Shaughnessy #: 109702

Due Date: 5-20-85

Init:

MAY 16 1985

To: A. Heyward
Product Manager # 17
Registration Division (TS-767)

From: Joseph C. Reinert, Ph.D., Chief
Special Review Section
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Attached please find the EAB review of:

Reg./File No.: 4F2986

Chemical: Cypermethrin

Type Product: Insecticide

Product Name: Cymbush 3E

Company Name: ICI Americas

Submission Purpose: Review of exposure assessment submitted by by ICI-Americas and calculation of exposure assessment

ZBB Code: ---

ACTION CODE: 232

Date In: 1/14/85

EAB # 5252

Date Completed: 5-16-85

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62	20

Deferrals To:

____ Ecological Effects Branch

____ Residue Chemistry Branch

_X_ Toxicology Branch

1.0 INTRODUCTION

An exposure assessment has been conducted in response to a request from Toxicology Branch in order for them to perform a risk assessment for oncogenic effects for supplemental federal registration of cypermethrin, a synthetic pyrethrin used as an insecticide. Six supplemental registrations have been applied for, and seven more potential applications are proposed. BUD and HED members of the cypermethrin team agreed that analysis of exposure to field corn, sweet corn, cabbage and pecans would yield information covering the range of exposure expected for all the crops proposed for treatment. This assessment includes aerial and groundboom application to the first three crops and airblast application to pecans. Exposure estimates were calculated for mixer/loaders, pilots, flaggers and ground applicators based on surrogate data available in the literature.

The request for an exposure assessment includes a request for evaluation of exposure calculated by ICI Americas during application of Cymbush to pecans. We have included a comment on our policy with regard to this type of submission at the end of this report.

1.1 Chemical Formulation

Cymbush is ICI America's trade name for their 22.86% EC formulation of cypermethrin, a synthetic pyrethrin pesticide. Ammo is FMC's trade name for their 30.6% oil formulation of cypermethrin. Cypermethrin is ± cyano(3-phenoxyphenyl)-methyl(±)cis/trans-3-2,2-dichloroethenyl-2,2-dimethylcyclopropane carboxylate.

1.2 Application

Supplemental labels have been submitted for emulsifiable concentrates of the above two formulations at the same concentrations as the original labels. ICI is applying for use of Cymbush on pecans, while FMC's applications are for use of Ammo on field corn, sweet corn and cabbage.

2.0 ASSUMPTIONS AND USE PATTERNS

2.1 Assumptions

In conducting the exposure assessment, EAB has made several assumptions.

1) The average worker weighs 70 kg.

2) The different tasks (mixing/loading, and application) will be performed by the same individual for airblast or ground boom operations. Aerial crews generally are performed by separate individuals on the crew, which consists of pilot, mixer/loader, and flagger when used. Exposures

are calculated separately for each task and combined for reporting airblast and ground boom exposures.

3) Exposure during the mixing operation is the same whether open or closed systems are used. Although the mixing system was described as modified closed (500 gallon nurse tank, premixed, pumped in), it has not been adequately demonstrated that a closed loading system affords greater protection than the open system. See Section 3.3.

4) Exposure is not reduced more than 90% by the use of protective clothing specified on the label. The Ammo label states that mixer/loaders must wear "full face shield, impermeable gloves, rubber apron, boots and protective clothing," while "applicators must wear protective clothing". The Cymbush label lists protective clothing for all workers, and in addition, impermeable gloves and full face shield when handling concentrate. Protective clothing is defined on the Ammo supplementary labels only, as "a hat or other suitable head covering, a long-sleeved shirt, long legged trousers or a coverall-type garment (all of closely woven fabric covering the body, including the arms and legs), shoes and socks". It will be assumed that applicators will wear hats, long sleeved shirts, long pants, socks and shoes.

5) Adjustment of worker exposure for dermal penetration was not done. EAB defers to the Toxicology Branch to determine dermal absorption.

6) Flaggers where used have the same exposure time as pilots.

