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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Subject: Response to Cheminova's "Comments on EPA's Draft Reregistration Eligibility Decision Chapters for Ethyl Parathion" (typographical and mathematical errors only)

To: Dennis Deziel, Chemical Review Manager
Special Review and Reregistration Division

From: Amer Al-Mudallal, Chemist
Kevin Costello, Geologist
Edward W. Odenkirchen, Ph.D., Chemist
Environmental Risk Branch 1, Environmental Fate and review Division

Through: Arnet Jones, Chief
Environmental Risk Branch 1, Environmental Fate and review Division

The Office of Pesticide Programs offered registrants of organophosphate pesticides a 30-day period for the review of the draft RED chapters in order to identify typographical, mathematical and transcription errors. Although in some cases a registrant may raise other than clear errors as part of the 30-day review, EFED will give careful consideration to scientific questions after the public comment period. Cheminova, through their consultant Jellinek, Schwartz and Connally, has provided three pages of comments for this round of review of the EFED RED chapter. Responses to those comments are detailed below. The responses either: 1) detail the corrections made to EFED's RED chapter, 2) explain why suggested changes were not made, or 3) indicate that a particular comment was outside the scope of "typographical, mathematical and transcription errors".

Comment 1: *In many places throughout this document, EPA states that "EFED concludes with a great deal of certainty that the use of ethyl parathion poses a high risk to…". . . Cheminova believes that it is not appropriate for EPA to state that it has a high degree of certainty that there are high levels of risk to any organism.*

Response: This comment falls outside of the scope of "typographical, mathematical and transcription errors", and will be considered in the subsequent round of comment review.

Comment 2: *On page 2 of the draft chapter, EPA states that "Sunflower, sorghum, and corn account for two-thirds of the 2.3 million pounds used annually. EPA's estimate of the amount*

of ethyl parathion used annually is an error because, on average, each year Cheminova sells much less than the amount estimated by EPA.

Response: This memo, which was prepared by consulting firm Jellinek, Schwartz and Connally, contradicts tables and charts on annual usage provided to EFED by Cheminova during the "smart meeting" for ethyl parathion. No changes were made for this round of revision. EFED will consult with Cheminova and SRRD, and ensure that the next draft reflects accurate usage data for ethyl parathion on the crops.

Comment 3: *There is a typographical error on page 2, in the sentence that begins "Substantial data suggest…". The reference to "methyl parathion" should be changed to "ethyl parathion".*

Response: The EFED RED chapter has been revised to correct this error.

Comment 4: *On page 2 of the draft chapter, EPA states that there is "Extensive incident data compiled for ethyl parathion [that] confirm adverse affects to both humans and wildlife". Cheminova notes that since the use restrictions were implemented in 1992, there have been very few, if any, incidents that are considered adverse effects to exposure to ethyl parathion. The human incident data for ethyl parathion since 1992 is limited to 8 reports; none of which can confirm health effects caused by exposure to ethyl parathion.*

Response: This comment falls outside of the scope of "typographical, mathematical and transcription errors", and will be considered in the subsequent round of comment review.

Comment 5: *EPA's reference on page 2 to OPP's Draft 1991 Notice of Intent to Cancel is not relevant to current terms and conditions of registration for ethyl parathion, as a result of the 1991 agreement. EPA should delete this reference.*

Response: Reference to the OPP's Draft 1991 Notice of Intent to Cancel does not constitute a typographical, mathematical and transcription error. The relevance of the cited incidents from this document will be evaluated during the next round of review.

Comment 6: *On page 3, EPA is inconsistent on whether there is any targeted surface and/or drinking monitoring data for ethyl parathion. In the second bullet on this page, EPA states that there is none, while in the last bullet, EPA cites targeted monitoring data. Cheminova notes that extensive surface, ground and drinking water monitoring data are available for ethyl parathion.*

Response: The sentence referring to targeted monitoring data has been revised.

