

041721

5-28-96



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

MAY 28 1996

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Fonofos in/on Potatoes
(PP# 2F2716).

FROM: Brian Steinwand *BS*
Dietary Risk Evaluation Section
Science Analysis Branch/HED (7509C)

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

TO: M. Metzger, Chief *M. Metzger*
RCAB (7509C)

Action Requested

Provide a dietary exposure analysis for the use of fonofos in/on potatoes. The petition requests and CBTS recommends that a tolerance of 0.2 ppm be established on potatoes.

Discussion

A root crop tolerance (which includes potatoes) already exists (9F0760) at 0.1 ppm. Thus, for the purposes of this analysis, a new tolerance for potatoes of 0.1 ppm was added.

Toxicological Endpoint:

The Reference Dose (RfD) used in the analysis is 0.007 mg/kg bwt/day, based on a NOEL of 0.7 mg/kg bwt/day from a 2 year rat feeding study with an uncertainty factor of 100 that demonstrated brain, plasma, and red blood cell cholinesterase inhibition in females (See IRIS). The RfD has been approved by the HED RfD committee (8/12/93). Fonofos is classified as a Group E (non-carcinogen) chemical by the HED Carcinogenicity Peer Review Committee (See IRIS).

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Residue Information

Tolerances for fonofos are published in 40 CFR §180.221. Tolerance level residues and 100 percent crop treated assumptions were made for the proposed commodities.

Results

A summary of the residue information considered in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. Summaries of the TMRCs and their representations as percentages of the Reference Dose (RfD) are included as Table 2 and 3.

Chronic Exposure Analysis

Exposure from Existing Tolerances for fonofos:

<u>Subgroup</u>	<u>Exposure (mg/kg/day)</u>	<u>%RfD</u>
U.S. Population	0.000646	9.2
Children (1-6 years old)	0.001310	18.7

Proposed new Tolerances on the proposed commodities:

U.S. Population	0.000114	1.6
Children (1-6 years old)	0.000226	3.2

If the new tolerances on the proposed commodities are approved:

U.S. Population	0.000760	10.8
Children (1-6 years old)	0.001535	21.9

Conclusions

The chronic analysis for fonofos is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with fonofos. Thus, the chronic dietary risk exposure to fonofos appears to be minimal for this petition on potatoes, and does not exceed the RfD for any of the DRES subgroups.

Attachments

cc: DRES; Caswell 661A; PM-25 R. Taylor; CBTS (J. Garbus)