7) Respiratory exposure is negligible compared to dermal exposure except for aerial pilots.

2.2 Airblast Application to Pecans

Based on information provided by the Benefits and Use Division (BUD)(Gross, 1), application of Cymbush to pecans would be by means of a trailer-mounted airblast sprayer. Applications might involve separate applicators and mixers at each application site, but more probably the applicator would do the mixing as well as cleaning of the spray tank when finished.

Mixing is done by a modified closed system. The concentrate is metered mechanically into a 500 gallon capacity spray tank sufficient to give a concentration of 0.06 to 0.1 pound active ingredient per 100 gallons. Application is done at the rate of 100 gallons per acre. The applicator can spray 5 acres per load and 6 loads per 6 hour day, for a total of 30 acres per day. A full day's work would involve the applicator for 5 hours per day and the mixer for 70 minutes per day. The average pecan orchard is 19 acres and the pesticide is applied a maximum of 8 times per year. BUD states that in practice the applicators would rarely spray pecans more than once per year.

2.3 Ground Boom Application to Field Corn, Sweet Corn and Cabbage

BUD supplied information on application of AMMO to field corn, sweet corn and cabbage. Mixing and loading operations are essentially the same as in the application of Cymbush to pecans, except for differences in application rate and concentration. Application is by tractor-drawn ground boom equipment. Again, the applicator probably also does the mixing and loading and tank cleanup.

2.4 Aerial Application to Field Corn, Sweet Corn and Cabbage

BUD indicates (Gross, 1) that aerial application of AMMO amounts to 50% of the use for field corn, 90% of the use for sweet corn and 25% of the use for cabbage. Mixing and loading are done in a modified closed system utilizing a 500 gallon nurse tank, as was described for airblast and ground boom application. Flaggers are used for sweet corn and cabbage.

Two BUD memos (2, 3) list total acre treatments and total number of aerial pilots licensed to spray each of the crops, and annual pilot exposure time in Florida. Use patterns for sweet corn in Florida are different from those for rest of the U.S. (Gross, 1).

3.0 EXPOSURE ASSESSMENT

3.1 Open vs. Closed Mixing System in Aerial Operations

BUD states that the farmers generally use a system that opens the concentrate package and meters the concentrate into the tank so that the mixer does not have to handle the container. However, we have assumed, based on Lunchick's conclusions from data in the monitoring studies he surveyed, that some exposure does occur, and therefore we have used the values compiled by Lunchick (4) for mixer/loaders using both closed and open mixing systems in aerial operations.

3.2 Adjustment for Use of Protective Clothing

Protective clothing specified in the label for mixer/loaders (face shield, rubber gloves, rubber apron, boots and coveralls) will reduce dermal exposure 80-90% if worn. Published literature generally does not include sufficient information to make an adjustment for variations in protective clothing worn, and experience has shown that workers do not always wear protective clothing. To account for the label requirement that mixer/loaders must wear the above clothing, and considering the fact that hand exposure accounts for most of the dermal exposure, we used surrogate data from studies of workers who used gloves during the mixing operation. For other operations (aerial applicators and flaggers) we list exposure estimated for workers wearing no special protective clothing.

3.3 Extrapolation to Low Application Rates

EAB's data base does not include any studies that used application rates in the range proposed for cypermethrin, i.e., 0.04-0.1 pound active ingredient per acre. Calculation of applicator exposure presumes that extrapolation can be made from application rates of 1-2 pounds per acre to the lower rate, but in doing so, an error in the values used could lead to a 50 fold error in the exposure.

Calculations for mixer/loader exposure may suffer from the same error, in that the amount of concentrate handled per tank is much lower than the normal, e.g. one lb. compared to 25 lb. for the surrogate.

3.4 Airblast and Ground Boom Application

Exposure of workers to cypermethrin during airblast and ground boom application were calculated using data bases EAB has accumulated for these methods (Reinert and Severn, 5; British Agrochemicals Association Limited, 6). Results are summarized in Table 1, Airblast and Table 2, Ground Boom.

