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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

OPP OFFICIAL RECORD  
HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
EPA SERIES 361

Date: August 28, 2000

**MEMORANDUM**

Subject: PP 9F05046/9F05051. Permanent Tolerance Petition for Use of **Thiamethoxam** on Canola, Barley, Cotton, Sorghum, Wheat, Tuberos and Corn Vegetables, Fruiting Vegetables, Cucurbit Vegetables, and Pome Fruits. **Amendment to the Dietary Exposure Assessment.**

DP Barcode D268606  
PC Code 060109

Submission Number S558105  
Case Number 290734

From: Michael Doherty, Chemist  
Registration Action Branch 2  
Health Effects Division (7509C)

Through: William Cutchin, Dietary Exposure SAC

Through: Richard Loranger, Branch Senior Scientist  
Registration Action Branch 2  
Health Effects Division (7509C)

To: G. Jeffrey Herndon, Branch Senior Scientist  
Registration Action Branch 1  
Health Effects Division (7509C)

**Action Requested**

Amend the previous Tier 3 chronic and cancer dietary exposure assessments (M. Doherty, 5/23/2000, D265606) to reflect updated percent market share data (see Attachment 4). Only chronic and cancer reassessments are required since the acute assessment did not incorporate % market share data. Additionally, evaluate the effect of restricting the application of thiamethoxam to 2% of the market share for apples.

## Executive Summary

For chronic dietary exposure, the Tier 3 risk estimate is approximately 13% of the chronic Population-Adjusted Dose (cPAD) for children aged 1-6 years; the percentage of the cPAD occupied is lower for all other representative population subgroups. **Estimates of dietary (food only) exposure to thiamethoxam for the requested use sites slightly exceeds HED's level of concern for cancer risk.** For the general U.S. population, the Tier 3 estimated dietary exposure to thiamethoxam resulting from its proposed uses is 0.000027 mg/kg/day. Applying the unit risk ( $Q_1^*$ ) value of 0.0377 (mg/kg/day)<sup>-1</sup> results in an estimated cancer risk of  $1.02 \times 10^{-6}$ , which is greater than HED's level of concern (generally  $1 \times 10^{-6}$ ). Consumption of apple commodities and fruiting vegetables contributes the most to the risk estimate. Restricting the application of thiamethoxam to 2% of the market share for apples results in a cancer risk estimate of  $0.70 \times 10^{-6}$ .

## Toxicological and FQPA Considerations

The dietary exposure portion of the toxicological database for thiamethoxam was summarized as part of the previous dietary assessment. Pertinent doses and endpoints are given in Table 1.

Table 1. Summary of Dietary Toxicological Doses and Endpoints for Thiamethoxam			
Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Acute Dietary (General Population including Infants & Children)	NOAEL= 100 UF = 100 FQPA SF = 10	Drooped palpebral closure, lower rectal temperature, increased forelimb grip strength, decreased locomotor activity at 500 mg/kg	Acute neurotoxicity - rat
	Acute RfD = 1 mg/kg Acute Population-Adjusted Dose = 0.1 mg/kg		
Chronic Dietary	NOAEL = 0.6 UF = 100 FQPA SF = 10	Increased incidence and severity of tubular atrophy in testes at $\geq$ 1.8 mg/kg/day	2-Generation reproduction study - rat
	Chronic RfD = 0.006 mg/kg/day Chronic Population-Adjusted Dose = 0.0006 mg/kg/day		
Cancer	$Q_1^* = 0.0377$ (mg/kg/day) <sup>-1</sup>	Benign and malignant hepatocellular tumors in both sexes of mice	18-month carcinogenicity study in Tif:MAG(SPF) mice

## Residue Information

The chronic and cancer dietary exposure analyses are refined to a Tier-3 level, incorporating chronic anticipated residues (memo, G. J. Herndon, DP Barcode D265607, 5/17/00) and revised projected % market share information (8/23/2000 e-mail from Neil Anderson; Attachment 4). The market share estimate for wheat did not change and the estimate for cotton changed by 1%. Since these were the only two commodities used to estimate dietary

burden to livestock, residues of thiamethoxam residues in meat and milk have not been recalculated for this assessment. The complete listing of the input parameters for the chronic and cancer analyses is given in Attachment 1. Note that the data used previously to estimate the acute dietary exposure are unaffected by the change in the % market share data and a new acute assessment is not required. An additional analysis using an estimated market share of 2% for apples was also made, as requested by the Registration Division. This value is the registrant's estimate market share for apples (BEAD's estimate is 15-20%).

Crop [Recommended Tolerance]	Commodity	Anticipated Residue <sup>1</sup> (ppm)	% Crop Treated	
			Original (5/17/00)	Revised (8/23/00)
Tuberous and Corm Vegetables - Crop Subgroup 1C [ 0.02 ppm]	Potato, White-peel Only	0.01	26	19
	Potato, White-peeled	0.01	26	19
	Potato, White-unspecified	0.01	26	19
	Potato, White-whole	0.01	26	19
	Potato, White-dry	0.01	26	19
	All Others in 1c	0.01	100	100
Fruiting Vegetables (Except Cucurbits) - Crop Group 8 [0.25 ppm]	Tomato, Whole	0.052	21	15
	Tomato, Juice	0.052	21	15
	Tomato, Catsup	0.052	21	15
	Tomato, Puree	0.052	21	15
	Tomato, Paste	0.052	21	15
	Tomato, Dried	0.052	21	15
	Peppers-sweet (Garden)	0.072	21	15
	Peppers-other	0.072	21	15
	Paprika	0.072	21	15
	Eggplant	0.072	21	15
	Ground Cherries	0.072	21	15
	Peppers-chile Including Jalapeno	0.074	21	15
	Pimentos	0.074	21	15