CHEMICAL INFORMATION FOR CASHELL NUMBER 4548

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fonotos (Dyfonate) Caswell #548 CAS No. 944-22-9 A.I. CODE: 041701 CFR No. 180.221	2Yr feeding- rat NOEL= 0.7000 mg/kg 15.00 ppm LEL= 2.8000 mg/kg 60.00 ppm ONCO: E (RD/PR Committee)	Brain, plasma, & RBC CHE inhibition in females. No evidence of carcinogenicity in rats or mice.	PADI UF -->100 OPP RD= 0.007000 EPA RD= 0.002000	Chronic feeding- dog Reproduction- rat 90-day rat neurotoxicity study is con-critical - NOEL=0.75 mg/kg; LEL=2.5 mg/kg (Brain CHE inhibit)	HED reviewed 05/08/86 EPA verified 06/24/86 RD/PR reviewed 08/12/93 On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	PENDING	PUBLISHED
01016AA	STRAWBERRIES	0F0960		0.100000		
06002AA	BANANAS-UNSPECIFIED	0E3836		0.100000		
06002AB	BANANAS-FRESH	0E3836		0.100000		
06002DA	BANANAS-DRIED	0E3836		0.100000		
06016AA	PLANTAINS	0E3836		0.100000		
07006AA	CHICORY	9F0760		0.100000		
08004AA	ANICE	0F0960		0.100000		
08015AA	DILL	3F1379		0.100000		
11001AA	EGGPLANT	3F1379		0.100000		
11003AA	PEPPERS,SWEET GARDEN	3F1379		0.100000		
11003AB	CHILI PEPPERS	3F1379		0.100000		
11003AD	PEPPERS-OTHER	3F1379		0.100000		
11004AA	PIMENTOS	3F1379		0.100000		
11005AA	TOMATOES-WHOLE	3F1379		0.100000		
11005JA	TOMATOES-JUICE	3F1379		0.100000		
11005RA	TOMATOES-PUREE	3F1379		0.100000		
11005TA	TOMATOES-PASTE	3F1379		0.100000		
11005UA	TOMATOES-CATSUP	3F1379		0.100000		
13001AA	BETS-TOPS(GREENS)	0F0960		0.100000		
13002AA	CELERY	0F0960		0.100000		
13003AA	CHICORY (FRENCH OR BELGIAN ENDIVE)	0F0960		0.100000		
13005AA	BROCCOLI	0F0960		0.100000		
13006AA	BRUSSEL SPROUTS	0F0960		0.100000		
13007AA	CABBAGE-GREEN AND RED	0F0960		0.100000		
13008AA	CAULIFLOWER	0F0960		0.100000		
13009AA	COLLARDS	0F0960		0.100000		
13010AA	CABBAGE-CHINESE/CELERY, INC. BOK CHOY	0F0960		0.100000		
13011AA	KALE	0F0960		0.100000		
13012AA	KOHLRABI	0F0960		0.100000		
13013AA	LETTUCE-LEAFY VARIETIES	0F0960		0.100000		
13014AA	DANDELION	0F0960		0.100000		
13015AA	ENDIVE,CURLEY AND ESCAROLE	0F0960		0.100000		
13016AA	FENNEL	0F0960		0.100000		
13020AA	LETTUCE-UNSPECIFIED	0F0960		0.100000		
13021AA	MUSTARD GREENS	0F0960		0.100000		
13022AA	PARSLEY	0F0960		0.100000		
13023AA	RHUBARB	0F0960		0.100000		
13024AA	SPINACH	0F0960		0.100000		
13025AA	SWISS CHARD	0F0960		0.100000		
13026AA	TURNIPS-TOPS.	0F0960		0.100000		

CHEMICAL INFORMATION FOR CASWELL NUMBER 454B

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fonofos (Dyfonate) Caswell #454B CAS No. 944-22-9 A.I. CODE: 041701 CFR No. 180.221	2yr feeding- rat NOEL= 0.7000 mg/kg 15.00 ppm LEL= 2.8000 mg/kg 60.00 ppm	Brain, plasma, & RBC CHE inhibition in females. No evidence of carcinogenicity in rats or mice.	PADI UF -->100 OPP RfD= 0.007000 EPA RfD= 0.002000	Chronic feeding- dog Reproduction- rat 90-day rat neurotoxicity study is con-critical - NOEL=0.75 mg/kg; LEL=2.5 mg/kg (Brain CHE inhibit)	HED reviewed 05/08/86 EPA verified 06/24/86 RfD/PR reviewed 08/12/93 On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	PUBLISHED
13027AA	WATERCRESS	0F0960			0.100000
13045AA	LETTUCE-HEAD VARIETIES	0F0960			0.100000
14001AA	BEETS-ROOTS	9F0760			0.100000
14003AA	CARROTS	9F0760			0.100000
14013AA	POTATOES(WHITE)-WHOLE	9F0760		0.100000	0.100000
14013AA	POTATOES(WHITE)-WHOLE	2E2716		0.100000	0.100000
14013AB	POTATOES(WHITE)-UNSPECIFIED	2E2716		0.100000	0.100000
14013AB	POTATOES(WHITE)-UNSPECIFIED	9F0760			0.100000
14013AC	POTATOES(WHITE)-PEELED	2E2716		0.100000	0.100000
14013AC	POTATOES(WHITE)-PEELED	9F0760			0.100000
14013DA	POTATOES(WHITE)-DRY	9F0760		0.100000	0.100000
14013DA	POTATOES(WHITE)-DRY	2E2716		0.100000	0.100000
14013HA	POTATOES(WHITE)-PEEL ONLY	9F0760			0.100000
14013HA	POTATOES(WHITE)-PEEL ONLY	2E2716		0.100000	0.100000
14014AA	RADISHES-ROOTS	9F0760			0.100000
14015AA	RUTABAGAS-ROOTS	9F0760			0.100000
14016AA	SALSIFY(OYSTER PLANT)	9F0760			0.100000
14018AA	SWEETPOTATOES (INCLUDING YAMS)	9F0760			0.100000
14019AA	TURNIPS-ROOTS	9F0760			0.100000
14021AA	PARSNIPS	9F0760			0.100000
15001AA	BEANS-DRY-GREAT NORTHERN	3F1379			0.100000
15001AB	BEANS-DRY-KIDNEY	3F1379			0.100000
15001AC	BEANS-DRY-LIMA	3F1379			0.100000
15001AD	BEANS-DRY-NAVY (PEA)	3F1379			0.100000
15001AE	BEANS-DRY-OTHER	3F1379			0.100000
15001AF	BEANS-DRY-PINTO	3F1379			0.100000
15002AA	BEANS-SUCCULENT-LIMA	3F1379			0.100000
15003AA	BEANS-SUCCULENT-GREEN	3F1379			0.100000
15003AB	BEANS-SUCCULENT-OTHER	3F1379			0.100000
15003AC	BEANS-SUCCULENT-YELLOW, MAX	3F1379			0.100000
15004AA	CORN, POP	7F0548			0.100000
15005AA	CORN, SWEET	7F0548			0.100000
15006AA	PEANUTS-WHOLE	3F1379			0.100000
15007AA	PEAS(GARDEN)-MATURE SEEDS, DRY	3F1379			0.100000
15009AA	PEAS(GARDEN)-GREEN IMMATURE	3F1379			0.100000
15011AA	LENTILES-WHOLE	3F1379			0.100000
15011AB	LENTILES-SPLIT	3F1379			0.100000
15013AA	MUNG BEANS (SPROUTS)	3F1379			0.100000
15015AA	OKRA	3F1379			0.100000
15022AA	BEANS-DRY-BROADBEANS(MATURE SEED)	3F1379			0.100000

