1998.

In a worst-case risk assessment, such as that referenced by Mr. Abbotts for cadusofos, EPA typically assumes tolerance level residues and 100% crop treated. These worst-case assessments are used for screening purposes only and are an attempt to conserve Agency resources. If further refinements are needed to characterize dietary exposure, EPA calculations may include percent-crop-treated data, averages of field trial data or other information. The refined exposure estimates are so designated because they are more likely to approximate the pesticide residues people will actually consume in their diets.

Often, a residue chemistry data set contains some samples that are reported as not bearing detectable or quantifiable residues, i.e., residues are less than the LOD. This is frequently the case for early season applications, long treatment-to-harvest intervals, and/or monitoring of the food supply closer to the point of consumption. Given the above information, the Agency has chosen to assign a residue value of ½ LOD (or ½ LOQ if an LOD has not been determined) to samples with no detectable residues if it is known or believed that these samples have been treated with a pesticide. This is believed to represent a minimal distortion of reality if only a small proportion (e.g., less than approximately 10-15%) of the data are below detectable limits. The use of ½ LOD for nondetectable samples is widely used in EPA risk assessments when the appropriate conditions are met, as in the cadusafos risk assessment. For further discussion, please see the draft science policy paper entitled, "Assigning Values to Nondetected/Nonquantified Pesticide Residues in Human Health Dietary Exposure Assessments," (dated 11/30/98).

EPA currently establishes import tolerances in a manner similar to that used to establish

11819

domestic tolerances. Translations of the labels used overseas and the foreign field trial data are evaluated. A number of field trials are required which must demonstrate the range of climate conditions and cultural practices. These variations can lead to a range of residue values, which can vary from non-detectable to large concentrations. Using data from the field trials, EPA performs its risk assessment, refining residue estimates as necessary. If the risk is acceptable, EPA establishes a tolerance at a level that is higher than the highest residue value obtained in the field trial data as it does when establishing a tolerance for use of a pesticide domestically.

Mr. Abbotts is suggesting that import tolerances be set by a process in which the toxicity data are combined with the consumption data to generate the highest allowable pesticide concentration in the commodity. However, such a process would provide no assurances to farmers applying pesticides to their crops at the labeled application rates that the resulting produce would contain residues below the established tolerance levels at the farmgate where these levels are monitored for enforcement purposes. EPA must ensure that use at the labeled application rate will not result in produce containing residues that are greater than the tolerance level. Field trial data are needed to ensure that the produce grown will indeed contain residues at levels below the established tolerance. Currently the USDA's Pesticide Data Program (PDP) monitoring data is the best indication of actual pesticide residue levels at or near the point of consumption.

The Agency appreciates Private Citizen Abbotts proposals for risk mitigation strategies and, in fact, has initiated preliminary discussions about particular risk mitigation strategies that may cut across pesticides or commodities. The Agency expects that these discussions will likely address the value of particular pesticide uses irrespective of the identity of the registrant.

EPA recognizes that farmworkers may be exposed to multiple chemicals, however, as Mr. Abbotts mentions, occupational risk is not included in the FQPA statutory requirements for cumulative assessments. Currently EPA does not have a methodology for conducting such assessments and must continue to assess occupational risk based on a single chemical. Once the Agency establishes a method for determining cumulative exposure, it may be able to expand its guidelines to include occupational exposure scenarios.

See also responses to II.A.1, II.A.2, II.A.5, II.A.6 and II.A.7 above.

Comment: Thirteen individuals, who identified themselves as pest control operators requested that EPA: base its decisions on actual pesticide use, obtain necessary information through data call-ins, establish and communicate uniform policies to guide consistent implementation of FQPA, refrain from taking regulatory action based on unrealistic default assumptions.

Response: See responses to II.A2, II.A.5 and II.A.6 above.

13219

2. Comments from Universities and Extension Services

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).

Response: This comment was submitted in response to the second group of seven OPs. However, because it pertains to some of the first nine, it was addressed it the response to comment document for the first nine OPs.