3.5 Aerial Application

Published monitoring studies of aerial applications were reviewed in a recent report by Lunchick (4). Mean exposure values were calculated and used as a surrogate for the determination of aerial exposure of workers to cypermethrin. Table 3 lists the unit exposure for the range of application rates given. Yearly exposures for aerial crews can only be calculated for sweet corn in Florida because BUD was only able to determine the annual exposure time for Florida pilots.

TABLE 1: DERMAL EXPOSURE DURING AIRBLAST APPLICATION

	hrs/day	mg/kg/hr	mg/kg/day	hrs/year
PECANS				
Mixer/loader/[1] (protected)	1	11.	11.	--/[2]
Applicator/[3] (unprotected)	5	0.14	0.7	--/[2]

/[1] Mixer/loader dermal exposure is calculated from a surrogate in which workers wore no impermeable gloves (5). Correction for gloves is made by multiplying by 0.1:

$$\frac{7800 \text{ mg/hr (unprotected)} \times 0.1}{70 \text{ kg body weight}} = 11 \text{ mg/kg/hr}$$

/[2] Yearly exposure could not be determined. BUD estimates one application per year although the label permits eight applications.

/[3] Applicator exposure is calculated from the data base for airblast application (5), which assumes workers wore short sleeved shirts, long pants, shoes and socks (see sample calculations, p. 8). Correction for use of long sleeved shirts as specified in the supplementary label for Ammo is done as follows:

Body skin surface areas:

face, back of neck, front of neck and V	= 910 cm^2
hands	= 820 cm^2
total area, long sleeved shirt, pants	= 1730 cm^2
forearms	= 1210 cm^2
total area, short sleeved shirt, pants	= 2940 cm^2

0.23 mg/kg/hr (short sleeves) x 1730 cm^2/2940 cm^2 = 0.14 mg/kg/hr (long sleeves)

The hourly respiratory exposure for airblast workers is 0.00027-0.00086 mg/kg/hr, thus lower than the hourly dermal exposure by 10^{-3}, so respiratory exposure can be considered negligible.

TABLE 2: DERMAL EXPOSURE DURING GROUND BOOM APPLICATION

	Unit exposure mg/kg/replicate/[1]	Replicates per year	Yearly exposure mg/kg/year
Mixer/loader (Protected)			
field corn	0.017	8	0.14
sweet corn	0.0064	30-69/[2]	0.019-4.4
cabbage	0.0064	20	0.013
Applicator (Unprotected)			
field corn	0.034	11	0.37
sweet corn	0.028	35/[2]	0.98
cabbage	0.028	10	0.28

/[1] Replicate refers to surrogate data (6). See sample calculations.

/[2] The number of applications per year varies with location. See Section 4.2. BUD lists 46 hours for yearly exposure time to sprayer/loader to treat 28 acres 23 times. For every hour, 45 minutes is spent spraying, so yearly exposure is 0.75 x 46 = 35 hours. Presumably this is the average and the same range would apply as for mixer/ loaders.

The hourly respiratory exposure for ground boom application is 0.00051 mg/kg/hr for applicators and not detectable for mixer/ loaders.

TABLE 3: EXPOSURE TO CYPERMETHRIN DURING AERIAL APPLICATION

JOB	DERMAL EXP RATE/[1] ug/kg/hr	HOURS PER YEAR	EXP PER YEAR	RESPIRATORY EXPOSURE RATE/[2] ug/kg/hr	EXP PER YEAR
MIXER/LOADER					
field corn	9-23	--	--	(negligible)	--
sweet corn-U.S.	9-23	--	--	"	--
" " -Fla.	9-23	--	--	"	--
cabbage	12-23	--	--	"	--
PILOT					
field corn	2.7-6.7	--	--	0.1-0.26	--
sweet corn-U.S.	2.7-6.7	--	--	0.1-0.26	--
" " -Fla	4.7 ave	12-24	56-110	0.1-0.26	2.2-4.3
cabbage	3.3-6.7	--	--	0.13-0.26	--
FLAGGER					
field corn	23-58	--	--	(negligible)	--
sweet corn-U.S.	23-58	--	--	"	--
" " -Fla	23-58	--	--	"	--
cabbage	29-58	--	--	"	--

/[1] The surrogate rate (5) expressed in ug/kg/hr/pound active ingredient per acre is adjusted for the minimum and maximum application rates for the crops (0.04 or 0.05 to 0.1 pound active ingredient per acre) to give the range of exposure rates shown.