Comment 7: *There is a typographical error in the first sentence of the top of page 6; EPA references methyl parathion instead of ethyl parathion.*

Response: The EFED RED chapter has been revised to correct this error.

Comment 8: *On page 7, EPA recommends language for public health uses. Because ethyl parathion is not registered for public health uses, this language is not necessary for ethyl parathion and should be deleted from EPA's document.*

Response: EFED did not recommend language for public-health uses. However, for the purposes of clarity, the sentence beginning "For non-public health uses" has been deleted.

Comment 9: *In the second paragraph on page 1 of the environmental risk assessment, EPA states that Cheminova produces an 8 EC and a 6-3 EC mixture. Cheminova also produces a 4.0 lb a.i. EC formulation.*

Response: Information provided to EFED by Cheminova during the "smart meeting" for ethyl parathion indicated that "a 4EC formulation is registered, but is not currently being marketed". No changes were made for this round of revision. EFED will consult with Cheminova and SRRD, and ensure that the next draft reflects accurate formulation information. However, EFED does not believe that inclusion of this formulation will change the conclusions of the risk assessment.

Comment 10: *In the fifth paragraph on page 1 of the environmental risk assessment, EPA states that "Ethyl parathion <u>should</u> be applied from nozzles located not more than 75% of the distance from the center of the aircraft to the wing tip or helicopter rotor tip" (emphasis added). Because this is a specific label requirement, Cheminova believes that EPA should replace the work "should" with the word "must."*

Response: The EFED RED chapter has been revised to correct this error.

Comment 11: *EFED states in Table 10 on page 18 of the environmental risk assessment that the aerobic aquatic half-life is 15.6 days, presumably derived by multiplying the half-life of 5.2 days calculated in MRID 41249802 by 3. However, Cheminova duplicated EFED's modeling results using PRZM and EXAMS input files supplied by EFED. In the EXAMS output, the biolysis half-life for the littoral phase was 5.2 hours. It appears EFED used the value from MRID 41249802 (an aerobic aquatic metabolism study) without multiplying by 3 and mistook hours for days.*

Response: The EXAMS model inputs have been changed to reflect a littoral-phase half-life of 15.6 days. It should be noted that this change results in increases in predicted surface-water concentrations. The new predicted EECs are presented in the attached table (Table 9 from the EFED RED chapter). These new EECs result in increased risk quotients for aquatic organisms. Specifically, concerns for aquatic organism chronic risks associated with alfalfa are now evident.

Based on this review of the model, EFED anticipates that there may be additional changes to the model input parameters after the public comment period. However, EFED believes that these additional adjustments to the model will not alter the conclusions of the risk assessment**.**

Comment 12: *On page 19 of the environmental risk assessment, EFED states in regard to PRZM that "The entire annual application of the pesticide is assumed to occur over the 10 hectares*

within one day." This statement is erroneous because EPA's PRZM model is structured to allow daily pesticide applications throughout the growing season. Moreover, EFED utilized this capability in its PRZM modeling, thereby modeling individual applications occurring on specific days of the year.

Response: The EFED RED chapter has been revised to state that each individual application occurs over the 10 hectares in one day. EFED does not believe that this revision changes the conclusions of the risk assessment.

Comment 13: *Some citations referenced in the text of the draft EFED chapter are not listed in the chapter's Reference section. For example, in the environmental risk assessment, the "Mulla, 1981"citation listed in the third full paragraph on page 7 and citation number "60" listed in the third full paragraph on page 23 do not appear in EPA's Reference section.*

Response: The EFED RED chapter has been revised to include these references.

Comment 14: *There is a typographical error in the first full paragraph on page 23; EPA references methyl parathion instead of ethyl parathion.*

Response: The EFED RED chapter has been revised to correct this error.

