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OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

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MEMORANDUM

DATE: September 13, 1999

SUBJECT: EFED's response to the TPTH Task Force rebuttal of the EFED TPTH RED Chapter.

TO: Robert McNally, PM 60  
Loan Phan, PM Team Reviewer  
Special Review and Reregistration Division (7508W)

FROM: Dirk F. Young, Ph.D., Environmental Engineer  
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THROUGH: Mah Shamim, Ph.D., Branch Chief  
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This memo serves as EFED's response to comments on the TPTH RED Chapter. Comments were received from Landis International (representing the TPTH Task Force) on July 28, 1999 and on August 31, 1999. EFED first addresses the 8/31/99 comments in order to capture some of the duplication between the two letters and then covers unique comments of the 7/28/99 letter. A summary is first given of each of Landis's comments followed by EFED's response in italics.

Comments/Responses for Letter Dated August 31, 1999

Landis claims that EFED uses worst-case scenarios and suggests that EFED use input parameters that are more representative of typical application scenarios.

*EFED based its risk analyses on standard scenarios, labeled application rates, and input parameters that were provided in accepted registrant-supplied reports (if submitted). This is standard EFED procedure for performing risk analysis.*

Landis compared EFED's assessment with their own assessment that was based on typical application rates and parameters that Landis suggested are more representative of typical values. The comparison showed that by using "typical" application rates and "typical" input parameters, environmental concentrations will be lower than for the case of using the maximum allowable application rate and EFED's standard scenario.

*EFED recognizes that the use of typical application rates will result in lower environmental concentrations than concentrations developed by using the maximum allowable application rate. Nevertheless, the maximum labeled rate is the allowable rate that may be applied, and therefore EFED must base its risk assessment on this rate. With regard to EFED's chosen input parameters and scenarios, EFED's screening models for calculating EECs must represent a wide variety of use and environmental conditions and exposures to a wide spectrum of non-target populations of receptors must be evaluated. Therefore EFED chose parameters and scenarios with consideration for this variability.*

Landis suggests that the soil half life is 5 days in Georgia.

*Accepted aerobic soil metabolism studies from the TPTH Task Force indicate that the soil half life is 21 days. EFED notes that literature indicates that the half life is much higher (see draft RED). EFED welcomes additional quality data in support of better characterizing the metabolic soil degradation of TPTH.*

Landis suggests that EFED did not consider grass grown under pecan trees.

*The standard EFED pecan scenario does consider the presence of sparse grass.*

Landis suggests that the EXAMS pond is located too close to the PRZM-simulated pecan field. In support of this argument Landis cites evidence that cotton fields are typically located more distant from ponds (citation information was insufficient for EFED to locate this reference). Landis suggests that this distance will offer a physical buffer that would impede the flow of TPTH into the pond.

*EFED agrees that physical buffers will likely reduce the flow of TPTH into water bodies. Buffer-zone requirements may be considered as a mitigation option.*

Landis disagrees with using the closed-pond scenario to represent marine environments, since marine environments are flushed with tides.

*EFED agrees that the closed-pond model is not the ideal tool to estimate pesticide concentrations in marine environments, particularly in areas of high flushing. However, at this point, it is the only model available to us as we work to address this limitation.*

Landis disagrees with EFED's assumption of an infinite foliage half-life for the Terrestrial EEC analysis. Landis also implies that foliage half lives of from 3 to 5 days should be used.

*EFED agrees that half-life should be considered. For terrestrial EECs, it is now EFED policy to apply a 30-day foliage half life to chemicals that are stable to hydrolysis and photolysis. EFED has recalculated the terrestrial EECs for the multiple application scenarios with consideration for the 30-day half life. Revised tables are attached. The 3 to 5 day half lives that Landis refers to are for dislodgable TPTH on foliage and foliage/soil mixtures that are pertinent to worker dermal exposure in the fields and are not relevant to EFED's terrestrial exposure assessments.*

Comments/Responses for Letter Dated July 28, 1999

Most of the issues discussed in the memo of July 28, 1999 are addressed by the responses given above. Issues that were not previously addressed are as follows:

Landis disagrees with the inclusion of short and long grasses and broadleaf weeds in the terrestrial assessments for sugar beets and potatoes, since grasses are not grown along with these crops.

*EFED believes that grasses and broadleaf weeds will occur at the edges of these fields and that they will get exposure to TPTH. Inclusion of grasses and broadleaf weed is standard EFED procedure.*

Landis disagrees with the EFED request for additional studies on aerobic and anaerobic metabolism. Landis's states that the only aquatic exposures will come from runoff and that when TPTH does reach an aquatic environment, it will partition into the sediments.