<b>Table 2. Summary of Residues and % Market Share Data Used in the Dietary Exposure Assessment</b>				
Crop [Recommended Tolerance]	Commodity	Anticipated Residue <sup>1</sup> (ppm)	% Crop Treated	
			Original (5/17/00)	Revised (8/23/00)
Cucurbit Vegetables - Crop Group 9 [0.2 ppm]	Cucumbers	0.038	44	5
	Melons-cantaloupe-juice	0.045	44	13
	Melons-cantaloupe-pulp	0.045	44	13
	Casabas	0.045	44	No Change
	Crenshaws	0.045	44	No Change
	Melons-honeydew	0.045	44	13
	Melons-persian	0.045	44	13
	Watermelons	0.045	44	13
	Bitter Melons	0.045	44	13
	Squash-summer	0.046	44	No Change
	Squash-winter	0.046	44	No Change
	Pumpkin	0.046	44	No Change
Pome Fruit - Crop Group 11 [0.2 ppm]	Apples	0.057	53	15-20
	Crabapples	0.057	53	No Change
	Apples-juice/cider	0.057	53	15-20
	Apples-juice-concentrate	0.057	53	15-20
	Apples-dried	0.057	53	15-20
	Pears	0.054	18	9
	Pears-juice	0.054	18	9
	Pears-dried	0.054	18	9
	Quinces	0.054	53	No Change
	Loquats	0.054	53	No Change
Barley [0.02 ppm]	Barley	0.01	100	0.1
Sorghum (Including Milo) [0.02 ppm]	Sorghum	0.01	12	9
Wheat [0.02 ppm]	Wheat-rough	0.01	2	No Change
	Wheat-germ	0.01	2	No Change

<b>Table 2. Summary of Residues and % Market Share Data Used in the Dietary Exposure Assessment</b>				
Crop [Recommended Tolerance]	Commodity	Anticipated Residue <sup>1</sup> (ppm)	% Crop Treated	
			Original (5/17/00)	Revised (8/23/00)
	Wheat-bran	0.01	2	No Change
	Wheat-flour	0.01	2	No Change
	Wheat-germ Oil	0.01	2	No Change
Canola [0.02 ppm]	Canola Oil	0.01	100	55
Cotton [0.1 ppm]	Cottonseed-meal	0.016	21	20
	Cottonseed-oil	0.016	21	20
Milk [0.02 ppm]	Milk Sugar (Lactose)	0.000098	100	No Change
	Milk-based Water	0.000098	100	No Change
	Milk-fat Solids	0.000098	100	No Change
	Milk-nonfat Solids	0.000098	100	No Change
Beef, Veal, Sheep, Goat [0.02 ppm]	Lean(fat Free) W/o Bones	0.000043	100	No Change
	Dried	0.000043	100	No Change
	Kidney	0.000032	100	No Change
	Liver	0.0018	100	No Change
	Meat Byproducts	0.000032	100	No Change
	Other Organ Meats	0.000032	100	No Change
Horse [0.02 ppm]	Horsemeat	0.000043	100	No Change

### Consumption Data

HED conducts dietary risk assessments using the Dietary Exposure Evaluation Model (DEEM™), which incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. For this acute dietary risk assessment, the entire distribution of single day food consumption events is combined with a single residue level (deterministic analysis) to obtain a distribution of exposure in mg/kg/day. For chronic and cancer dietary risk assessments, the three-day average of consumption for each sub-population is combined with residues in commodities to determine average exposure in mg/kg/day.

HED notes that there is a degree of uncertainty in extrapolating exposures for certain population subgroups which may not be sufficiently represented in the consumption surveys, (e.g., nursing and non-nursing infants or Hispanic females). Therefore, risks estimated for these

subpopulations were included in representative populations having sufficient numbers of survey respondents (e.g., all infants or females, 13-50 years).

## Results and Discussion

*Acute Analysis.* The previous acute exposure estimates (M. Doherty, 5/23/2000, D265606) are summarized in Table 2. The acute dietary (food only) risk estimates associated with thiamethoxam use on the subject-listed commodities are below HED's level of concern.

Population Subgroup <sup>a</sup>	aPAD, mg/kg	95th Percentile		99th Percentile		99.9th Percentile	
		Exposure, mg/kg	% aPAD <sup>b</sup>	Exposure, mg/kg	% aPAD <sup>b</sup>	Exposure, mg/kg	% aPAD <sup>b</sup>
U.S. pop - all seasons:	0.1	0.002837	3	0.006202	6	0.012772	13
All infants (<1 year):	0.1	0.007793	8	0.013123	13	0.029155	29
Children (1-6 years):	0.1	0.007037	7	0.012337	12	0.028265	28
Children (7-12 years):	0.1	0.003782	4	0.006434	6	0.008564	9
Females (13-50 years):	0.1	0.001737	2	0.003038	3	0.005112	5

<sup>a</sup> Population subgroups shown include the U.S. general population, those of infants, children, and women of child-bearing age, and other populations whose exposure exceeds that of the U.S. general population at the 95<sup>th</sup> percentile of exposure.

