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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: February 8, 2007

SUBJECT: Etofenprox Human Health Risk Assessment for Increase in Section 18 Use Rate on Rice (PC Code:128965; DP Barcode: D335103)

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INTRODUCTION

The Louisiana Department of Agriculture and Forestry, in anticipation of an emergency situation for rice growers, has been granted by the US EPA, an exemption under Section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for the use of etofenprox in Louisiana for control of rice water weevil in rice for the 2006 crop season. This document addresses the human health risk from increasing the application rate for the aforementioned Section 18 use on rice for the 2007 crop season. The residue chemistry/dietary assessment was provided by Leung Cheng (RAB3); the drinking water assessment by Greg Orrick (ERB4/EFED); and the occupational/residential assessment by Jack Arthur (RAB3).

SUMMARY

Etofenprox is currently authorized for a Section 18 use on rice in the State of Louisiana. The Section 18 is for the use of an etofenprox granular formulation (Etofenprox 0.9% G), applied on rice fields at a rate of 0.19 pounds of active ingredient (ai) per acre immediately after flooding the rice fields. A chronic dietary risk assessment was conducted for the current Section 18 use, incorporating food and water exposures. In addition, short- and intermediate-term aggregate risks (food, drinking water and residential exposures), and risks to occupational handlers and re-entry workers resulting from the existing Section 18 use were previously evaluated.

Time-limited tolerances for residues of etofenprox to support the current Section 18 exemption were established as follows:

<u>Commodity</u>	<u>ppm</u>
rice grain	0.01
rice straw	0.02

For details on the current etofenprox Section 18 on rice, refer to, "*Etofenprox Human Health Risk Assessment for the Section 18 Request for Use on Rice*" (DP# 325108, April 7, 2006).

This document addresses the human health risk resulting from a request by the State of Louisiana to increase the current Section 18 single application rate from 0.19 to 0.27 lb ai per acre for the 2007 crop season. The toxicology database, hazard assessment and much of the background support information for etofenprox have not changed since the previous assessment, and therefore have not been repeated in this document. This assessment only includes any changes to the *dietary*, *aggregate* and *occupational* risk estimates resulting from the proposed increased application rate.

Dietary Risk

A chronic dietary risk assessment was conducted for etofenprox use on rice at the increased application rate of 0.27 lb ai/acre, using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.02) which uses food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. Acute and cancer dietary risk assessments were not conducted because acute dietary toxicity and cancer endpoints were not identified. Screening level estimates of etofenprox in surface water and groundwater from use on rice were provided by the Environmental Fate and Effects Division (EFED: DP Barcode: 335102; G. Orrick; 01/31/07). EFED estimated the maximum chronic (annual average) surface water at 4.7 ppb, and groundwater at 0.0017 ppm. The estimated 4.7 ppb chronic surface water residue was incorporated directly into the dietary assessment; specifically into the DEEM-FCID food categories, "water, direct, all sources" and "water, indirect, all sources."

The concentration of etofenprox in rice commodities is assumed at the limit of quantitation and 100 percent of rice grown is assumed to be treated. The chronic dietary risk estimates are below HED's level of concern (<100% cPAD) for the general U.S. population and all population subgroups. The most highly exposed population subgroup (<1% of the cPAD) was all infants (<1 year old).

Table 4. Summary of Chronic Dietary (Food + Drinking Water) Exposure and Risk for Etofenprox^a			
Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	%PAD
U.S. Population (total)	0.037	0.000102	<1
All Infants (< 1 year old)		0.000332	<1
Children 1-2 years old		0.000153	<1
Children 3-5 years old		0.000143	<1
Children 6-12 years old		0.000099	<1
Youth 13-19 years old		0.000074	<1
Adults 20-49 years old		0.000095	<1
Adults 50+ years old		0.000099	<1
Females 13-49 years old		0.000094	<1

^a The values for the population with the highest risk for each type of risk assessment are bolded.

Aggregate Risk

There are a number of conditionally registered etofenprox residential use products. These include outdoor yard foggers, indoor crack and crevice, indoor total-release foggers and cat spot-on products. All handler and postapplication risks from these products were found to not exceed HED's level of concern. For aggregate risk assessment, average food and drinking water exposures are aggregated with exposures to toddlers from inhalation and hand-to-mouth activities following the use of an indoor total-release fogger and hand-to-mouth from contact with a companion cat treated with the etofenprox spot-on product. Aggregate assessment for adults combines average food and water exposures for the total U.S. population with adult handler and postapplication inhalation exposures from the use of the indoor total-release fogger. These residential uses are believed to be the ones most likely to co-occur (comprehensive flea treatment approach), and also present the most conservative (worst-case) scenario for potential aggregate exposures.

