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

OCT 17 1994

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Dietary Exposure Analysis for Carbofuran through
the Proposed Use on Canola.

FROM: Jennifer M. Wintersteen *Jennifer Wintersteen*
Dietary Risk Evaluation Section
Science Analysis Branch/HED (7509C)

TO: Dennis Edwards, PM Team 19
Insecticide-Rodenticide Branch
Registration Division (7505C)

THROUGH: Elizabeth A. Doyle, Section Head *E.A. Doyle*
Dietary Risk Evaluation Section
SAB/Health Effects Division *W. Brown*

Action Requested

Provide an estimate of chronic dietary risk for the proposed use of carbofuran on rape seed/canola.

Toxicological Endpoint

The chronic DRES analysis used a reference dose for carbofuran of 0.005 mg/kg/day, based upon a NOEL of 0.5 mg/kg/day from a 1-year dog feeding study and an Uncertainty factor of 100. The effects seen at the LEL (12.5 mg/kg/day) were decreased cholinesterase, aspermia, uterine hyperplasia, and hydrometria. Carbofuran has not been shown to produce carcinogenic effects in two species. (HED reassessment of 3/6/87 and Agency verification 3/18/87).

Residues

The chronic exposure analysis used the existing DRES file, which incorporated only tolerances (Table 1). The 1977-78 USDA food consumption survey, which DRES estimates are based on, does not contain any consumption information estimates for canola/rape seed. BEAD (R. Griffin personal communication with R. Torla, 5/14/93) estimates 877 million pounds domestic canola production/usage for 1992/1993.

Based on the above and assuming a residue value of 1.0 ppm for rape seed (M. Flood personal communication, 10/17/94), DRES estimates an exposure of 0.000077 mg/kg/day for the average (58.9 kg) U.S. person (Attachment A). A consumption estimate based on sex, race, age, or other subgroups cannot be made from the above production/usage estimate.

Chronic Risk Estimates

Published Uses: tolerance x 100 percent use (TMRC)

	Exposure (mg/kg/day)	% RfD
Overall U.S. population:	0.005183	104
Non-nursing Infants:	0.013129	263
Children (1-6):	0.011921	238

Canola: 1 ppm x 100 percent use

Average person (58.9 kg):	0.000077	1.5
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See Table 2 for a summary of published uses for carbofuran on all DRES subgroups.

Results

Granting this tolerance would increase the TMRC as a percentage of carbofuran's RfD by 1.5 percent to 106% for the general population. This value could overestimate the dietary risk in that no refinements were made to residue or percent of crop treated estimates. For several subgroups, especially non-nursing infants and children 1-6 years old, the RfD is considerably exceeded.

cc:
DRES
Caswell files (160A)
CBTS (M. Flood)

BEAD data was used to help estimate a consumption value for canola as follows:

$$\text{CONSUMPTION (g/kg/day)} \times \text{RESIDUE (mg/kg)} = \text{EXPOSURE (mg/kg/day)}$$

The consumption value for canola was taken as the U.S. production volume (877 million lbs. or 3.98×10^{11} g) divided by the U.S. population in the 1977-78 USDA food consumption survey (240 million) to get grams of canola consumed per year. Further division was done to estimate consumption per day for an average person body weight (58.9 kg) to get consumption per person per day. The tolerance (1.0 ppm) was used as the residue for canola and 100 percent crop treated was assumed. Conversion factors were also taken into calculations, e.g., 1 lb. = 454 g and 1 kg = 1000 g. The estimated exposure for canola is 7.7×10^{-5} mg/kg bwt/day.

$$\text{Consumption} = 3.98 \times 10^{11} \text{ g food} \div 2.4 \times 10^8 \text{ persons} = 1.66 \times 10^3 \text{ g/person}$$

$$\frac{1.66 \times 10^3 \text{ g/person}}{58.9 \text{ kg bwt} * 365 \text{ day/year}} = 7.7 \times 10^{-2} \text{ g food/kg bwt/day}$$

With the consumption estimate now calculated, exposure can be estimated as follows:

$$\begin{array}{rcl} \text{Consumption} & \times & \text{Residue} & = & \text{Exposure} \\ 0.077 \text{ g food/kg bwt/day} & \times & 1.00 \text{ mg chemical/kg food} & \times & 1 \text{ kg/1000 g} & = & 7.7 \times 10^{-5} \text{ mg/kg bwt/day} \end{array}$$

This exposure represents 1.5% of the RfD:

$$7.7 \times 10^{-5} \text{ mg/kg bwt/day} \div 0.005 \text{ mg/kg bwt/day} \times 100 = 1.5\%$$

Table 1.

