

APPENDIX A.

**ESTIMATION OF EXPOSURE OF PERSONS IN CALIFORNIA TO PESTICIDE
PRODUCTS THAT CONTAIN ENDOSULFAN**

APPENDIX A.

ENDOSULFAN DIETARY EXPOSURE ASSESSMENT (1998)

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I. Endosulfan Introduction (July 1998)

Acute and chronic dietary exposure assessments and an acute tolerance assessment were conducted for endosulfan (40 CFR #180.182). All available endosulfan raw agricultural commodity (RAC) residue data were evaluated (Table 1). The 40 CFR 180.182 tolerance is characterized as total endosulfan which includes endosulfan I, endosulfan II and endosulfan sulfate [EI, EII and ES (CFR, 1997)].

All of the federal and state regulatory pesticide residue monitoring programs check for endosulfan and its main isomers and sulfate form. The detections are reported as endosulfan. The Food and Drug Administration (FDA) monitoring program analyzes for all endosulfan (EI, EII and ES). The United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) and the Pesticide Data Program (PDP) monitor for the same forms. The California Department of Pesticide Regulation (DPR) residue screens can also detect the same endosulfan forms.

Residues analyzed by the FDA regulatory monitoring surveillance program (domestic commodities) from July 1, 1995 through June 30, 1997 were considered for use in the DPR dietary exposure analysis. The FDA multiple residue screen minimum detection level (MDL) for endosulfan is 0.1 ppm for many RACs (FDA, 1998). The lowest reported FDA MDL was 0.03 ppm for tomato. The FDA data were not used, instead DPR, PDP and registrant data were used.

The DPR total endosulfan MDL was between 0.03 and 0.09 for program 4, the years 1993 to 1995, residue data. The consulted DPR program was the market basket surveillance (program 4). There were extensive findings of total endosulfan residues, at various levels, detected on label approved RACs in the DPR programs during 1993, 1994 or 1995 (DPR, 1994, 1995, 1997).

The USDA monitors for endosulfan including endosulfan I, II and sulfate with their multi-residue screen analytical program and the results are reported in two different annual surveys, the Pesticide Data Program (PDP) and the Food Safety Inspection Service (FSIS). The PDP program targets at raw agricultural commodities that are likely to be heavily consumed by infants and children. The FSIS looks for residues on various commercial meat animals such as cattle, sheep and poultry. The USDA Food Safety Inspection Service (FSIS) meat monitoring program LOD for total endosulfan is 0.06 ppm (0.02 ppm each for endosulfan I, II and sulfate) and over 2,400 samples of meat were tested during 1995 (USDA, 1994c, 1995). No endosulfan residues were detected.

The USDA Pesticide Data Program (PDP), established May 1991, has monitored for endosulfan using the multi residue methods (MRMs) since 1992. Only the 1994 and 1996 PDP data were used since the 1994 had no detected residues on RACs that are no longer examined and the 1996 program break endosulfan down and characterize the residues as endosulfan I, II and endosulfan sulfate. The endosulfan residue limits of detection (LOD) range is generally between 0.002 - 0.006 ppm for each of the analytes (USDA, 1996b, 1998). The upper end of the LOD range (0.011 ppm total endosulfan) which was the total non detect value for California analyzed samples. The 0.011 ppm value was also reported for all samples without any detected endosulfan residues in the DPR dietary analysis. The following RACs were included from the PDP annuals; apple, carrot, celery (1994), grapes, green beans, lettuce (1994), peaches, potatoes (sweet), spinach, tomatoes and sweet corn. The following processed commodities from the PDP surveys were also used; sweet pea, apple juice, milk and wheat.

The FMC Corporation endosulfan compound name used in the submitted field residue studies is: Thiodan® (6,7,8,9,10,10 hexachloro 1,5,5a,6,9,9a,-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide) and endosulfan sulfate. The potential dietary exposure from residues with the endosulfan and its

metabolite was evaluated together with residues expressed as total endosulfan residues by FMC and reported in the few, submitted field studies. The registrant limit of detection (LOD) for endosulfan ranged from 0.05 - 0.1 ppm depending on the commodity or the age of the submitted field study.