<sup>b</sup> % aPAD = Exposure (mg/kg) ÷ aPAD (mg/kg) × 100

*Chronic Analysis.* The chronic dietary (food only) risk estimates associated with thiamethoxam use on the subject-listed commodities are below HED's level of concern. The Tier 3 analysis estimates that exposure to the most highly exposed representative population subgroup (children aged 1-6 years) will be 0.000076 mg/kg/day. This is approximately 13% of the cPAD. Exposure estimates and associated risk estimate, as % cPAD, are shown in Table 3 for representative population subgroups. A complete listing of chronic exposure estimates for all DEEM™ population subgroups is included as Attachment 2.

Population Subgroup <sup>1</sup>	cPAD, mg/kg/day <sup>2</sup>	Exposure, mg/kg/day	% cPAD
U.S. Population (total)	0.0006	0.000027	5
All infants (< 1 year)	0.0006	0.000075	13
Children 1-6 yrs	0.0006	0.000076	13
Children 7-12 yrs	0.0006	0.000042	7
Females 13-50 yrs	0.0006	0.000018	3

<sup>1</sup> Population subgroups shown include the U.S. general population, those of infants, children, and women of child-bearing age, and other, representative populations whose exposure exceeds that of the U.S. general population.

<sup>2</sup> % cPAD = Exposure (mg/kg) ÷ cPAD (mg/kg) × 100

*Cancer.* The dietary (food only) cancer risk estimate associated with the requested uses

for thiamethoxam is slightly above HED's level of concern (generally  $1 \times 10^{-6}$ ). The Tier 3 analysis estimates that exposure to the U.S. general population will be 0.000027 mg/kg/day. Applying the unit risk ( $Q_1^*$ ) value of  $0.0377 \text{ (mg/kg/day)}^{-1}$  results in an estimated cancer risk of  $1.02 \times 10^{-6}$  (Attachment 3). Consumption of apple commodities and fruiting vegetables lead to the greatest contribution to this risk estimate. A complete listing of exposure contributions for each commodity is given in Attachment 3.

This risk estimate is fairly refined, incorporating both anticipated residues and percent of market share data into the analysis. Further refinement, in the form of market basket surveys or other monitoring data (e.g., USDA's Pesticide Data Program) may further reduce the estimated exposure, resulting in a lower cancer risk estimate for thiamethoxam.

The cancer risk described above is based on a percent market share estimate of 20%. Because of the linear nature of the chronic/cancer exposure assessment modules in DEEM™, the exposure estimates for apples can be multiplied by 0.1 ( $2\% \div 20\%$ ) in order to assess the effects of limiting the application of thiamethoxam to 2% of the apple crop. Applying the 0.1 factor to apple exposure estimates (see Attachment 3) results in a lowering of the total exposure to 0.0000186 mg/kg/day and a concomitant decrease in the cancer risk estimate to  $0.70 \times 10^{-6}$ .

List of Attachments:

- Attachment 1. Input parameters for DEEM™ chronic and cancer analyses.
- Attachment 2. Tier 3 Chronic DEEM™ analysis results.
- Attachment 3. Estimates of commodity exposure contributions and cancer risk.
- Attachment 4. Review of Percent Crop Treated Estimates for Thiamethoxam Insecticide.

cc: M. Doherty, RAB2 Reading File, L. Richardson (CEB1)



Attachment 1: Input parameters for DEEM™ chronic and cancer analyses.

