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Attachment 3

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OF
Pesticides and
Other Substances

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MEMORANDUM

SUBJECT: Current ORE Issues Related to Terbufos (Chem # 105001) RED Status

DP BARCODE: D241134 & D243778

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This memo was prepared in order to clarify the critical issues pertaining to the ORE aspects of the terbufos RED. This review considers the HED RED that was released on 10/17/95 and any current efforts pertaining to this chemical by American Cyanamid.

Three critical issues were considered in the development of this memo. The issues can be summarized by the following:

- Existing 1995 HED Chapter (i.e., is it still applicable given the current state-of-the-art and potential use patterns?);
- American Cyanamid Exposure Protocols (i.e., how do they impact the status and what are the issues with them?); and
- Miscellaneous Issues (i.e., are they generating a refined dermal absorption or dermal toxicity study?).

EXISTING HED CHAPTER (10/17/95)

The existing HED RED chapter dated October 17, 1995 was quickly reviewed based on the use patterns included in REFS (2/23/98 review of REFS) and the common data sources currently used in the development of ORE assessments (e.g., current version of PHED surrogate exposure values). The 1995 RED document is based on two occupational exposure scenarios and no residential exposure scenarios. The occupational exposure scenarios addressed in the 1995 document are loading of granulars and the agricultural application of granulars to corn, sugar beets, and grain sorghum. Based on information included in REFS, these exposure scenarios would still be the only ones considered by HED as appropriate for terbufos. The 1995 assessment considered use data from the "Corn Cluster" and maximum application rates of 1.97 lb ai/A for corn, 3.92 lb ai/A for grain sorghum, and 4.35 lb ai/A for sugar beets. [Note: These application rates may have been altered since the completion of the 1995 assessment but not so substantively alter the calculated risk picture. Also, it should be considered that no exposure data exist to differentiate between the exposure potential using a classical granular formulation versus a CR, or polymer-based formulation (see protocols described below).]

No chemical-specific exposure data were submitted in support of the development of the 1995 RED chapter. As such, all exposure calculations were based on surrogate exposure values calculated using the Pesticide Handlers Exposure Database (PHED). The MOEs calculated for terbufos resulting from dermal exposure did not exceed 5 for any scenario even at the highest levels of risk mitigation. Likewise, the highest MOE calculated for terbufos resulting from inhalation exposure did not exceed 6. For most scenarios (whether dermal or inhalation is considered), MOEs ranged from much less than 1 to approximately 2. The PHED surrogate exposure data upon which this assessment was based is low quality data. The PHED exposure estimates for these scenarios have been reevaluated, but even the revised values are still considered low quality data. The revised surrogate exposure values do not differ significantly from the values used in the original assessment. As a result, the risk picture would not significantly change if the current dataset was used to further refine the assessment.

In summary, any redux of the 1995 assessment would be time consuming and HED would gain HED little refinement. The real refinement will come from the development of chemical-specific exposure data and by addressing the dermal absorption/dermal toxicity issue.

AMERICAN CYANAMID EXPOSURE PROTOCOLS

American Cyanamid submitted two exposure protocols pertaining to the development of chemical-specific exposure data for terbufos. These documents were submitted in a September 23, 1997 letter from John Wrubel of American Cyanamid to Lisa Nisenson of SRRD. The protocols can be identified by the following information:

- Worker Exposure Study: Exposure of Farm Workers to Terbufos (CL 92,100) While Loading COUNTER CR SYSTEMIC INSECTICIDE/NEMATICIDE from a bag and applying COUNTER CR to corn at planting time (9/18/97 draft, protocol # EEA98-02), and
- Worker Exposure Study: Exposure of Farm Workers to Terbufos (CL 92,100) While Loading COUNTER 15G SYSTEMIC INSECTICIDE/NEMATICIDE with a LOCK-n-LOAD Closed Handling System and Applying COUNTER 15G to Corn at planting time (9/18/97 draft, protocol # EEA98-01).