Currently there are 14 active registrations of endosulfan approved for use in California. Two of the registrations are for non agricultural use and are either a home and garden product or the 1 technical product registration. The remaining 12 are registrations for agricultural uses. These ag end use products are for general insect pest control on raw agricultural commodities. The percent active ingredient formulations range from 33.7% to 50% crop sprays using endosulfan active ingredient. The crop pre-harvest intervals (PHI) ranged from 0 day for melon crops to 30 days for peach and other tree fruit. The typical PHI was between 1-7 days for most labeled crop uses.

The total pounds of endosulfan used in 1994 on California commodities was 475,740 lbs and during 1995 it was 229,160 lbs. (DPR, 1996 a,b). The evident decrease in pounds applied in 1995 versus 1994 is due almost completely to a decreased use on melons. Only about 4,800 lbs of endosulfan were applied to melons in 1995. The use on melons was 152,350 lbs during 1994. It is possible that some other pesticide was granted a California registration which was easier or more efficacious to use on melons than endosulfan before the start of the 1995 season.

II. Residue Database

The majority of the RAC residue data used for the DPR endosulfan dietary exposure analysis were obtained from the following sources: a) registrant commodity field residue studies, b) DPR residue monitoring program data (1993 - 1995), c) USDA 1994 or 1996 PDP monitoring program data, or d) USDA 1995 FSIS residue monitoring. A U.S. EPA tolerance value was used in the dietary exposure analysis for just one raw agricultural commodity, sugar cane, and its refined products (molasses and refined sugar). Use of the U.S. EPA tolerance is done only when registrant field residue or government regulatory monitoring data are not available.

All of the analyzed commodities had their residue values combined to represent total endosulfan. The acute and chronic commodity endosulfan values were not modified using any type of toxicological equivalency factor (TEF) method applied to the endosulfan I, II or endosulfan sulfate residues because of their same relative toxicity. All available endosulfan raw agricultural commodity residue data, expressed as total endosulfan, used to conduct the DPR dietary analyses are presented in Table 1.

Table 1. Summary of Endosulfan (E α , E β and Sulfate) Expressed as Total Endosulfan Residues (July, 1998).