Filename: 060109new ct.rs7

Chemical: Thiamethoxam

RfD(Chronic): .006 mg/kg bw/day NOEL(Chronic): 0 mg/kg bw/day

RfD(Acute): 1 mg/kg bw/day NOEL(Acute): 0 mg/kg bw/day Q\* = .0377

Date created/last modified: 08-28-2000/09:20:50/8

Program ver. 7.075

Food Code	Crop Grp	Food Name	Def Res (ppm)	Adj. Factors #1	Adj. Factors #2	Comment #
301	O	Canola oil (rape seed oil)	0.010000	1.000	0.550	
291	O	Cottonseed-meal	0.016000	0.150	0.200	
290	O	Cottonseed-oil	0.016000	0.100	0.200	
323	M	Beef-dried	0.000043	1.920	1.000	
325	M	Beef-kidney	0.000032	1.000	1.000	
327	M	Beef-lean (fat/free) w/o bones	0.000043	1.000	1.000	
326	M	Beef-liver	0.001800	1.000	1.000	
321	M	Beef-meat byproducts	0.000032	1.000	1.000	
322	M	Beef-other organ meats	0.000032	1.000	1.000	
331	M	Goat-kidney	0.000032	1.000	1.000	
333	M	Goat-lean (fat/free) w/o bone	0.000043	1.000	1.000	
332	M	Goat-liver	0.001800	1.000	1.000	
328	M	Goat-meat byproducts	0.000032	1.000	1.000	
329	M	Goat-other organ meats	0.000032	1.000	1.000	
334	M	Horsemeat	0.000043	1.000	1.000	
339	M	Sheep-kidney	0.000032	1.000	1.000	
341	M	Sheep-lean (fat free) w/o bone	0.000043	1.000	1.000	
340	M	Sheep-liver	0.001800	1.000	1.000	
336	M	Sheep-meat byproducts	0.000032	1.000	1.000	
337	M	Sheep-other organ meats	0.000032	1.000	1.000	
429	M	Veal-dried	0.000043	1.920	1.000	
426	M	Veal-kidney	0.000032	1.000	1.000	
425	M	Veal-lean (fat free) w/o bones	0.000043	1.000	1.000	
427	M	Veal-liver	0.001800	1.000	1.000	
430	M	Veal-meat byproducts	0.000032	1.000	1.000	
428	M	Veal-other organ meats	0.000032	1.000	1.000	
398	D	Milk-based water	0.000098	1.000	1.000	
319	D	Milk-fat solids	0.000098	1.000	1.000	
318	D	Milk-nonfat solids	0.000098	1.000	1.000	
320	D	Milk sugar (lactose)	0.000098	1.000	1.000	
203	1CD	Artichokes-jerusalem	0.010000	1.000	1.000	
222	1CD	Cassava (yuca blanca)	0.010000	1.000	1.000	
124	1CD	Ginger	0.010000	1.000	1.000	
210	1C	Potatoes/white-dry	0.010000	1.900	0.190	
209	1C	Potatoes/white-peeled	0.010000	1.000	0.190	
211	1C	Potatoes/white-peel only	0.010000	1.000	0.190	
208	1C	Potatoes/white-unspecified	0.010000	1.000	0.190	
207	1C	Potatoes/white-whole	0.010000	1.000	0.190	
218	1CD	Sweet potatoes (incl yams)	0.010000	1.000	1.000	
201	1CD	Taro-root	0.010000	1.000	1.000	
137	1CD	Turmeric	0.010000	1.000	1.000	
221	1CD	Yam-bean tuber (jicama)	0.010000	1.000	1.000	
224	1CD	Yautia (tanier)	0.010000	1.000	1.000	
154	8	Eggplant	0.072000	1.000	0.150	
164	8	Groundcherries	0.072000	1.000	0.150	
139	8	Paprika	0.072000	1.000	0.150	
156	8	Peppers-chilli incl jalapeno	0.074000	1.000	0.150	
157	8	Peppers-other	0.072000	1.000	0.150	
155	8	Peppers-sweet (garden)	0.072000	1.000	0.150	
158	8	Pimientos	0.074000	1.000	0.150	
163	8	Tomatoes-catsup	0.052000	3.800	0.150	
423	8	Tomatoes-dried	0.052000	14.300	0.150	
160	8	Tomatoes-juice	0.052000	1.000	0.150	
162	8	Tomatoes-paste	0.052000	3.800	0.150	

161	8	Tomatoes-puree	0.052000	1.700	0.150
159	8	Tomatoes-whole	0.052000	1.000	0.150
497	9B	Balsam pear	0.045000	1.000	0.440
152	9B	Bitter melon	0.045000	1.000	0.440
143	9A	Casabas	0.045000	1.000	0.440
386	9B	Christophine	0.045000	1.000	0.440
144	9A	Crenshaws	0.045000	1.000	0.440
148	9B	Cucumbers	0.038000	1.000	0.050
141	9A	Melons-cantaloupes-juice	0.045000	1.000	0.130
142	9A	Melons-cantaloupes-pulp	0.045000	1.000	0.130
145	9A	Melons-honeydew	0.045000	1.000	0.130
146	9A	Melons-persian	0.045000	1.000	0.130
397	9B	Okra/chinese (luffa)	0.045000	1.000	0.440
149	9B	Pumpkin	0.046000	1.000	0.440
150	9B	Squash-summer	0.046000	1.000	0.440
415	9B	Squash-spaghetti	0.046000	1.000	0.440
151	9B	Squash-winter	0.046000	1.000	0.440
147	9A	Watermelon	0.045000	1.000	0.130
436	9A	Watermelon-juice	0.045000	1.000	0.130
439	9B	Wintermelon	0.045000	1.000	0.440
52	11	Apples	0.057000	1.000	0.200
53	11	Apples-dried	0.057000	8.000	0.200
54	11	Apples-juice/cider	0.057000	0.750	0.200
377	11	Apples-juice-concentrate	0.057000	2.250	0.200
55	11	Crabapples	0.057000	1.000	0.530
81	11	Loquats	0.054000	1.000	0.530
56	11	Pears	0.054000	1.000	0.090
57	11	Pears-dried	0.054000	6.250	0.090
404	11	Pears-juice	0.054000	0.750	0.090
58	11	Quinces	0.054000	1.000	0.530
265	15	Barley	0.010000	1.000	0.001
275	15	Sorghum (including milo)	0.010000	1.000	0.090
278	15	Wheat-bran	0.010000	1.000	0.020
279	15	Wheat-flour	0.010000	1.000	0.020
277	15	Wheat-germ	0.010000	1.000	0.020
437	15	Wheat-germ oil	0.010000	1.000	0.020
276	15	Wheat-rough	0.010000	1.000	0.020

Attachment 2: Tier 3 Chronic DEEM™ analysis results.

U.S. Environmental Protection Agency  
 DEEM™ Chronic analysis for THIAMETHOXAM  
 Residue file name: 060109new ct.rs7

Ver. 7.075  
 (1989-92 data)

Adjustment factor #2 used.