The information provided by the Fruit Workers Conference 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.

3. Comments from Growers, Commodity and Marketing Groups

Comment: The National Cotton 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, methyl parathion, phorate, profenofos, naled, dicrotophos, and tribufos) The Council is working with the Agency to "adjust" these assumptions and indicated that they would be submitting additional data.

Response: EPA representatives met October 13, 1998, 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 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. Information submitted should be able to be independently verified by OPP. The NCC submitted a protocol for obtaining such information. EPA has approved the protocol and is currently awaiting submission of this information.

See also responses to II.A.2, II.A.5, and II.A.6 above.

4. Comments from Environmental and Consumer Groups

Comment: The Natural Resources Defense Council (NRDC) submitted a copy of their report, "Trouble on the Farm," 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 farm worker children; 3) EPA must conduct a cumulative assessment; and 4) Often, e.g. azinphos-methyl, occupational risks are unacceptable even with maximum mitigation. These should be eliminated expeditiously

In addition, the NRDC urged EPA to account for "enantiomer" and metabolite toxicity in reassessing tolerances for the OPs. Enantiomers are mirror image molecules produced in the manufacture of organophosphate active ingredients. Specifically, the commentor 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's assessments.

Response: With respect to worker risks, EPA intends to complete risk assessments for individual OPs, taking into account any comments received during the public comment period. For the seven OPs, the public comment period closed on the risk assessments in November, 1998. According to the plan developed by the TRAC, EPA will respond to comments on the risk assessments and work with USDA and stakeholders to develop risk management options for risks of concern, including workers.

Regarding enantiomer toxicity, this issue was also raised in the comments and responses for the first nine OPs. Enantiomers of a given substance are isomers whose mirror images are not superimposable. Enantiomers have identical physicochemical properties, except in the direction in which they rotate a plane of polarized light. The Agency agrees with NRDC's comment that enantiomers of a given substance may vary in toxicity and, therewith, pose different risks to human health or the environment. In a given manufacturing process it is possible that more than one specific enantiomer can form, unless the reaction conditions and feedstocks are such that formation of only one enantiomer is possible. It is also possible that one enantiomer may be produced more readily than another enantiomer, and may predominate in the technical product.

Even if an enantiomer is formed in low concentration relative to another enantiomer during synthesis of a technical 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. Technical products of pesticide substances that can exist as two or more enantiomers usually do not undergo purification procedures that remove a specific enantiomer. These pesticide substances are generally used as obtained from synthesis, and are often comprised of more than one enantiomer. Individual enantiomers of a substance may interconvert in plants, mammals or the environment. Hence, a specific enantiomer of a substance may be converted into its other enantiomer as a result of plant or animal metabolism, or release into the environment. It is also possible for a substance that cannot exist in enantiomeric forms (i.e., is achiral) to be metabolized to other substances for which enantiomers are possible and are formed.

The Agency also agrees with NRDC's comment that metabolites (e.g., plant, farm animal, or mammalian metabolites) of a pesticide substance are often sufficiently toxic so as to contribute to the overall risks associated with use of the pesticide and consumption of foods that contain the pesticide and its residues. In some instances a metabolite may have substantially greater toxicity than its parent substance.

EPA believes, however, that its risk assessments of the seven subject organophosphorus pesticides adequately take into account the toxicity of any of their enantiomers or metabolites. In assessing the risks posed by a given pesticide substance, EPA evaluates a number of factors that may contribute to risk. These include, for example: the mammalian toxicity of the parent substance; its mammalian metabolism from different routes of exposure; its metabolism in plants and livestock (e.g., dairy cows, steer, poultry); the known or potential toxicity of mammalian, plant and livestock metabolites; the environmental fate and ecotoxicity of the parent substance; dietary exposure to the parent substance and its plant and livestock metabolites; exposure that may result from consumption of waters that contain the pesticide or environmental degradates thereof; and exposure that may result from residential or occupational use of the pesticide. Plant and livestock metabolites of toxicological concern are identified by EPA from an evaluation of plant and animal metabolism studies required for registration or reregistration.