CHEMICAL INFORMATION FOR CASWELL NUMBER 4548

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FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)		EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
				PENDING	PUBLISHED				
	CHEMICAL								
	STUDY TYPE								
	Fonofos (Dyfonate) Caswell #4548 CAS No. 944-22-9 A.I. CODE: 041701 CFR No. 180.221	2yr feeding- rat NOEL= 0.7000 mg/kg 15.00 ppm LEL= 2.8000 mg/kg 60.00 ppm	Brain, plasma, & RBC CHE inhibition in females.	PADI UF -->100 OPP RfD= 0.007000 EPA RfD= 0.002000	Chronic feeding- dog Reproduction- rat 90-day rat neurotoxicity study is con-critical - NOEL=0.75 mg/kg; LEL=2.5 mg/kg (Brain CHE inhibit)	HED reviewed 05/08/86 EPA verified 06/24/86 RfD/PR reviewed 08/12/93 On IRIS.			
	ONCO: E (RfD/PR Committee)					No evidence of carcinog- enicity in rats or mice.			
15022AB	BEANS-SUCCULENT-BROADBEANS(IMMAT. SEED)	3F1379			0.100000				
15023AA	BEANS-DRY-PIGEON BEANS	3F1379			0.100000				
15027AA	BEANS-UNSPECIFIED	3F1379			0.100000				
15029AA	SOYBEANS-SPROUTED SEEDS	3F1379			0.100000				
15030AA	BEANS-DRY-HYACINTH(MATURE SEEDS)	3F1379			0.100000				
15030AB	BEANS-SUCCULENT-HYACINTH(YOUNG PODS)	3F1379			0.100000				
15031AA	BEANS-DRY-BLACKEYE PEAS(COMPEAS)	3F1379			0.100000				
15032AA	BEANS-DRY-GARBANZO(CHICK PEA)	3F1379			0.100000				
16002AA	ASPARAGUS	0F0960			0.500000				
24002EA	CORN, GRAIN-ENDOSPERM	7F5048			0.100000				
24002HA	CORN, GRAIN-BRAN	7F0548			0.100000				
24002SA	CORN SUGAR	7F0548			0.100000				
24006AA	SORGHUM (INCLUDING MILO)	3F1379			0.100000				
25002SA	BET SUGAR	9F0760			0.100000				
25003SA	SUGAR	0F0960			0.100000				
25003SB	CANE SUGAR	0F0960			0.100000				
26011AA	GUAR BEANS	3F1379			0.100000				
27002DA	CORN, GRAIN-OIL	7F0548			0.100000				
27007DA	PEANUTS-OIL	3F1379			0.100000				
27010DA	SOYBEANS-OIL	3F1379			0.100000				
28023AA	SOYBEANS-UNSPECIFIED	3F1379			0.100000				
28023AB	SOYBEANS-MATURE, SEEDS DRY	3F1379			0.100000				
28023AA	SOYBEANS-MATURE, SEEDS DRY	3F1379			0.100000				
28023WA	SOYBEANS-FLOUR, FULL FAT	3F1379			0.100000				
28023WB	SOYBEANS-FLOUR, LOW FAT	3F1379			0.100000				
28023WC	SOYBEANS-FLOUR, DEFATTED	3F1379			0.100000				
28080AA	PEPPERMINT	0F0960			0.100000				
28080AA	PEPPERMINT-OIL	0F0960			0.100000				
28081AA	SPERMINT	0F0960			0.100000				
28081AA	SPERMINT-OIL	0F0960			0.100000				