Analysis Date 08-28-2000/09:23:44      Residue file dated: 08-28-2000/09:20:50/8  
 Reference dose (Rfd, Chronic) = .006 mg/kg bw/day

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 Total exposure by population subgroup  
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Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
U.S. Population (total)	0.000027	0.5%
U.S. Population (spring season)	0.000025	0.4%
U.S. Population (summer season)	0.000027	0.5%
U.S. Population (autumn season)	0.000030	0.5%
U.S. Population (winter season)	0.000026	0.4%
Northeast region	0.000030	0.5%
Midwest region	0.000026	0.4%
Southern region	0.000025	0.4%
Western region	0.000028	0.5%
Hispanics	0.000027	0.4%
Non-hispanic whites	0.000028	0.5%
Non-hispanic blacks	0.000023	0.4%
Non-hisp/non-white/non-black	0.000030	0.5%
All infants (< 1 year)	0.000075	1.3%
Nursing infants	0.000034	0.6%
Non-nursing infants	0.000093	1.5%
Children 1-6 yrs	0.000076	1.3%
Children 7-12 yrs	0.000042	0.7%
Females 13-19 (not preg or nursing)	0.000021	0.3%
Females 20+ (not preg or nursing)	0.000018	0.3%
Females 13-50 yrs	0.000018	0.3%
Females 13+ (preg/not nursing)	0.000023	0.4%
Females 13+ (nursing)	0.000031	0.5%
Males 13-19 yrs	0.000022	0.4%
Males 20+ yrs	0.000018	0.3%
Seniors 55+	0.000018	0.3%
Pacific Region	0.000028	0.5%

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Attachment 3: Estimates of commodity exposure contributions and cancer risk.

U.S. Environmental Protection Agency  
 DEEM™ Chronic analysis for THIAMETHOXAM  
 Residue file name: 060109new ct.rs7

Ver. 7.075  
 (1989-92 data)

Analysis Date 08-28-2000/09:24:49      Residue file dated: 08-28-2000/09:20:50/8  
 Q\* = 0.0377      Adjustment factor #2 used.

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 Complete commodity contribution analysis for \*  
 U.S. Population (total)  
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Crop Group = (O) Other

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis	
				mg/kg body wt/day	Lifetime risk (Q*= .0377)
Cottonseed-oil	0.016000	0.100	0.200	0.0000000	3.12E-10
Cottonseed-meal	0.016000	0.150	0.200	0.0000000	5.43E-14
Canola oil (rape seed oil)	0.010000	1.000	0.550	0.0000000	9.39E-10
Crop group subtotal				0.0000000	1.25E-09

Crop Group = (M) Meat

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis	
				mg/kg body wt/day	Lifetime risk (Q*= .0377)
Beef-meat byproducts	0.000032	1.000	1.000	0.0000000	1.20E-11
Beef-other organ meats	0.000032	1.000	1.000	0.0000000	4.49E-12
Beef-dried	0.000043	1.920	1.000	no exposure	
Beef-kidney	0.000032	1.000	1.000	0.0000000	1.69E-14
Beef-liver	0.001800	1.000	1.000	0.0000000	3.01E-10
Beef-lean (fat/free) w/o bon	0.000043	1.000	1.000	0.0000000	1.23E-09
Goat-meat byproducts	0.000032	1.000	1.000	no exposure	
Goat-other organ meats	0.000032	1.000	1.000	no exposure	
Goat-kidney	0.000032	1.000	1.000	no exposure	
Goat-liver	0.001800	1.000	1.000	no exposure	
Goat-lean (fat/free) w/o bon	0.000043	1.000	1.000	0.0000000	1.30E-14
Horsemeat	0.000043	1.000	1.000	no exposure	
Sheep-meat byproducts	0.000032	1.000	1.000	no exposure	
Sheep-other organ meats	0.000032	1.000	1.000	no exposure	
Sheep-kidney	0.000032	1.000	1.000	no exposure	
Sheep-liver	0.001800	1.000	1.000	no exposure	
Sheep-lean (fat free) w/o bo	0.000043	1.000	1.000	0.0000000	1.32E-11
Veal-lean (fat free) w/o bon	0.000043	1.000	1.000	0.0000000	1.49E-11
Veal-kidney	0.000032	1.000	1.000	no exposure	
Veal-liver	0.001800	1.000	1.000	no exposure	
Veal-other organ meats	0.000032	1.000	1.000	no exposure	
Veal-dried	0.000043	1.920	1.000	no exposure	
Veal-meat byproducts	0.000032	1.000	1.000	no exposure	
Crop group subtotal				0.0000000	1.58E-09

Crop Group = (D) Dairy Products

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis	
				mg/kg body wt/day	Lifetime risk (Q*= .0377)
Milk-nonfat solids	0.000098	1.000	1.000	0.0000000	1.54E-09

Milk-fat solids	0.000098	1.000	1.000	0.0000000	1.19E-09
Milk sugar (lactose)	0.000098	1.000	1.000	0.0000000	1.51E-09
Milk-based water	0.000098	1.000	1.000	0.0000006	2.22E-08