Raw Agricultural Commodity (RAC)	Source ^a (Reference Year)	Tolerance ^b (ppm)	Residue Used (ppm)		N ^c	Additional Information	%CT
			Acute	Chronic			
Almond	REG-f (Beckman, 1962)	0.2(N) ^e	0.20	0.10	2	LOD = EPA tolerance	
Apple, whole	PDP (1996)	2.0	0.021	0.0064	530	1 yr. Acute 95th %.	33%
Apple, juice	PDP (1996)	2.0	0.002	0.002	179	0.002 (½ LOD) mix, all ND.	33%
Apricot	DPR (1993-1995)	2.0	0.15	0.031	95	Ac = hi #, LOD = 0.06 ppm	
Artichoke	REG-f (Gowen,1967)	2.0	0.10	0.05	4	all nondetect (ND)	
Barley (grain)	PDPsur (1996)	0.1(N)	0.021	0.0105	340	wheat as surrogate, all ND	
Beans, dry & succ.	PDP (1996)	2.0	0.010	0.004	531	green bean sur.,0.008 LOD	
Beet (sugar)	PDPsur (1996)	0.2	0.0082	0.0042	500	carrot as surrogate RAC	
Blueberry	PDPsur (1996)	2.0	0.065	0.0077	525	grape as surrogate RAC	
Broccoli	DPR (1993 - 1995)	2.0	0.1	0.0303	312	0.06 LOD, ac = hi number	12%
Brussels Sprouts	DPRsur (1993 - 1995)	2.0	0.1	0.0303	312	broccoli as surrogate RAC	
Cabbage	DPR (1993 - 1995)	2.0	0.12	0.045	266	0.09 LOD, ac = hi number (#)	
Carrot	PDP (1996)	0.2	0.0082	0.0042	500	1 yr. Acute=95th %	
Cauliflower	DPR (1993 - 1995)	2.0	0.1	0.0303	312	broccoli as surrogate RAC	
Celery	PDP (1994)	2.0	0.005	0.00153	176	0.003 LOD, ac = hi number (#)	
Cherry	DPR (1993 - 1995)	2.0	0.18	0.033	59	0.06 LOD, ac = hi #	
Collards	DPRsur (1993 - 1995)	2.0	0.1	0.0303	312	broccoli as surrogate RAC	
Corn (sweet)	PDP (1996)	0.2	0.007	0.0035	173	0.007 LOD, all ND	
Cottonseed meal/oil	REG-fp (FMC,1967)	1.0	0.03	0.015	6	0.03 LOD, all ND	
Cucumbers	DPRsur (1993 - 1995)	2.0	0.57	0.049	211	0.06 LOD, cantaloupe as sur	
Eggplant	DPRsur (1993 - 1995)	2.0	0.092	0.027	580	0.03 ppm LOD, squash as sur	
Grape fresh/dry/juice	PDP (1996)	2.0	0.065	0.0077	525	CA LOD=0.011, ac=95%. 7%	
Kale	DPRsur (1993 - 1995)	2.0	0.1	0.0303	312	broccoli as surrogate RAC	
Lettuce, head & leaf	PDP (1994)	2.0	0.108	0.014	546	0.009 LOD, ac = 95th %	
Melons, all types	DPR (1993 - 1995)	2.0	0.57	0.049	211	0.06 LOD, cantaloupe hi # = ac	
Milk, fat	PDP (1996)	0.5	0.0015	0.0015	575	0.0015 ppm (½ LOD) mixture	
Mustard Greens/Seed	DPRsur (1993 - 1995)	2.0	0.1	0.0303	312	broccoli as surrogate RAC	
Nectarine	PDPsur (1996)	2.0	0.053	0.009	329	peach as surrogate RAC.	6%
Nuts (all but almond)	REG-f (1962)	0.2(N)	0.2	0.1	--	almond as surrogate, all ND	
Oat (grain)	PDPsur (1996)	0.1(N)	0.021	0.0105	340	wheat as surrogate, all ND	
Peach	PDP (1996)	2.0	0.053	0.009	329	0.011 ppm LOD, ac = 95%.	6%
Pear	DPR (1993 - 1995)	2.0	0.077	0.0202	402	0.03 LOD, acute=95th%.	54%
Peas, succulent	PDP (1996)	2.0	0.0071	0.0037	355	0.007 ppm LOD, ac=95th%.	
Peppers, bell & chili	DPR (1993 - 1995)	2.0	0.18	0.037	745	0.03 ppm LOD, acute=95th%.	
Pineapple	DPR (1993 - 1995)	2.0	0.09	0.0454	43	0.03 ppm LOD, acute=hi number	
Plum	DPR (1993 - 1995)	2.0	0.07	0.0302	217	0.06 ppm LOD, acute=hi number	
Potato	PDP (1996)	0.2(N)	0.00703	0.0036	507	0.007 ppm LOD, ac=hi number	
Prune	DPR (1993 - 1995)	2.0	0.12	0.045	11	0.06 ppm LOD, acute=hi number	
Pumpkin	DPRsur (1993 - 1995)	2.0	0.092	0.027	580	0.03 ppm LOD, squash as surro	
Rape seed (canola)	DPRsur (1993 - 1995)	2.0(N)	0.1	0.0303	312	broccoli as surrogate RAC	
Raspberry	PDPsur (1996)	2.0	0.065	0.0077	525	grape as surrogate RAC.	
Red meat, fat ^f	FSIS (1996)	0.2	0.06	0.03	2,484	0.06 LOD, all ND. 2,484 =	
Red meat, mby	FSIS (1996)	0.2	0.06	0.03	2,484	combined N for cattle, hogs	
Red meat, meat	FSIS (1996)	0.2	0.06	0.03	2,484	sheep & goats together.	
Rye (grain)	PDPsur (1996)	0.1(N)	0.021	0.0105	340	wheat as surrogate, all ND	
Safflower seed (oil)	REG-fp (Gowan, 1967)	0.2(N)	0.05	0.008	6	0.05 ppm LOD, ac = hi #	
Spinach	PDP (1996)	2.0	0.357	0.026	525	0.011 CA LOD, ac=95th%.	
Squash-sum/winter	DPR (1993 - 1995)	2.0	0.092	0.027	580	0.03 LOD, acute = 95 th %	
Strawberry (& juice)	DPR (1993 - 1995)	2.0	0.18	0.0603	228	0.12 ppm LOD, ac=hi #	14%
Sugarcane (sugar)	EPA (1997)	0.5	0.5	0.25	--	U.S. EPA tolerance as acute #	
Sunflower seed (oil)	REG-fp (Gowan, 1967)	0.2(N)	0.05	0.008	6	safflower as surrogate RAC	
Sweet Potato	PDP (1996)	0.2(N)	0.00703	0.0036	507	0.007 ppm LOD, ac=hi #	
Tomato	PDP (1996)	2.0	0.048	0.0105	179	0.011 CA LOD, ac=hi #.	46/10%
Turnip (greens)	PDP (1994)	2.0	0.108	0.014	546	lettuce as surrogate RAC	
Watercress	PDP (1994)	2.0	0.108	0.014	546	lettuce as surrogate RAC	
Wheat (grain)	PDP (1996)	0.1(N)	0.021	0.0105	340	0.021 ppm LOD, all ND	