CHEMICAL INFORMATION FOR CASWELL NUMBER 160A

DATE: 10/17/94

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Carbofuran Caswell #160A CAS No. 1563-66-2 A.I. CODE: 090601 CFR No. 180.254 185.600	1yr feeding- dog NOEL= 0.5000 mg/kg LEL= 12.5000 mg/kg 0.00 ppm ONCO: Negative- 2 species.	Decreased plasma & RBC CHE; aspermitia, uterine hyperplasia, hydrometria. No evidence of oncogenic- ity in rats or mice.	ADI UF -->100 OPP RfD= 0.005000 EPA RfD= 0.005000	No data gaps. RfD agrees with Barton memo of 1/85.	WHO last reviewed 1982 HED complete 02/21/86 HED complete 03/06/87 EPA verified 03/18/87 On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		
			NEW	PENDING	PUBLISHED
01010AA	CRANBERRIES	1E2526			0.5000
01010JA	CRANBERRIES -JUICE	1E2526			0.5000
01014AA	GRAPES - FRESH	6F1787			0.4000
01014DA	GRAPES -RAISINS	6H5103			2.0000
01014JA	GRAPES -JUICE	6F1787			0.4000
01016AA	STRAWBERRIES	4F1482			0.5000
06002AA	BANANAS -UNSPECIFIED	2E1205			0.1000
06002AB	BANANAS -FRESH	2E1205			0.1000
06002DA	BANANAS -DRIED	2E1205			0.1000
06016AA	PLANTAINS	4E1483			0.1000
07002AA	COFFEE	2F1219			1.0000
08048DA	PAPRIKA	6F1789			0.4000
10002AA	CANTALOUPE -UNSPECIFIED	6F1789			0.4000
10002AB	CANTALOUPE -PULP	6F1789			0.4000
10003AA	CASABAS	6F1789			0.4000
10004AA	CRENSHAWNS	6F1789			0.4000
10005AA	HONEYDEW MELONS	6F1789			0.4000
10007AA	PERSION MELONS	6F1789			0.4000
10008AA	WATERMELON	6F1789			0.4000
10010AA	CUCUMBERS	6F1789			0.8000
10011AA	PUMPKIN	6F1789			0.8000
10013AA	SQUASH -SUMMER	6F1789			0.8000
10014AA	SQUASH -WINTER	2F1219			1.0000
11003AA	PEPPERS, SHEET, GARDEN	2F1219			1.0000
11003AB	CHILL PEPPERS	2F1219			1.0000
11003AD	PEPPERS -OTHER	2F1219			1.0000
11004AA	PIMIENTOS	4E3123			0.4000
13018AA	ARTICHOKES - GLOBE	4E3123			0.4000
14009AA	ARTICHOKES - JERUSALEM	6F1875			2.0000
14013AA	POTATOES(WHITE) -WHOLE	6F1875			2.0000
14013AB	POTATOES(WHITE) -UNSPECIFIED	6F1875			2.0000
14013AC	POTATOES(WHITE) -PEELED	6F1875			2.0000
14013DA	POTATOES(WHITE) -DRY	6F1875			2.0000
14013HA	POTATOES(WHITE) -PEEL ONLY	8F0711			0.2000
15004AA	CORN, POP	6F1672			1.0000
15005AA	CORN, SHEET	6F1701			4.0000
15006AA	PEANUTS -WHOLE	2F2683			1.0000
15018AA	SUNFLOWER -SEEDS	5F1557			1.0000
15029AA	SOYBEANS -SPROUTED SEEDS	6F1803			0.2000
24001AA	BARLEY				

Table 1.