An acute aggregate risk assessment is not required because an acute dietary toxicity endpoint was not identified. Likewise an aggregate cancer risk assessment is not required because etofenprox is classified as not likely carcinogenic to humans. Also, a long-term or chronic aggregate risk assessment is not required because there are no chronic exposure scenarios associated with currently registered residential use sites. Short- and intermediate-term aggregate risk assessments are appropriate.

Short-Term Aggregate Risk

For toddlers, two short-term aggregate risks are possible; in one, the average food and drinking water exposure is combined with toddler incidental oral exposures, and in a second one, the average food and drinking water exposure is combined with short-term inhalation exposure. Separate aggregate risks are required because the short-term inhalation toxicity endpoint effect is different from the short-term incidental oral endpoint effect. Since no dermal endpoint was identified, dermal exposure is not applicable. For adults, the short-term aggregate risk combines average food and drinking water exposure with short-term inhalation exposure. Adults are not exposed by incidental oral activities. **Short-term aggregate MOEs for adults (950) and toddlers (350 for inhalation and 560 for incidental oral) do not exceed HED's level of concern.**

Adult Short-term Aggregate Risk (Food + Drinking Water + Inhalation)		
Average food and water ¹	Total inhalation ²	Aggregate MOE ³
0.00102 mg/kg/day	0.011 mg/kg/day	950

¹ Dietary exposure for total U.S. Population.

² Total inhalation = exposure from using and following use of total-release fogger.

³ Aggregate MOE = Short-term inhalation NOAEL (10.6 mg/kg/day) ÷ [(average food and water) + (total inhalation)] × 100 = 100.

Note: Adult short-term aggregate risk is same as intermediate-term aggregate risk because inhalation toxicity NOAEL is the same for both.

Toddler Short-term Aggregate Risk (Food + Drinking Water + Inhalation)		
Average food and water ¹	Total inhalation ²	Aggregate MOE ³
0.00332 mg/kg/day	0.03 mg/kg/day	350

¹ Dietary exposure for most highly exposed subpopulation (all infants <1 year).

² Total incidental oral = exposure from inhalation following use of total-release fogger.

³ Aggregate MOE = Short-term inhalation NOAEL (10.6 mg/kg/day) ÷ [(average food and water) + (total inhalation)] × 100 = 100.

Toddler Short-term Aggregate Risk (Food + Drinking Water + Incidental Oral)		
Average food and water ¹	Total incidental oral ²	Aggregate MOE ³
0.000332 mg/kg/day	0.18 mg/kg/day	560

¹ Dietary exposure for most highly exposed subpopulation (all infants <1 year).

² Total incidental oral = exposure from hand-to-mouth and object-to-mouth following use of total-release fogger, plus hand-to-mouth from contact with cat following spot-on treatment.

³ Aggregate MOE = Short-term oral NOAEL (100 mg/kg/day) ÷ [(average food and water) + (total incidental oral)] (LOC = 100)

Intermediate-term Aggregate Risk

For intermediate-term aggregate risk, the average food and water exposure can be combined with adult inhalation exposures and with toddler inhalation and incidental oral exposures because the intermediate-term toxicity endpoint effect is the same for all these routes of exposure. The reciprocal MOE approach is necessary to calculate the toddler aggregate risk because, while the toxicity endpoint effect is the same, the endpoint NOAELs for ingestion and inhalation are different. The **intermediate-term aggregate MOEs for adults (950) and toddlers (130) do not exceed HED's level of concern.**

Adult Intermediate-term Aggregate Risk (Food + Drinking Water + Inhalation)		
Average food and water ¹	Total inhalation ²	Aggregate MOE ³
0.000102 mg/kg/day	0.011 mg/kg/day	950

¹ Dietary exposure for total U.S. Population.

² Total inhalation = exposure from using and following use of total-release fogger.

³ Aggregate MOE = intermediate-term inhalation NOAEL (10.6 mg/kg/day) ÷ [(average food and water) + (total inhalation)] LOC = 100.

Note: Adult short-term aggregate risk is same as intermediate-term aggregate risk because inhalation toxicity NOAEL is the same for both.