I met Jim Devine (Associate Director of Environmental/Exposure Assessment at American Cyanamid) at a recent meeting. We discussed the technical issues associated with these protocols. Subsequently, we had a phone conversation concerning various technical issues associated with the protocols. Cyanamid plans to run these studies this growing season so an estimated submission date is approximately 1 year from now.

Essentially, both protocols are in very good shape in that only a few technical issues required discussion. Jim Devine indicated that a letter would be sent to the agency clarifying the technical concerns and any logistical issues associated with the studies. The technical issues that were identified with the protocols include the following:

- **Cab Type:** Open cabs are preferable, but because of the use patterns, no-cab tractors are relatively uncommon. As a result, it is anticipated that closed cab tractors with windows open are going to make up the majority of the replicates because of logistical considerations. This point was reiterated in a 2/23/98 fax to Bill Hazel of OPP/HED from John Wrubel of American Cyanamid.



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- **Formulation/Packaging Type:** Cyanamid apparently intends to have all 15G formulation in Lock-n-Load over the long-term and a nonfriable 20CR formulation marketed in open bags over the long-term. The protocols are appropriately set up to evaluate this scenario. The surrogate use of the CR data to evaluate open-bag 15G scenarios was discussed. We do not believe it would be appropriate to use open-bag 20CR exposure data to calculate exposures to a 15G formulation because of the special characteristics of the CR formulation should Cyanamid alter the marketing strategy.
- **Quality Control Issues:** Several specific comments were made concerning specifics of the proposed quality control regimens (e.g., sample shipment in separate coolers was altered to require intermingling of samples). This was going to be altered to meet current EPA guidance.
- **Combining Job Functions:** The protocol is written using separate replicates for loading and application scenarios. The question was to keep them separate or to combine them and have each replicate represent both loading and application procedures. This issue is generally raised because of analytical sensitivity issues. In this case, the analytical method is extremely sensitive and American Cyanamid wants to look at each job function separately. If the job functions were combined, the plan was to still collect hand and inhalation samples to represent each job function and only collect dermal (nonhand) samples over the entire day. Cyanamid believes that this process may introduce potential contamination into the process that results solely from the sample collection process. This point was reiterated in a 2/23/98 fax to Bill Hazel of OPP/HED from John Wrubel of American Cyanamid

In summary, any exposure data that are generated for the exposure scenarios of concern, particularly for these scenarios, will allow the agency to significantly refine the assessment that has been completed for terbufos. The only data available for the terbufos exposure scenarios currently are "low quality" PHED data. Additionally, when the available PHED data are used, a series of protection factors must be used to complete the assessments.

MISCELLANEOUS ISSUES

Several other miscellaneous issues have been identified that may impact any refinement to the ORE assessment for terbufos. These include the following:

- Using the results of the 28-day dermal toxicity studies currently underway (as discussed in letter to L. Nisenson of 9/23/98) to significantly refine the ORE assessment as 100 percent dermal absorption was used.
- Revising the assessment to reflect current application rates and to incorporate the new exposure data.

- Appropriate risk characterization language should be added to any refinement of the ORE assessment. I have a few sets of “canned language” that can be sent over for incorporation into any HED product if needed. Historical ORE REDs were pretty lacking in this area.
- Terbufos is applied as a soil incorporated granular in all instances. The 1995 assessment essentially wrote-off any post-application exposure concerns because of the application method and because of the seasonal timing of the applications. This reflects the current ORE approach. Additionally, terbufos is not used in any residential setting. Therefore, FQPA concerns are not applicable for nondietary ingestion exposure pathways.

SUMMARY

Any refinement of the ORE aspects of the 1995 HED RED Chapter using the current exposure databases would be insignificant as the appropriate databases have not significantly evolved since then, the use patterns are similar, and the pertinent toxicity endpoints have not been altered. The additional data proposed by Cyanamid can potentially provide the basis for significant refinement to this assessment.