/[2] The hourly respiratory exposure figure for aerial mixer/loaders and flaggers (0.01-0.03 and 0.05-0.12 respectively), drops out when added to the hourly dermal exposure figure rounded to two significant figures, so respiratory exposure can be considered negligible. In the case of pilots, respiratory exposure may be significant since the dermal exposure is so low.

SAMPLE CALCULATIONS:

1. AIRBLAST EXPOSURE:

Applicator Dermal Exposure:

$Y = (4.8 \times lb/A) + 16$ mg/hr

Application rate for sweet corn = 0.04-0.1 lb/A

$(4.8 \times 0.04) + 16 = 16.2$ Minimum application rate
$(4.8 \times 0.1) + 16 + 16.5$ Maximum application rate

Rounded off, this is 16 mg/hr; exposure to a 70 kg applicator is:

$\frac{16 \text{ mg/hr}}{70 \text{ kg}} = 0.23$ mg/kg/hr ; adjustment for long sleeves = 0.59;

$0.23 \times 0.59 = 0.14$ mg/kg/hr x 5 hrs/day = 0.7 mg/kg/day

Mixer/Loader Dermal Exposure:

Exposure is 11 mg/kg/hr for a mixer/loader wearing gloves:

Daily: 11 mg/kg/hr x 1 hr/day = 11 mg/kg/day

2. GROUND BOOM EXPOSURE:

Exposure was calculated from the surrogate study conducted on 2,4 D application by the British Agrochemical Association, Ltd. (6). In this study, exposures were expressed as mg/replicate; for sprayers, one replicate was one hour's spraying, while the mixers made one or two tank mixes per replicate, depending on tank size. Thus mixer/loader exposure is directly related to pounds handled per tank load, while applicator exposure is related to concentration of active ingredient in the tank and hours spent applying.

Calculations are as follows:

Two tank sizes were used in the surrogate study; the concentration in the tank was expressed in g/l, and tank size in liters. Conversion was made to pounds per tank as follows:

Tank A (2,4 D): 7.0 g/l x 1600 l/tank x 2.2×10^{-3} lb/g

$= 25$ lb/tank (420 gal tank)

Tank B (2,4 D): By similar calculation, 925 liters is approximately 240 gal, and contains 14 pounds 2,4 D.

Application Rate: For both tanks the application rate was 200 l/hectare, at a concentration of 7 g/l. Converting;

$$\frac{7 \text{ g/l} \times 200 \text{ l/hectare} \times 2.2 \times 10^{-3} \text{ lb/g}}{2.47 \text{ A/hectare}} = 1.2 \text{ lb/A, 2,4 D}$$

Cypermethrin was applied from 200 and 450 gal tanks; the nurse tank used by the mixer was 500 gal, but for calculating exposure, the surrogate exposures for both mixer/loaders and applicators were related to the size of tank used for application.