Toddler Intermediate-term Aggregate Risk (Food + Drinking Water + Incidental Oral + Inhalation)			
MOE food and water ¹	MOE total incidental oral ²	MOE inhalation ³	Aggregate MOE ⁴
60,000	210	350	130

¹ MOE food and water = intermediate-term oral NOAEL (20 mg/kg/day)/chronic food and water exposure for most highly exposed subpopulation (all infants <1 year: 0.000332 mg/kg/day).

² MOE total incidental oral = intermediate-term oral NOAEL (20 mg/kg/day)/total intermediate-term incidental oral exposure (0.094 mg/kg/day).

³ MOE inhalation = intermediate-term inhalation NOAEL (10.6 mg/kg/day)/total intermediate-term inhalation exposure (0.03 mg/kg/day).

Aggregate MOE = 1 ÷ [1/MOE food and water) + (1/MOE total incidental oral) + (1/MOE inhalation)] (LOC = 100)

Occupational Exposure and Risk

Handler Exposure & Risk

The potential exposures and associated risks for handlers mixing, loading and applying etofenprox to rice and postapplication workers re-entering fields are based on the proposed new use rate for the etofenprox granular formulation (Etofenprox 0.9% G) of 0.27 lb a.i. per acre per application, with a pre-harvest interval (PHI) of 60 days. Applications are to be made using aerial application equipment.

Short- and intermediate-term dermal and inhalation exposures are anticipated for occupational handlers mixing, loading, and applying etofenprox to rice fields. A dermal toxicity endpoint was not identified for etofenprox. Only inhalation exposures are assessed. Because etofenprox-specific exposure data were not submitted, handler scenarios were assessed using surrogate PHED unit exposure data (version 1.1, 1998). Table 5 below presents the risks to occupational handlers. For all mixers, loaders, and applicators, the MOEs for short- and intermediate-term exposures range from 1300 to 53,000, and therefore, do not exceed HED's level of concern (MOEs ≥ 100).

Table 5. Occupational Handler Exposure & Risk Estimates for Etofenprox Section 18 Use on Rice to Control Rice Water Weevil					
Short- & Intermediate-term Exposure	Unit Exposure¹ (mg/lb ai handled)	Application Rate² (lb ai/Acre)	Units Treated³ (Acres/Day)	Average Daily Dose⁴ (mg a.i./kg bw/day)	Short- and Intermediate-term MOE⁵
Mixer/Loader - Granular - Open Loading (for Aerial)					
Inhalation	0.0017	0.27	1200	0.0079	1300
Applicator - Granular - Aerial					
Inhalation	0.0013	0.27	1200	0.006	1800
Flagger - Granular - Aerial					
Inhalation	0.00015	0.27	350	0.0002	53,000

¹ Unit Exposure = mg a.i./lb a.i. handled from the Pesticide Handler Exposure Database (PHED), Version 1.1, August 1998.

² Application Rate from new Section 18 Request, Louisiana Dept. Agriculture and Forestry.

³ Units Treated taken from Science Advisory Council for Exposure, Standard Operating Procedure 9.1, Standard Values for Daily Acres Treated in Agriculture, Rev. 25 SEP 2001.

⁴ Average Daily Dose (ADD) = Unit Exposure * Application Rate * Units Treated * Absorption Factor (inhalation 100%) ÷ Body Weight (70 kg).

⁵ Margin Of Exposure (MOE) = NOAEL (mg/kg/day) ÷ ADD (mg/kg/day); where the NOAEL = 10.6 mg/kg/day for all durations of inhalation exposure.

Postapplication Risk

This proposed Section 18 use on rice involves foliar applications; therefore, there is a potential for short- and intermediate-term dermal exposure to workers entering etofenprox-treated areas to perform a variety of agricultural/occupational tasks, including scouting. However, because no dermal toxicity endpoint was identified for etofenprox and inhalation exposure is not considered to be a postapplication exposure route, no occupational postapplication exposure/risk assessment is required. An interim restricted entry interval (REI) of 12 hours applies under the Worker Protection Standard (WPS) for pesticides, including etofenprox, that have acute toxicity categories of III and IV.

CONCLUSIONS

For the proposed new Section 18 use rate of etofenprox on rice to control rice water weevil (i.e., 0.27 lb ai/acre), the exposure and risk estimates for occupational handlers that mix, load, or apply etofenprox do not exceed HED's level of concern. Chronic dietary (food plus drinking water) exposure/risk does not exceed HED's level of concern. Likewise, short- and intermediate-term aggregate risks (food, drinking water and residential exposures) do not exceed HED's level of concern.

cc: Registration Action Branch 3, Health Effects Division (7509C)



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