Crop group subtotal 0.0000007 2.65E-08

Crop Group = (1) Root and Tuber Vegetables

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis	
				mg/kg body wt/day	Lifetime risk (Q* = .0377)
Ginger	0.010000	1.000	1.000	0.0000000	5.73E-11
Turmeric	0.010000	1.000	1.000	0.0000000	7.69E-11
Taro-root	0.010000	1.000	1.000	0.0000000	3.62E-10
Artichokes-jerusalem	0.010000	1.000	1.000	no exposure	
Potatoes/white-whole	0.010000	1.000	0.190	0.0000002	9.23E-09
Potatoes/white-unspecified	0.010000	1.000	0.190	no exposure	
Potatoes/white-peeled	0.010000	1.000	0.190	0.0000014	5.37E-08
Potatoes/white-dry	0.010000	1.900	0.190	0.0000000	1.14E-09
Potatoes/white-peel only	0.010000	1.000	0.190	0.0000000	5.29E-11
Sweet potatoes (incl yams)	0.010000	1.000	1.000	0.0000003	1.03E-08
Yam-bean tuber (jicama)	0.010000	1.000	1.000	0.0000000	1.49E-10
Cassava (yuca blanca)	0.010000	1.000	1.000	0.0000000	5.52E-10
Yautia (taniaer)	0.010000	1.000	1.000	no exposure	
Crop group subtotal				0.0000020	7.57E-08

Crop Group = (1C) Tuberous and Corm Vegetables

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis	
				mg/kg body wt/day	Lifetime risk (Q* = .0377)
Ginger	0.010000	1.000	1.000	0.0000000	5.73E-11
Turmeric	0.010000	1.000	1.000	0.0000000	7.69E-11
Taro-root	0.010000	1.000	1.000	0.0000000	3.62E-10
Artichokes-jerusalem	0.010000	1.000	1.000	no exposure	
Potatoes/white-whole	0.010000	1.000	0.190	0.0000002	9.23E-09
Potatoes/white-unspecified	0.010000	1.000	0.190	no exposure	
Potatoes/white-peeled	0.010000	1.000	0.190	0.0000014	5.37E-08
Potatoes/white-dry	0.010000	1.900	0.190	0.0000000	1.14E-09
Potatoes/white-peel only	0.010000	1.000	0.190	0.0000000	5.29E-11
Sweet potatoes (incl yams)	0.010000	1.000	1.000	0.0000003	1.03E-08
Yam-bean tuber (jicama)	0.010000	1.000	1.000	0.0000000	1.49E-10

Crop Group = (1C) Tuberous and Corm Vegetables (continued)

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis	
				mg/kg body wt/day	Lifetime risk (Q* = .0377)
Cassava (yuca blanca)	0.010000	1.000	1.000	0.0000000	5.52E-10
Yautia (taniaer)	0.010000	1.000	1.000	no exposure	
Crop group subtotal				0.0000020	7.57E-08

Crop Group = (1D) Tuberous/Corm Vegetables (exc sugar beet)

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis	
				mg/kg body wt/day	Lifetime risk (Q* = .0377)

Ginger	0.010000	1.000	1.000	0.0000000	5.73E-11
Turmeric	0.010000	1.000	1.000	0.0000000	7.69E-11
Taro-root	0.010000	1.000	1.000	0.0000000	3.62E-10
Artichokes-jerusalem	0.010000	1.000	1.000	no exposure	
Sweet potatoes (incl yams)	0.010000	1.000	1.000	0.0000003	1.03E-08
Yam-bean tuber (jicama)	0.010000	1.000	1.000	0.0000000	1.49E-10
Cassava (yuca blanca)	0.010000	1.000	1.000	0.0000000	5.52E-10
Yautia (tanier)	0.010000	1.000	1.000	no exposure	

Crop group subtotal 0.0000003 1.15E-08

Crop Group = (8) Fruiting Vegetables

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis	
				mg/kg body wt/day	Lifetime risk (Q* = .0377)
Paprika	0.072000	1.000	0.150	0.0000000	8.92E-11
Eggplant	0.072000	1.000	0.150	0.0000000	1.25E-09
Peppers-sweet (garden)	0.072000	1.000	0.150	0.0000001	4.56E-09
Peppers-chilli incl jalapeno	0.074000	1.000	0.150	0.0000004	1.60E-08
Peppers-other	0.072000	1.000	0.150	no exposure	
Pimientos	0.074000	1.000	0.150	0.0000000	7.72E-10
Tomatoes-whole	0.052000	1.000	0.150	0.0000032	1.22E-07
Tomatoes-juice	0.052000	1.000	0.150	0.0000003	1.18E-08
Tomatoes-puree	0.052000	1.700	0.150	0.0000027	1.00E-07
Tomatoes-paste	0.052000	3.800	0.150	0.0000035	1.32E-07
Tomatoes-catsup	0.052000	3.800	0.150	0.0000015	5.50E-08
Groundcherries	0.052000	1.000	0.150	no exposure	
Tomatoes-dried	0.052000	14.300	0.150	0.0000000	8.41E-12
Crop group subtotal				0.0000118	4.44E-07