The amount of cypermethrin mixed per tank was calculated as follows:

Tank A: $\frac{450 \text{ gal/tank}}{30 \text{ gal/A}} \times 0.075$ lb (ave rate) a.i./A = 1.1 lb a.i/tank

Tank B: $\frac{200 \text{ gal/tank}}{20 \text{ gal/A}} \times 0.07$ lb (ave rate) a.i./A = 0.7 lb a.i./tank

Exposure to cypermethrin per replicate was calculated as follows (0.1 is the correction for use of gloves):

Mixer/loader, 450 gal tank:

$$\frac{102.1 \text{ mg/tank load} \times 1.1 \text{ lb cyper/tank} \times 0.1}{25 \text{ lb 2,4 D/tank} \times 70 \text{ kg}} = 0.0064 \text{ mg/kg/replicate}$$

Mixer/loader, 200 gal tank:

$$\frac{244.2 \text{ mg/tank load} \times 0.7 \text{ lb cyper/tank} \times 0.1}{14 \text{ lb 2,4 D/tank} \times 70 \text{kg}} = 0.017 \text{ mg/kg/replicate}$$

Applicator, 450 gal tank:

$$\frac{33.7 \text{ mg/hr} \times 0.07 \text{ lb cypermethrin/A}}{1.2 \text{ lb 2,4 D/A} \times 70 \text{ kg}} = 0.028 \text{ mg/kg/hr}$$

Applicator, 200 gal tank:

$$\frac{38 \text{ mg/hr} \times 0.075 \text{ lb cypermethrin/A}}{1.2 \text{ lb 2,4 D/A} \times 70 \text{ kg}} = 0.034 \text{ mg/kg/hr}$$

3. AERIAL EXPOSURE:

Aerial exposures are calculated as shown in the table, using the surrogate value for hourly exposure, corrected for pounds active ingredient applied per acre. Since hours per year were not given (1), yearly exposures could not be calculated, except for Florida pilots.

4.0 DISCUSSION OF CALCULATION OF EXPOSURE:

4.1 CABBAGE

A. Ground Boom Application

BUD (1) determined yearly exposure for sprayer/loaders combined, assuming the average farm is 26 A, and each is sprayed 10 times per year. From information provided on the time spent at each part of the task (e.g. 14 minutes mixing/loading, 45 " spraying), the yearly number of hours was proportioned to each task. Yearly exposure was calculated for mixer/loaders from the number of loads needed to treat the average farm for each crop, while applicator exposure used the proportional number of hours spent spraying times the hourly exposure rate.

The surrogate study used no protective clothing, so the mixer/loader exposure was corrected for use of rubber gloves by multiplying by 0.1.

B. Aerial Application

Aerial applications are 25% of the total 72000 acre treatments, or 1800 A treated ten times per season, one growing season per year. If each farm = 26 acres, there are 69 farms in the country treated aerially. This is expected to be custom application, and there are 50 aerial applicators licensed to spray cabbage in the U.S.

BUD was unable to determine the annual exposure in hours for the mixer/loader, applicator or flagger, so a yearly rate cannot be calculated. Values shown are exposure in ug/kg/hour.

4.2 FIELD CORN AND SWEET CORN

A. Ground Boom Application

The yearly exposure for sprayer/loaders was given for these crops, and as for cabbage, from the information provided by BUD (1), the yearly number of hours spent on each task was determined. Field corn (average farm = 95 A) is treated two times per year, while sweet corn (average farm = 28 A) is sprayed ten times per year in the U.S., and 23 times per season, three seasons per year in Florida. Consequently a range of replicates is given for the mixer/loaders, based on the Florida rates. The applicator exposure is calculated from the number of hours spent spraying per year, and BUD listed this as the number of hours needed to treat 95 acres two times for field corn, and 26 acres 23 times for sweet corn.

B. Aerial Application

As noted in Table 3, BUD was unable to determine the annual exposure in hours for aerial crew, so a yearly rate cannot be

calculated except for Florida pilots. The values shown are unit exposures (ug/kg/hr).

Aerial applications to field corn are 50% of the total 302,000 acre treatments, or 75000 acres treated twice per year. There are 280 aerial applicators for field corn in the U.S.

Aerial applications to sweet corn are 90% of the total 416000 acre treatments or 16000 acres treated 23 times per year (23 per season, three seasons per year in Florida). There are 280 aerial applicators for sweet corn in the U.S. including 68 in Florida alone.