CHEMICAL INFORMATION FOR CASWELL NUMBER 160A DATE: 10/17/94 PAGE: 2

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Carbofuran Caswell #160A CAS No. 1563-66-2 A.I. CODE: 090601 CFR No. 180.254 185.600	1Yr feeding- dog NOEL= 0.5000 mg/kg 0.00 ppm LEL= 12.5000 mg/kg 0.00 ppm ONCO: Negative- 2 species.	Decreased Plasma & RBC CHE; aspermita, uterine hyperplasia, hydrometria. No evidence of oncogenic- ity in rats or mice.	ADI Uf -->100 OPP RfD= 0.005000 EPA RfD= 0.005000	No data gaps. RfD agree with Barton memo of 1/85.	WHO last reviewed 1982 HED complete 02/21/86 HED complete 03/06/87 EPA verified 03/18/87 ON IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		
			NEW	PENDING	PUBLISHED
24002EA	CORN, GRAIN-ENDOSPERM	8F0711			0.2000
24002HA	CORN, GRAIN-BRAN	8F0711			0.2000
24002SA	CORN SUGAR	8F0711			0.2000
24003AA	OATS	6F1803			0.2000
24004AA	RICE-ROUGH	9F0822			0.2000
24004AB	RICE-MILLED	9F0822			0.2000
24006AA	SORGHUM (INCLUDING MILO)	2F1283			0.1000
24007AA	WHEAT-ROUGH	6F1803			0.2000
24007GA	WHEAT-ROUGH	6F1803			0.2000
24007HA	WHEAT-GERM	6F1803			0.2000
24007MA	WHEAT-FLOUR	6F1803			0.2000
25002SA	BEEF SUGAR	1F1163			0.1000
25003SA	CANE SUGAR	9F0829			0.1000
25003SB	SUGAR-MOLASSES	9F0829			0.1000
270020A	CORN, GRAIN-OIL	8F0711			0.2000
270030A	COTTONSEED-OIL	5F1530			1.0000
27003MA	COTTONSEED-MEAL	5F1530			1.0000
270070A	PEANUTS-OIL	6F1701			4.0000
270100A	SOYBEANS-OIL	5F1557			1.0000
270170A	SUNFLOWER-OIL	2F2683			1.0000
28023AA	RAPE SEED	NOPTNUM	1.0000		
28023AB	SOYBEANS-UNSPECIFIED	5F1557			1.0000
28023AC	SOYBEANS-MATURE, SEEDS DRY	5F1557			1.0000
28023MA	SOYBEANS-FLOUR, FULL FAT	5F1557			1.0000
28023MB	SOYBEANS-FLOUR, LOW FAT	5F1557			1.0000
28023MC	SOYBEANS-FLOUR, DEFATTED	5F1557			1.0000
50000DB	MILK-NON-FAT SOLIDS	0F0898			0.1000
50000FA	MILK-FAT SOLIDS	0F0898			0.1000
50000SA	MILK SUGAR (LACTOSE)	0F0898			0.1000
53001BA	BEEF-MEAT BYPRODUCTS	1F1163			0.0500
53001BB	BEEF(ORGAN MEATS)-OTHER	1F1163			0.0500
53001DA	BEEF-DRIED	1F1163			0.0500
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	1F1163			0.0500
53001KA	BEEF(ORGAN MEATS)-KIDNEY	1F1163			0.0500
53001LA	BEEF(ORGAN MEATS)-LIVER	1F1163			0.0500
53001MA	BEEF(BONELESS)-LEAN (H/O REMOVEABLE FAT)	1F1163			0.0500
53002BA	GOAT-MEAT BYPRODUCTS	1F1163			0.0500
53002BB	GOAT(ORGAN MEATS)-OTHER	1F1163			0.0500
53002FA	GOAT(BONELESS)-FAT	1F1163			0.0500
53002KA	GOAT(ORGAN MEATS)-KIDNEY	1F1163			0.0500

Table 1.