Crop Group = (9) Curcubit Vegetables

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis	
				mg/kg body wt/day	Lifetime risk (Q* = .0377)
Melons-cantaloupes-juice	0.045000	1.000	0.130	no exposure	
Melons-cantaloupes-pulp	0.045000	1.000	0.130	0.0000003	1.32E-08
Casabas	0.045000	1.000	0.130	0.0000000	5.05E-11
Crenshaws	0.045000	1.000	0.130	no exposure	
Melons-honeydew	0.045000	1.000	0.130	0.0000001	1.94E-09
Melons-persian	0.045000	1.000	0.130	no exposure	
Watermelon	0.045000	1.000	0.130	0.0000004	1.55E-08
Cucumbers	0.038000	1.000	0.050	0.0000001	5.18E-09
Pumpkin	0.046000	1.000	0.440	0.0000001	4.00E-09
Squash-summer	0.046000	1.000	0.440	0.0000008	3.02E-08
Squash-winter	0.046000	1.000	0.440	0.0000004	1.46E-08
Bitter melon	0.045000	1.000	0.440	0.0000000	2.02E-11
Christophine	0.045000	1.000	0.440	no exposure	
Okra/chinese (luffa)	0.045000	1.000	0.440	no exposure	
Squash-spaghetti	0.046000	1.000	0.440	no exposure	
Watermelon-juice	0.045000	1.000	0.130	no exposure	
Wintermelon	0.045000	1.000	0.440	no exposure	
Balsam pear	0.045000	1.000	0.440	no exposure	
Crop group subtotal				0.0000022	8.47E-08

## Crop Group = (9A) Melons

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis	
				mg/kg body wt/day	Lifetime risk (Q* = .0377)
Melons-cantaloupes-juice	0.045000	1.000	0.130	no exposure	
Melons-cantaloupes-pulp	0.045000	1.000	0.130	0.0000003	1.32E-08
Casabas	0.045000	1.000	0.130	0.0000000	5.05E-11
Crenshaws	0.045000	1.000	0.130	no exposure	
Melons-honeydew	0.045000	1.000	0.130	0.0000001	1.94E-09
Melons-persian	0.045000	1.000	0.130	no exposure	
Watermelon	0.045000	1.000	0.130	0.0000004	1.55E-08
Watermelon-juice	0.045000	1.000	0.130	no exposure	
Crop group subtotal				0.0000008	3.06E-08

## Crop Group = (9B) Squash/Cucumbers

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis	
				mg/kg body wt/day	Lifetime risk (Q* = .0377)
Cucumbers	0.038000	1.000	0.050	0.0000001	5.18E-09
Pumpkin	0.046000	1.000	0.440	0.0000001	4.00E-09
Squash-summer	0.046000	1.000	0.440	0.0000008	3.02E-08
Squash-winter	0.046000	1.000	0.440	0.0000004	1.46E-08
Bitter melon	0.045000	1.000	0.440	0.0000000	2.02E-11
Christophine	0.045000	1.000	0.440	no exposure	
Okra/chinese (luffa)	0.045000	1.000	0.440	no exposure	
Squash-spaghetti	0.046000	1.000	0.440	no exposure	
Wintermelon	0.045000	1.000	0.440	no exposure	
Balsam pear	0.045000	1.000	0.440	no exposure	
Crop group subtotal				0.0000014	5.41E-08

## Crop Group = (11) Pome Fruits

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis	
				mg/kg body wt/day	Lifetime risk (Q* = .0377)
Apples	0.057000	1.000	0.200	0.0000050	1.90E-07
Apples-dried	0.057000	8.000	0.200	0.0000001	5.60E-09
Apples-juice/cider	0.057000	0.750	0.200	0.0000037	1.39E-07
Crabapples	0.057000	1.000	0.530	no exposure	
Pears	0.054000	1.000	0.090	0.0000004	1.43E-08
Pears-dried	0.054000	6.250	0.090	0.0000000	6.63E-10
Quinces	0.054000	1.000	0.530	no exposure	
Loquats	0.054000	1.000	0.530	no exposure	
Apples-juice-concentrate	0.057000	2.250	0.200	0.0000005	2.04E-08
Pears-juice	0.054000	0.750	0.090	0.0000001	4.11E-09
Crop group subtotal				0.0000099	3.74E-07

Crop Group = (15) Cereal Grains

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis	
				mg/kg body wt/day	Lifetime risk (Q* = .0377)
Barley	0.010000	1.000	0.001	0.0000000	3.34E-11
Sorghum (including milo)	0.010000	1.000	0.090	no exposure	
Wheat-rough	0.010000	1.000	0.020	0.0000000	5.15E-10
Wheat-germ	0.010000	1.000	0.020	0.0000000	2.18E-11
Wheat-bran	0.010000	1.000	0.020	0.0000000	* 1.99E-10
Wheat-flour	0.010000	1.000	0.020	0.0000003	1.04E-08
Wheat-germ oil	0.010000	1.000	0.020	0.0000000	4.67E-13
Crop group subtotal				0.0000003	1.12E-08
Population subgroup total				0.0000270	1.02E-06



Attachment 4: Review of Percent Crop Treated Estimates for Thiamethoxam Insecticide.

**MEMORANDUM**

**SUBJECT:** Review of Percent Crop Treated Estimates from Novartis Crop Protection, Inc. for Thiamethoxam (Actara™ and Platinum™) Insecticide

**FROM:** Neil Anderson, Agronomist  
Herbicide and Insecticide Branch

Jihad Alsadek, Ph.D., Economist  
Economic Analysis Branch  
Biological and Economic Analysis Division (7503C)

**TO:** Tina Levine, PM  
Insecticide and Rodenticide Branch  
Registration Division (7505C)

On August 10, 2000 Novartis Crop Protection, Inc. (Novartis) submitted revised estimates of percent crop treated for their new insecticide thiamethoxam. We have reviewed the information provided and offer the following comments.