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

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CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fonofos (Dyfonate) Caswell #4548 CAS No. 944-22-9 A.I. CODE: 041701 CFR No. 180.221	2yr feeding- rat NOEL= 0.7000 mg/kg LEL= 2.8000 mg/kg 60.00 ppm ONCO: E (Rfd/PR Committee)	Brain, plasma, & RBC CHE inhibition in females. No evidence of carcinogenicity in rats or mice.	PADI UF -->100 OPP RfD= 0.007000 EPA RfD= 0.002000	Chronic feeding- dog Reproduction- rat 90-day rat neurotoxicity study is con-critical - NOEL=0.75 mg/kg; LEL=2.5 mg/kg (Brain CHE inhibit)	HED reviewed 05/08/86 EPA verified 06/24/86 RfD/PR reviewed 08/12/93 ON IRIS.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
	CURRENT TMRC*	NEW TMRC**				
U.S. POPULATION - 48 STATES	0.000646	0.000759	10.846571	1.618386		
U.S. POPULATION - SPRING SEASON	0.000632	0.000742	10.597271	1.566314		
U.S. POPULATION - SUMMER SEASON	0.000646	0.000755	10.781057	1.547986		
U.S. POPULATION - FALL SEASON	0.000648	0.000766	10.940886	1.681971		
U.S. POPULATION - WINTER SEASON	0.000646	0.000763	10.901900	1.677257		
NORTHEAST REGION	0.000605	0.000711	10.163243	1.521586		
NORTH CENTRAL REGION	0.000654	0.000781	11.151771	1.801786		
SOUTHERN REGION	0.000657	0.000771	11.017771	1.638929		
WESTERN REGION	0.000655	0.000756	10.794629	1.444471		
HISPANICS	0.000707	0.000820	11.716286	1.620143		
NON-HISPANIC WHITES	0.000640	0.000756	10.794714	1.644871		
NON-HISPANIC BLACKS	0.000632	0.000737	10.530743	1.506586		
NON-HISPANIC OTHERS	0.000625	0.000701	10.019600	1.088057		
NURSING INFANTS (< 1 YEAR OLD)	0.000479	0.000513	7.325886	0.482143		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.001158	0.001297	18.535643	1.992786		
FEMALES (13+ YEARS, PREGNANT)	0.000473	0.000548	7.823314	1.069686		
FEMALES 13+ YEARS, NURSING	0.000550	0.000632	9.033443	1.171300		
CHILDREN (1-6 YEARS OLD)	0.001310	0.001535	21.926943	3.215471		
CHILDREN (7-12 YEARS OLD)	0.000973	0.001142	16.310000	2.406371		
MALES (13-19 YEARS OLD)	0.000665	0.000791	11.305671	1.803871		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000570	0.000674	9.632986	1.493171		
MALES (20 YEARS AND OLDER)	0.000504	0.000601	8.591571	1.388514		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000478	0.000558	7.973814	1.152143		

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

TABLE 3

TOLERANCE ASSESSMENT SUMMARY FOR Fonofos (Dyfonate)
CASWELL #454B

DATE: 05/13/96

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000646	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	9.228	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000114	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	1.618	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.000760	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	10.847	% OF THE ADI.
NO OTHER PENDING TOLERANCES ARE IN THE FILE		

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (1-6 YEARS OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.001310	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	18.711	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000226	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	3.215	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.001535	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	21.927	% OF THE ADI.
NO OTHER PENDING TOLERANCES ARE IN THE FILE		