Comment 15: *Listed below are the errors that Cheminova identified in EFED's mammalian toxicity table on page 33-34.*

> *The correct value for mammalian oral LD_{50} (rat) is 2.7 mg/kg (females) and 10.8 mg/kg (males). In its mammalian toxicity table, EFED cites two different sets of LD_{50} values for the same MRID (MRID 243412). Also, the rat LD_{50} is not a 96-hour study; it is a single oral dose with a 14-day observation period.*

Response: The MRID 243412 rat oral LD_{50} values will stand as 2.7 mg/kg females and 2.7 mg/kg males. The second values for this study are associated with repeated toxicological evaluations with aged (stored) material and will be dropped from the toxicity summary for mammals. And the duration of the study will be corrected to remove reference to 96-hours. These changes will not alter the conclusions of the risk assessment

> *The percent active ingredient in the rat acute dermal study (MRIDs 40814001 and 40814002) is 76.8%, not 76.18%.*

Response: The percent active ingredient will be changed. This change will not alter the conclusions of the risk assessment

> *The plasma cholinesterase (ChE) NOEL in the rat acute dermal study (MRID 40814002) is >1.35, not 0.45.*

Response: This is not an error. EFED consultation with the Tox One-Liners and the summary of this study prepared by HED indicated that the plasma cholinesterase NOEL is indeed

0.45. EFED suspects that the comment author confused endpoints for RBC and/or brain cholinesterase activity with the endpoint for plasma cholinesterase.

The no-observed effect level (NOEL) in the mouse 28-day feeding study (MRID 244841) is 50 ppm, rather than <100 ppm.

Response: The change will be made to the NOEL. This change will not alter the conclusions of the risk assessment

Compound purity was 97.1%, not 98%, in the 3-month rat feeding study (MRID 41834502). Additionally, the NOEL in this study was 0.4 mg/kg/day, not 0.04 mg/kg/day.

Response: The active ingredient change will be made. This change will not alter the conclusions of the risk assessment.

The NOEL in the dog 1-year feeding study (MRIDs 246639 and 246642) is 0.01 mg/kg/day, not <0.01 mg/kg/day.

Response: The change to the NOEL will be made. This change will not alter the conclusions of the risk assessment.

The study assigned MRID 252087 is a rat developmental study, not a rat reproduction study.

Response: The study will be noted as a developmental study. This change will not alter the conclusions of the risk assessment.

Comment 16: *On page 43 of the draft EFED chapter, EPA erroneously states that MRID 1237807 (Eastern oyster shell deposition study), with a 96-hour EC_{50} > 1000 ppb, is classified as "highly toxic." The proper classification is "moderately toxic." Moreover, MRID 40644717 fully satisfies the estuarine mollusk data requirement and should be listed as "core" rather than as "supplemental."*

Response: The EFED RED chapter has been revised to correct these errors. EFED does not believe that these revisions change the conclusions of the risk assessment.

Comment 17: *EFED includes an Appendix 2 in its draft RED chapter which purports to be a compilation of aquatic toxicity (fish kill) incidents involving ethyl parathion. However, in only one of the incidents listed was ethyl parathion included among the group of pesticides either analyzed for or detected. In this incident, approximately half a dozen pesticides were detected in the water, all at sufficiently high concentrations to contribute to the reported fish kill. In all of the remaining incidents listed in this appendix, ethyl parathion was not detected, and investigation of the incidents assigned the cause of the kill to other factors (e.g., low dissolved oxygen) or other chemicals. Because this appendix does not contain aquatic incidents resulting from either use or misuse of ethyl parathion, it should be removed from the draft EFED RED chapter.*

Response: The fish kill incident data listed for the ethyl parathion was erroneously combined with the incident data for methyl parathion. The incidents for ethyl parathion will be listed as follows, and these changes will not alter the conclusions of the risk assessment.

Incident #	Location	Species Affected	Number Affected	Use	Certainty Index
B0000-216-21	Sacramento, CA	not reported	>1000	registered rice use	possible, compound detected in water
B0000-400-01, I000598-008	Harlan Co., NE	bass, catfish, minnow	several dozen	registered aerial application	probable