Thiamethoxam is being considered for registration on several use sites. Novartis submitted percent crop treated estimates for the following use sites: apples, pears, potatoes, lettuce, cole crops, fruiting vegetables (bell peppers, eggplant, tomatoes), melons (cantaloupe, honeydew, watermelons), cucurbits, barley, wheat, canola, sorghum and cotton. These data differed from those previously submitted by Novartis on December 3, 1998 in the "Reduced-Risk Rationale Document: Requesting Registration of a New Active Ingredient, CGA-293343 (proposed ISO name: thiamethoxam)." Other than differences in some of the use sites presented in the two documents, which are detailed below, we have only one disagreement with the most recent submission.

Novartis has made significant changes to their estimates for how much market share thiamethoxam will capture in the pome fruit market, apples in particular. In the original submission from December 1998, market share estimates were provided for each use site and target pest. Initial estimates of thiamethoxam market share for apples, depending on target pest, ranged from 7 to 19 percent of the crop treated. Estimates provided on a pest-by-pest basis are helpful in understanding how a particular chemicals use pattern will develop, but these are not helpful in determining a single estimate for how much of the whole crop will be treated. BEAD originally provided an estimate of 53 percent of the apple crop would be treated with thiamethoxam when it reaches its full market potential (memo from J. Alsadek to Dani Daniel). That number was derived simply by summing the point estimates provided by Novartis for each target pest/pest group (aphids = 16%, tentiform leafminers = 7%, leafhoppers = 11%, plum

curculio = 19%; 16+7+11+19=53). BEAD recognizes that this was likely an over estimate of potential market share because a single application of thiamethoxam will control more than one of these target pests. However, this method was sufficient as a screening mechanism for providing an estimate based on available information.

The new market share estimate Novartis has submitted for apples is 2 percent of the crop will be treated with thiamethoxam at market maturity. Accompanying the new estimate is a brief explanation detailing why their estimate has changed so significantly. The reason for the drastic change is a modification in the way Novartis expects thiamethoxam will be used. They no longer believe it will be used to a great extent for plum curculio control. Whether or not this will be the case remains to be seen. Based on contact that we made with extension research specialists in Michigan, Pennsylvania and New York, thiamethoxam is perhaps one of the first new compounds that will control this damaging pest. Plum curculio is a direct apple pest (causes damage to the fruit itself) that infests a large portion of the apple acreage east of the Mississippi River. Current standard treatments for plum curculio control are based on organophosphate insecticides, primarily azinphos-methyl and phosmet. According to the research personnel contacted, thiamethoxam is quite effective when used at the "petal fall" timing (the point at which the apple blossoms fall from the tree) for this pest. For plum curculio this is perhaps the most critical timing for effective control. Based on statements made by the research personnel contacted, thiamethoxam would likely capture a significant portion of the insecticide use that occurs at this timing targeted at plum curculio.

Thiamethoxam is also very efficacious against the other target pests listed in the submission, aphids, tentiform leafminers, and leafhoppers. One of thiamethoxam's main competitors will be imidacloprid which is from the same chemical class (neonicotinoids) and controls these same pests. Each researcher spoken to indicated that it was likely that thiamethoxam would capture from 1/3 to 1/2 of the market now held by imidacloprid. This is primarily because it effectively controls the same pests as imidacloprid, with the addition of plum curculio and perhaps some other locally important pests (European apple sawfly and apple maggot). According to the USDA National Agricultural Statistics Service, in 1999 imidacloprid was used on 46 percent of the apple acreage. Therefore, BEAD believes that 15 to 20 percent of the apple crop could be treated with thiamethoxam when it reaches market maturity.

The most recent submission (8/10/2000) did not contain estimates of thiamethoxam use for all use sites originally listed in the Reduced Risk Rationale (12/98) document. In particular, the original document provided estimates for tobacco, golf courses, lawn and landscape uses, ornamentals, and pets (dogs). The percent crop treated estimates provided by Alsadek earlier this year should be used in the absence of new data. The table below lists each use site and a corresponding estimate for percent of crop treated that BEAD suggests for regulatory use.

**Table 1. Thiamethoxam Uses and Estimates of Percent Crop Treated\***

Crop	Percent Crop Treated
Apples	15 - 20
Pears	9
Potatoes	19
Lettuce	26
Cole Crops	18
Fruiting Vegetables (bell peppers, eggplant, tomatoes)	15
Melons (cantaloupe, honeydew, watermelon)	13
Cucumbers	5
Barley	0.1
Wheat	2
Canola	55
Sorghum	9
Cotton	20

\* Does not include all use sites being requested for registration. Only those use sites that Novartis included in submission dated 8/10/2000 are listed.

## REFERENCES

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4. National Ag. Statistics Service, USDA, July 2000. Agricultural Chemical Usage - 1999 Fruit and Nut Summary.
5. Novartis Crop Protection, Inc., August 10, 2000. Forecast Thiamethoxam Percent Crop Treated Values.
6. Novartis Crop Protection, Inc., December 3, 1998. Reduced Risk Rationale Document: Requesting Registration of a New Active Ingredient, CGA-293343 (Proposed ISO Name: Thiamethoxam).
7. Reissig, H. New York Ag. Experiment Station. Personal communication with Neil Anderson. (315)787-2336.
  1. for the combined residues of thiamethoxam and CGA-322704