*Although aquatic studies are not required for the proposed uses, submission of these studies would better enable EFED to assess TPTH behavior in aquatic environments. EFED notes that in the Landis letter of August 31, 1999, Landis used an aquatic half life of from 2 to 10 days for their GENECC simulations. EFED would welcome a study that could support such half lives. EFED also notes that TPTH may reach aquatic environments by spray drift as well as by runoff.*

In opposing EFED's requirement for aquatic plant testing, Landis states that "the assumption that TPTH may move off site by runoff and by spray drift is not supported."

*EFED believes that runoff and spray drift are well-established physical processes. Aquatic plant testing is required for any fungicide that has outdoor non-residential uses and that may move off site by runoff and/or drift (aerial or irrigation).*

**ATTACHMENT: ERRATA for EFED's TPTH RED Chapter**

The following tables present avian and mammalian risk quotients that were calculated assuming a 30-day foliar dissipation half life and should replace the corresponding tables in EFED's RED chapter. In the original RED chapter, an infinite foliar dissipation half life was assumed. **Neither avian nor mammalian multiple-use acute or chronic risk conclusions have changed as a result of this revised assessment.**

Avian Acute and Chronic Risk Quotients for Multiple Applications of Nongranular Products (ground and aerial broadcast) Based on a quail LC50 of 253 ppm and a quail reproductive NOEC of 3 ppm.

Site/App. Method	App.Rate (lbs ai/A)/ No. of Apps./min interval between apps	Food Items	Maximum EEC <sup>1</sup> (ppm)	LC50 (ppm)	NOEC (ppm)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOEC)
Potatoes	0.1875/4/7	Short grass	144	253	3	0.60	48.00
		Tall grass	66	253	3	0.30	22.00
		Broadleaf plants/Insects	81	253	3	0.30	27.00
		Seeds	9	253	3	0.04	3.00
Pecans	0.375/10/14	Short grass	313	253	3	1.24	104.00
		Tall grass	143	253	3	0.60	48.00
		Broadleaf plants/Insects	176	253	3	0.70	59.00
		Seeds	20	253	3	0.08	7.00
Sugarbeets	0.25/3/10	Short grass	145	253	3	0.60	48.00
		Tall grass	67	253	3	0.30	22.00
		Broadleaf plants/Insects	82	253	3	0.32	27.00
		Seeds	9	253	3	0.04	3.00

<sup>1</sup> Revised EEC's using the default half life value of 30 days.

For multiple broadcast applications of nongranular products, avian acute high levels of concern are exceeded for all uses for short range grass and in pecans, for all feed items except seeds. Restricted use and endangered species levels of concern are exceeded for all registered maximum application rates for all food items other than seeds in the sugarbeet and potato use patterns. The avian chronic level of concern is exceeded at all registered maximum application rates for all food items.

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Mammalian Acute and Chronic Risk Quotients for Multiple Applications of Nongranular Products (Broadcast) Based on a calculated rat LC50 of 3210 ppm (ave. male/female LD50=160.5 mg/Kg/% body wt. consumed (0.05)=3210 ppm) and a rat reproductive NOEC of 5 ppm.

crop	App. Rate (lbs ai/A)/ No. of Apps./min app. interval	Food Items	Maximum EEC <sup>1</sup> (ppm)	LC50 (ppm)	NOEC (ppm)	Acute RQ (EEC/ LC50)	Chronic RQ (EEC/ NOEC)
Potatoes	0.1875/4/7	Short grass	144	3210	5	0.04	29.00
		Tall grass	66	3210	5	0.02	13.00
		Broadleaf plants/Insects	81	3210	5	0.03	16.00
		Seeds	9	3210	5	0.00	2.00
Pecans	0.375/10/14	Short grass	313	3210	5	0.10	63.00
		Tall grass	143	3210	5	0.04	29.00
		Broadleaf plants/Insects	176	3210	5	0.05	35.00
		Seeds	20	3210	5	0.00	4.00
Sugarbeets	0.25/3/10	Short grass	145	3210	5	0.05	29.00
		Tall grass	67	3210	5	0.02	13.00
		Broadleaf plants/Insects	82	3210	5	0.03	16.00
		Seeds	9	3210	5	0.00	2.00

1 Revised EEC's using the default half life value of 30 days.

An analysis of the results indicate that for multiple broadcast applications of nongranular products, mammalian acute levels of concern are not exceeded at registered maximum application rates for the sugarbeet and potato uses. However, endangered species levels of concern are exceeded for short grass for the pecan use. In addition, the mammalian chronic level of concern is exceeded at all registered maximum application rates for all food categories.

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