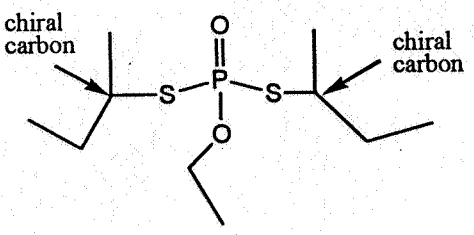
EPA also routinely evaluates the manufacturing processes used to synthesize pesticide active ingredients as part of its process to evaluate the risks posed by pesticides. Submission of information pertaining to method of manufacture is required for registration and reregistration of pesticides. The primary 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. EPA considers any impurities in the reactants or other substances used in the synthesis that may contaminate the technical product and contribute to overall risk. Once a method of manufacture has been reviewed and deemed acceptable by EPA, the registrant must use that method of manufacture. The registrant cannot

change or modify a method of manufacture until the Agency has evaluated the method and its impact on overall risk of the pesticide technical product. Thus, the composition of a pesticide technical product as manufactured from a process deemed acceptable by EPA should remain consistent among different lots.

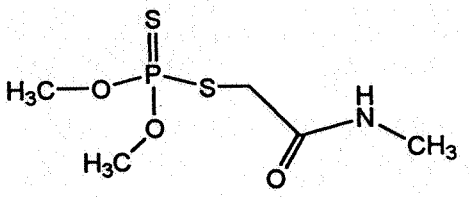
As stated above, technical products of pesticide substances that exist as two or more enantiomers often do not undergo purification procedures that remove a specific enantiomer, and these pesticide substances are generally used as obtained from synthesis. Current guidelines do not require that registrants provide EPA with information regarding which particular enantiomers are present, or their relative concentrations. EPA is generally unaware of which specific enantiomers or concentrations thereof are present in pesticide technical products. However, the presence and concentrations of specific enantiomers comprising a technical product are not expected to vary among manufactured lots because the same method of manufacture is used for each lot. While the Agency may not be aware of the presence or concentrations of specific enantiomers comprising the technical product of a pesticide substance for which enantiomers are possible, mammalian toxicity data required for registration (or reregistration) of the technical product represent the combined toxicity of the pesticide (including any enantiomers that are present) and its mammalian metabolites.

Environmental fate laboratory studies involving a pesticide substance are typically conducted using radio labeled substance in which the substance is radio labeled in at least at one site of the molecule. 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. EPA evaluates geometrical, configurational and/or conformational isomer interconversions that occur in the environment, 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.

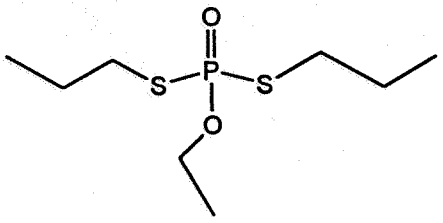
The structures of the seven subject organophosphorus substances are shown below:



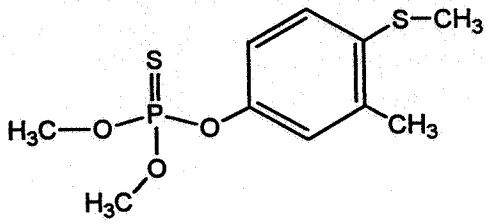
cadusafos



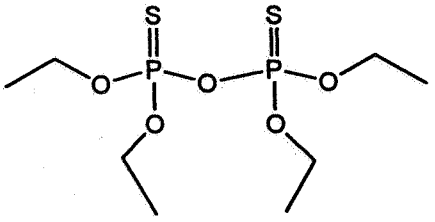
dimethoate



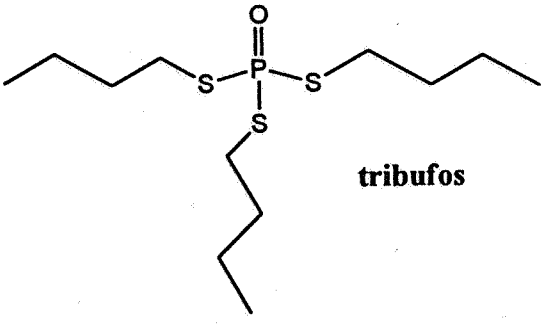
ethoprop



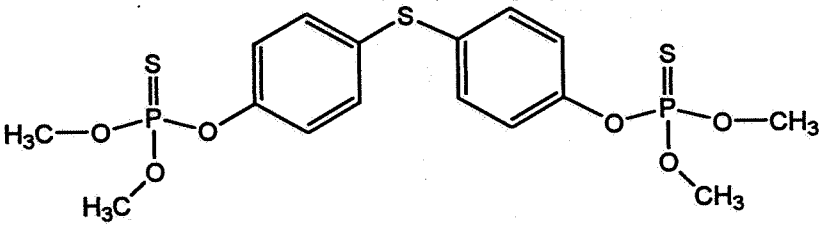
fenthion



sulfotep



tribufos



temephos

17819

Of these seven substances only cadusafos can exist in enantiomeric forms. This substance has two chiral carbon atoms (as indicated) and, thus, a total of four distinct enantiomers are possible. The other six substances do not contain any atoms that are chiral and, therefore, it is not possible for them to exist as enantiomers. It is theoretically possible, however, that any of the seven substances could be metabolized in plants or mammals or degraded in the environment to other substances that could exist as enantiomers. Hydrolysis of one of the S-P bonds in ethoprop, for example, would result in a substance that has a chiral phosphorus atom and could exist as two distinct enantiomers.

The Agency does not know the relative ratios of the specific enantiomers in the technical product of cadusafos. However, the mammalian toxicity studies submitted by the registrant correspond to the technical product as manufactured and reflect the actual toxicity of the technical product and its metabolites. The same is also true for the cadusafos ecotoxicity studies submitted to the Agency. Therefore, even if one (or more) of the four enantiomers of cadusafos is (are) substantially more toxic than the other enantiomers, and is present in the technical product, its toxicity is expressed in the mammalian and ecotoxicity data submitted to the Agency and used in risk assessment of the technical product. The Agency does not expect differences in the composition of technical cadusafos among lots because the method of manufacture is (or will be) the same for each lot.

The environmental fate studies submitted for cadusafos were not intended to follow the fate of its individual enantiomers, or monitor for enantiomeric interconversions. Hence, EPA does not know to what extent, if at all, if the individual enantiomers of cadusafos interconvert in the environment. However, ecotoxicity data collected under current OPPTS test guidelines represent the ecotoxicity of the technical product (including any of its enantiomers that may be present), and its environmental degradates.

As previously stated, dimethoate, ethoprop, fenthion, sulfotepp, tribufos, and temephos do not contain any chiral atoms. These substances cannot exist in isomeric forms that are enantiomeric. Thus, the possibility of specific enantiomers having greater toxicity than other enantiomers, or that one enantiomer may be interconverted to another in the environment do not apply to these substances. While it is possible that any of these substance can be metabolized to substances that contribute to the toxicity of the parent substance, the mammalian toxicity data submitted for each of these substances and used for risk assessment purposes represent the combined toxicity of the parent substance and metabolites thereof. Also, any plant or livestock metabolites of toxicological concern have been identified by EPA and included in the risk assessments.

See also responses to II.A.1, II.A.3, II.A.4 and II.A.5 above.

5. EPA's Response to Comments from Other Federal Agencies

Comment: The Fish and Wildlife Service, Division of Environmental Contaminants, pointed out that four of the seven OPs have Final Biological Opinions (1989) for Endangered Species. In addition, FWS and EPA are currently in consultation on fenthion. 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 options for these seven OPs. During Phase 5 of the TRAC process for each of these chemicals, the public is invited to provide comment on risk management options.