a - **DPR** = California Department of Pesticide Regulation, **EPA** = U.S. Environmental Protection Agency, **FSIS** = U.S. Department of Food and Agriculture Food Safety Inspection Service, **PDP** = U.S. Department of Agriculture Pesticide Data Program residue monitoring program, **PDPsur** = USDA Pesticide Data Program residue monitoring program - surrogate data used (similar crop types), **REG-f & REG-fp** = Registrant supplied field or field and processing residue studies.

b - **U.S. EPA** = Tolerances for U.S. EPA 40 CFR 180.182.

- c - N = The number of RAC composite samples analyzed from the selected submitted studies or monitoring programs.
d - %CT = Percent of the crop treated adjustment made to chronic dietary residues when sufficient use data are available.
e - (N) = U.S. EPA determined that residue is expected to be a negligible residue as defined.
f - The red meat tissues are all at limit of detection (LOD) based on USDA FSIS monitoring data..

III. Residue Adjustments

A. Percent of the Crop Treated

The current DPR chronic dietary exposure analysis default assumption is that 100% of any crop is treated with the pesticide under consideration. When quality data are available that indicate that less than 100% of a commodity is treated with a specific pesticide, then on an individual commodity by pesticide combination basis, exceptions to the default assumptions can be made.

The assumption that people under normal eating conditions would be continuously exposed to the averaged residue level of a pesticide for every labeled commodity for either for 1 year (chronic) or 70 years (lifetime) is unrealistic based on available substantial dietary information. This assumption does not take into account the fact that a significant amount of a commodity is often untreated with the pesticide under consideration. This is not reflective of actual practices and is borne out by the lower residue levels encountered in various market basket surveys versus the registrant field studies. The actual percentage of the crop treated with a specific pesticide varies from year to year depending upon biotic and abiotic factors. Using the existing percent crop treated data, it is reasonable to revise the 100% treated assumption downward using more realistic pesticide treatment rates and use patterns. Commodities that used residues obtained from registrant field trial or state and federal monitoring data in the chronic dietary exposure assessment were considered for percent crop treated adjustments.

The percent of the crop treated adjustment method has been employed as a comparison to the standard chronic dietary exposure assessment using 7 commodities that have endosulfan tolerances. The following commodities have reported endosulfan use at the federal and state levels: apple, broccoli, grape, peach, pear, strawberry and tomato. DPR Pesticide Use Reports and CDFA crop statistics together with USDA Ag Field Crops Summary annuals were used. Conservative, but realistic, assumptions were made when setting the percentage of crop treated adjustment factors for the chronic dietary exposure section for each commodity. Multiple years of endosulfan use and acreage harvested data were evaluated at the federal and state levels.