CHEMICAL INFORMATION FOR CASWELL NUMBER 160A

DATE: 10/17/94

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Carbofuran Caswell #160A CAS No. 1563-66-2 A.I. CODE: 090601 CFR No. 180.254 185.600	1yr feeding- dog NOEL= 0.5000 mg/kg LEL= 12.5000 mg/kg 0.00 ppm ONCO: Negative- 2 species.	Decreased plasma & RBC ChE; aspermita, uterine hyperplasia, hydrometria. No evidence of oncogenic- ity in rats or mice.	ADI UF -->100 OPP RfD= 0.005000 EPA RfD= 0.005000	No data gaps. RfD agrress with Barton memo of 1/85.	WHO last reviewed 1982 HED complete 02/21/86 HED complete 03/06/87 EPA verified 03/18/87 On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
53002LA	GOAT(ORGAN MEATS)-LIVER	1F1163			0.0500
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F1163			0.0500
53003AA	HORSE	1F1163			0.0500
53005BA	SHEEP-MEAT BYPRODUCTS	1F1163			0.0500
53005BB	SHEEP(ORGAN MEATS)-OTHER	1F1163			0.0500
53005FA	SHEEP(BONELESS)-FAT	1F1163			0.0500
53005LA	SHEEP(ORGAN MEATS)-KIDNEY	1F1163			0.0500
53005MA	SHEEP(ORGAN MEATS)-LIVER	1F1163			0.0500
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F1163			0.0500
53006BA	PORK-MEAT BYPRODUCTS	1F1163			0.0500
53006BB	PORK(ORGAN MEATS)-OTHER	1F1163			0.0500
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	1F1163			0.0500
53006KA	PORK(ORGAN MEATS)-KIDNEY	1F1163			0.0500
53006LA	PORK(ORGAN MEATS)-LIVER	1F1163			0.0500
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F1163			0.0500

Table 2.

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 10/17/94

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Carbofuran Caswell #160A CAS No. 1563-66-2 A.I. CODE: 090601 CFR No. 180.254 185.600	1yr feeding- dog NOEL= 0.5000 mg/kg LEL= 12.5000 mg/kg 0.00 ppm ONCO: Negative- 2 species.	Decreased plasma & RBC CHE: aspermita, uterine hyperplasia, hydrometria. No evidence of oncogenic- ity in rats or mice.	ADI UF -->100 OPP Rfd= 0.005000 EPA Rfd= 0.005000	No data gaps. Rfd agrees with Barton memo of 1/85.	WHO last reviewed 1982 HED complete 02/21/86 HED complete 03/06/87 EPA verified 03/18/87 On IRIS.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAV)		NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES
	CURRENT TMRC*	NEW TMRC**			
U.S. POPULATION - 48 STATES	0.005183	0.005183	103.667780	0.000020	ARC
U.S. POPULATION - SPRING SEASON	0.004996	0.004996	99.917760	0.000000	
U.S. POPULATION - SUMMER SEASON	0.005251	0.005251	105.010780	0.000000	
U.S. POPULATION - FALL SEASON	0.005276	0.005276	105.523080	0.000000	
U.S. POPULATION - WINTER SEASON	0.005176	0.005176	103.529800	0.000000	
NORTHEAST REGION	0.005090	0.005090	101.803420	0.000000	
NORTH CENTRAL REGION	0.005502	0.005502	110.049600	0.000000	
SOUTHERN REGION	0.004930	0.004930	98.608280	0.000000	
WESTERN REGION	0.005232	0.005232	104.635640	0.000000	
HISPANICS	0.005412	0.005412	108.244460	0.000000	
NON-HISPANIC WHITES	0.005258	0.005258	105.150240	0.000000	
NON-HISPANIC BLACKS	0.004601	0.004601	92.015860	0.000000	
NON-HISPANIC OTHERS	0.004520	0.004520	90.406740	0.000000	
NURSING INFANTS (< 1 YEAR OLD)	0.003411	0.003411	68.226180	0.000000	
NON-NURSING INFANTS (< 1 YEAR OLD)	0.013129	0.013129	262.588900	0.000000	
FEMALES (13+ YEARS, PREGNANT)	0.003537	0.003537	70.746720	0.000000	
FEMALES 13+ YEARS, NURSING	0.004278	0.004278	85.560140	0.000000	
CHILDREN (1-6 YEARS OLD)	0.011921	0.011921	238.417400	0.000000	
CHILDREN (7-12 YEARS OLD)	0.008299	0.008299	165.989080	0.000000	
MALES (13-19 YEARS OLD)	0.005581	0.005581	111.613300	0.000000	
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.004509	0.004509	90.170340	0.000000	
MALES (20 YEARS AND OLDER)	0.003897	0.003897	77.944700	0.000000	
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.003337	0.003337	66.734920	0.000000	

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.