5.0 ICI Americas Exposure Estimate

ICI Americas submitted a document entitled Cypermethrin: Applicator Exposure in Pecan Orchards, which is described as being applicator exposure information for workers using Cymbush 3E insecticide according to proposed label directions. This document contains a calculated exposure assessment based on selected surrogate studies. Although it may be an accurate description of expected exposure under certain specified conditions, it manipulates existing data rather than providing actual new monitoring data, and thus it does not contribute anything to the data base EPA has already accessed for its exposure assessment. EAB typically does not solicit such submissions from registrants; in fact we discourage the practice since it only adds to our workload if we take time to evaluate them. It is therefore our policy not to review such exercises, and we expect Toxicology Branch to complete its risk assessment based on EAB's exposure assessments.

NOTE to Project Manager, Registration Division:
Calculations in this assessment were made assuming the use of the protective clothing specified in FMC's label for AMMO. The label for Cymbush does not define protective clothing, but we assumed use of the clothing specified in the FMC label. All label language must conform to the April 1 recommendations of the Protective Clothing Working Group as detailed in the attached statement under "Proposed Label for Agricultural Uses."

In order to reduce unnecessary exposure further, the PM might consider proposing that the labels specify "eliminate use of human flaggers."

Anne R. Keller

Anne R. Keller, Chemist
Special Review Section
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

cc. W. Gross

Proposed Label for Agricultural Uses

When mixing/loading and spraying wear midforearm to elbow length chemical resistant gloves, boots or overshoes, one-piece overalls which have long sleeves and long pants, and face shield or goggles. Mixer/loaders should in addition wear a chemical resistant apron.

Any article of clothing worn while applying product must be cleaned before reusing. Clothing which has been drenched or heavily contaminated should be disposed of in accordance with state or local regulations.

Instead of clothing and equipment specified above, the applicator can use an enclosed tractor cab with filtered air supply.

Proposed Label for Homeowner Use

Harmful if swallowed, absorbed through the skin or inhaled. Causes moderate eye, skin, nose, and throat irritation. May cause allergic skin reaction in susceptible individuals. Avoid breathing spray mist. Avoid contact with skin, eyes, and clothing. Wear rubber gloves when using indoors. When using outdoors wear long pants, long sleeve shirt, and rubber gloves. Outdoors, spray with the wind to your back. Wash nondisposable gloves thoroughly with soap and water before removing. Provide adequate ventilation of indoor areas being treated. Do not apply to pets or contaminate feed, foodstuffs, dishes, or utensils. Do not use near fish bowls, aquariums, or varnished surfaces. Toxic to fish. Use with care.

Note: Agricultural label proposal is intended to be added to the existing labels.
The proposed homeowner label is intended as is for the label. Underlined words are the proposed additions to existing label language and are not intended to be highlighted on the label.

Al Nielsen, 1 Apr. 85
Alan Nielsen, Protective Clothing Working Group

Curt Lunchick 1 April 85
Curt Lunchick, Protective Clothing Working Group

6.0 REFERENCES

1. Gross, Bill 1985. Memorandum to Anne Keller, EAB. Projected Parameters for Applicator Exposure for Applying Cypermethrin to Cabbage, Field Corn, and Sweet Corn, and Projected Parameters for Applicator Exposure for Applying Cypermethrin to Pecans.

2. Gross, Bill 1985. Memorandum to Anne Keller, EAB. Exposure Parameters for Florida Aerial Applicators for Applying Cypermethrin to Sweet Corn.

3. Gross, Bill 1985. Memorandum to Anne Keller, EAB. Number of Aerial Applicators for corn and cabbage in the U.S. and for corn in Florida.

4. Lunchik, C., 1985. Aerial Applicator Exposure Assessment for Lorox L Herbicide.

5. Reinert, J.C., and Severn, D.J., 1985. Dermal Exposure to Pesticides: The Environmental Protection Agency's Viewpoint. ACS Symposium Series.

6. British Agrochemicals Association Limited. 1983. Alembic House, 93 Albert Embankment, London, SE1 7TU.