1. Apple

The total California apple acreage during 1993 was 33,000 acres and 40,000 acres for 1995 (USDA, 1994a, 1996a). The California apple acreage represents approximately 10% of both the 1993 and 1995 U.S. apple crops. Endosulfan was applied to less than 1,300 acres of California apples in both the 1994 and 1995 seasons (DPR, 1996a,b). The United States apple acreage, based on the eight major production states (California, Michigan, New York, North Carolina, Oregon, Pennsylvania, South Carolina and Washington), harvested during 1993 from 332,000 acres and 345,000 acres during 1995 (USDA, 1994a, 1996a). Based on USDA Agriculture Marketing Statistics and DPR data, endosulfan was applied to 31% (1993) and 16% (1996) of the national acreage in the major production states (USDA, 1994a, 1996b). Therefore the National 1993 treated acreage rate of 31% of the crop will be used to represent the domestic apple information. There was one year of data, 1994, showing that 243 million pounds of apples were imported into the United States compared to the 11,000 million pounds from domestic 1994 production (USDA, 1994b). The imported apples represented about 2% of the total U.S. apple market. Based on the USDA domestic production value and the imported apple information, a 33% crop adjustment factor to conservatively represent the 31% national higher annual value added together with the 2% imported apples overall total will be used.

2. Broccoli

The total California broccoli acreage during 1994 was 95,000 acres and 106,000 acres for 1996 (USDA, 1996c, 1997). The California broccoli acreage represents approximately 89% of both the 1994 and 1996 U.S. broccoli crops (USDA, 1996c, 1997). Endosulfan was applied to between 4,000-6,000 acres of California broccoli during both the 1994 and 1995 seasons (DPR, 1996a,b). The United States broccoli acreage, based on the four major production states (Arizona, California, Oregon and Texas), harvested 111,000 acres during 1994 (USDA, 1996c). Based on USDA Agriculture Marketing Statistics and DPR data, endosulfan was applied to about 12% of the 1994 national acreage in the major production states (USDA, 1996c). Therefore, the 12 percent of the national crop treated value will be used in the chronic dietary exposure residue file.

3. Grape (all)

California bearing grape acreage totaled 651,000 acres during 1993 and 701,000 during the 1995 seasons (USDA, 1994a, 1996a). The United States acreage originates from six principal states; California, Michigan, New York, Oregon, Pennsylvania and Washington, which during 1993 had bearing grapes on 743,000 acres and during 1995 from 796,000 acres (USDA, 1994a, 1996a). The California acreage represented approximately 88% of the total production for both 1993 and 1995 U.S. grapes (all types). Endosulfan was applied to about 11,000 acres, 1% of the California grapes in 1993 and to 13,000 acres (about 1%) of grapes during the 1995 season (USDA, 1994a, 1996a). The 1993 USDA data indicated that endosulfan was applied to less than 1% of the total national grape acreage. The 1995 USDA data also show endosulfan application on less than 1% of the national acreage (USDA, 1994a, 1996a). Therefore the California 1995 treated acreage rate of 1% of the crop will be used to represent the domestic grape information. There is also imported grape data available from the USDA (USDA, 1994b). The most recent single year of data, 1992, showing that 370,568 U.S. tons of grapes were imported into the United States compared to the 6,051,650 tons from domestic 1992 production (USDA, 1994b). The imported grapes represented about 6% of the total U.S. grape market. Based on the USDA domestic production value and the imported grape information, a 7% crop adjustment factor to conservatively represent the 1% California annual use added together with the 6% imported grapes overall total will be used.

4. Peach

Peaches were planted to a total of 60,200 acres during 1993 and 72,600 acres for the 1995 season in California (USDA, 1994a, 1996a). The United States primary acreage originates from four states; California, Georgia, New Jersey and South Carolina, which during 1995 produced peaches on 127,400 acres (USDA, 1996b). California production represented approximately 57% of the total 1995 U.S. peach crop. Endosulfan was applied to less than 900 acres in 1994 and 500 acres during the 1995 season (DPR, 1995b, 1996b). Endosulfan was applied to about 6% of the total 1993 and 1995 acreage from the major production states based on the USDA data (USDA, 1994a, 1996a). Based on the national data, a 6% crop adjustment factor to represent the endosulfan treatment total will be used for peaches.

