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

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SEP 17 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Ronald Landis, Ph.D.
Landis International
3185 Madison Highway
Post office Box 5126
Valdosta, GA 31603-5126

Dear Mr. Landis,

Re: Remaining Risk Concerns for TPTH Reregistration

We have completed our review of your comments on the TPTH RED Chapters, dated 5/14/99 and 6/8/99, which you sent the Agency on 8/13/99 (dietary), 8/25/99 (benefits), 8/26/99 (occupational), and 8/31/99 (ecological). EPA's responses to these comments were faxed to you on 9/2/99 (dietary and benefits) and 9/15/99 (worker and ecological). As you are aware, we will be completing our RED document for TPTH by September 30, 1999. Based on our revised assessment, as described below, we have remaining risk concerns related to TPTH use and based on our current assessment would find TPTH ineligible for reregistration on potatoes and sugarbeets and would require further mitigation measures as a condition of continuing TPTH use on pecans.

The Task Force has expressed concerns about the approaching deadline and the short time frame remaining in which to resolve all remaining risk concerns. However, I would like to point out that all registrants are given the same 30 days to respond to the Agency's risk assessment and we have allowed you to submit your rebuttal comments well over this 30 day period. As the last of the Task Force's comments were only received on 8/31/99, we have only now been able to complete our full review of the comments and to make the appropriate revisions to our risk assessment.

Although benefits assessments are not generally part of the RED process, when a risk of concern is identified with a chemical, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA cannot assess whether the benefits from use of the pesticide outweigh the risks without appropriate benefits information. As you may know, EPA developed this assessment as part of the TPTH Special Review. EPA determined it would be appropriate to address benefits information in the RED when we determined that the worker cancer risk exceeded EPA's level of concern.

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The Agency's remaining risk concerns, based on our review of the Task Force comments and subsequent revisions to our risk assessment, are briefly summarized below by type of risk:

Dietary Risk

We have revised our dietary risk assessment to account for the low volume and limited use periods for TPTH on sugarbeet tops that might be fed to cattle. As a result, the Agency does not have any concerns about the acute and chronic dietary risk exposure from food. With respect to cancer dietary risk exposure, however, we calculate risks to be between 9.4×10^{-7} and 1.1×10^{-6} for food alone. Further, this assessment does not take into account dietary exposure to TPTH from drinking water, which, as EPA's modeling suggests, could be a significant contributor to existing exposures, and therefore overall risk. As a result, EPA cannot determine that the existing TPTH tolerances are safe within the meaning of section 408(b)(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Occupational Risk

We have revised our occupational risk assessment for wettable powder formulations in water soluble bags (WSBs) since we have recently obtained the capability to combine PHED data with chemical specific data. As a result, we have included PHED data with the TPTH handler exposure study data. Although the exposure values decreased as a result of this revision, the MOEs for mixing and loading wettable powder in WSBs for aerial and chemigation applications continue to be unacceptable. At maximum application rates, risks for sugarbeets are also unacceptable for mixing and loading liquid formulation for aerial and chemigation. Cancer risks for mixing and loading also exceed 1×10^{-4} for wettable powder WSBs for aerial and chemigation and groundboom for potatoes (commercial application). Cancer risks for pecan harvesters are also of concern for harvesting without PPE or engineering controls.

In addition to those cancer and non-cancer occupational risks that clearly exceed our levels of concern, worker cancer risks for many other use scenarios also exceed EPA's target of 1×10^{-6} cancer risk for workers (see EPA's Non-Dietary Cancer Risk Policy of August 14, 1996 which we have already sent you for further explanation of the Agency's policy regarding EPA's consideration of occupational cancer risk). For occupational risks that fall between 1×10^{-6} and 1×10^{-4} , we consider the feasibility of implementing further risk reduction measures as well as the benefits associated with the pesticide use.

Ecological Risks

Acute and chronic levels of concern are exceeded for both aquatic and avian species at both maximum and typical application rates for all three crops. The Agency is concerned about exposure to aquatic habitats through spray drift and runoff and is particularly concerned about the chronic risks to avian species.

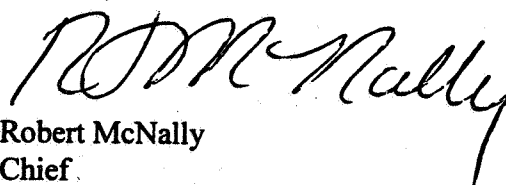
Next Steps

As noted, the Agency has remaining concerns about the dietary (cancer), occupational and ecological risks posed by TPTH under current use conditions. Furthermore, because there are many alternative chemicals presently registered and soon to-be registered for all three crops, EPA does not believe TPTH presents significant benefits that overcome the risks on sugarbeets and potatoes. However, EPA recognizes that the pecan use, at present, possesses greater benefits than the other uses and that with appropriate risk mitigation, this use is consistent with the reregistration standard. As a result, the Agency's analysis indicates that the TPTH registration on potatoes and sugarbeets should be declared ineligible for reregistration, and that pecans should be declared ineligible unless the registrants adopt further mitigation to include reductions in application rates, numbers of applications, formulation restrictions, buffer zones and pecan harvester worker protection.

On Monday, September 20, 1999, we would like to follow up on our preliminary discussions in August and turn our attention to the mitigation measures required for the TPTH reregistration eligibility decision. We believe we can do this via a conference call. If the Task Force would rather meet with us in person, we can do that as well. However, because the Agency plans to issue its RED determination no later than 9/30/99, any discussions directed toward that determination need to be completed no later than 9/22/99 to be considered in the RED document.

Please call Nancy Zahedi at (703) 308-8022 or Loan Phan at (703) 308-8008 to let us know what time would be convenient to set up a conference call with you and any other appropriate individuals.

Sincerely,



Robert McNally
Chief
Special Review Branch