5. Pear

Pears were planted to a total of 67,000 acres during 1993 and 68,000 acres for the 1995 season in the major production states (USDA, 1994a, 1996a). The United States primary national acreage originates from four states; California, New York, Oregon and Washington (USDA, 1996a). California production represented approximately 36% of the total 1995 U.S. pear crop. Endosulfan was applied to less than 300 acres in 1994 and 400 acres during the 1995 season (DPR, 1995b, 1996b). Endosulfan was applied to about

46% of the 1993 national acreage and to about 21% of the total 1995 acreage from the major production states based on the USDA data (USDA, 1994a, 1996a). Based on the California data, a 1% crop adjustment factor to represent the less than 1% treatment total will be used for peaches. Therefore the national 1993 treated acreage rate of 46% of the crop will be used to represent the domestic pear information. There is also imported pear data available from the USDA (USDA, 1994a). The most recent year of data, 1992, showed that 71,300 U.S. tons of pears were imported into the United States compared to the 926,000 tons from domestic 1992 production (USDA, 1994b). The imported pears represent about 8% of the total U.S. pear market. Based on the combined USDA domestic production value and the imported pear information, a 54% crop adjustment factor to conservatively represent all annual pear use will be used.

6. Strawberry

The California strawberry acreage totaled 23,300 acres during 1994 and 25,200 acres during the 1996 season (USDA, 1996c, 1997). The California acreage represented 51% and 57% of the total 1994 and 1996 U.S. strawberry crops respectively. The United States acreage originates from six main states; California, Florida, Michigan, New York, North Carolina and Oregon which during 1994 produced strawberries from 45,800 acres and 44,500 acres in 1996 (USDA, 1996c, 1997). Endosulfan was applied to 14% of the total 1994 acreage and 11% of the 1996 acreage from the major production states based on the USDA data (USDA, 1996c, 1997). An assumption was made that the total planted 1996 California acreage was the about the same as the 1995 surveyed acreage so that the 1995 DPR percent crop treated data could be combined together with the 1994 data to arrive at a hypothetical two season amount. This was done so as to be more representative. Endosulfan was applied to about 300 acres of California strawberries during both the 1994 and 1995 seasons (DPR, 1996 a,b). There are no USDA California specific endosulfan data for 1994 or 1996 strawberries. The 1994 and 1996 strawberry values, as reported by USDA marketing data, are based on national records (multiple applications to the same acreage are not counted again as is the case for DPR data) and are 14% and 11% respectively (USDA, 1996c, 1997). An adjustment factor of 14% to represent the 1994 percent of the endosulfan treated U.S. strawberry crop will be used in the chronic dietary residue file.

7. Tomatoes (fresh market and processed)

The United States fresh market acreage originates from eight main states; California, Florida, Georgia, Michigan, New Jersey, New York, North Carolina, and Texas which during 1994 produced tomatoes from 104,000 acres and 89,000 acres during 1996 (USDA, 1996c, 1997). The USDA endosulfan fresh market tomato records indicate that there was use on 41% of the acres during 1994 and 29% during 1996 (USDA, 1996c, 1997). The California fresh market tomato acreage totaled 37,000 acres during 1994 and 33,000 acres during 1996 (USDA, 1996c, 1997). The 1994 and 1996 California acreage represented approximately 36% of the total U.S. fresh market tomato crop. Endosulfan was applied to less than 15% of the California fresh market tomatoes in 1994 and 1995 seasons (DPR, 1996a,b). Therefore for the fresh market component of tomatoes, 41% representing the 1994 national use will be added to the processed tomatoes portion.

The California processed tomato acreage totaled 318,000 acres for both 1994 and 1996 seasons (USDA, 1996c, 1997). The 1994 and 1996 California tomato acreage represented virtually 100% of the total U.S. processed tomato harvest. The DPR and USDA processed tomato records for California indicate that 2% of the 1994 crop and 5% of the 1996 crop were treated with endosulfan (DPR, 1996a,b, USDA, 1996c, 1997).

The total U.S. domestic tomato production (fresh and processed combined) amounted to 11,451,490 tons during 1993 (USDA, 1994b). Foreign imports as fresh, canned and pureed tomatoes, during 1993, amounted to 556,440 tons which constitutes about 5% of the total U.S. market (USDA, 1994b). Based on

the U.S. domestic tomato endosulfan treatment rate 1994 value of 41% for fresh market plus 5% for foreign imports for a combined total of 46% will represent whole tomatoes. The combined value of 10% of the processed crop which represents the 1996 5% treated domestic processed tomatoes value together with 5% for imported tomatoes will be used for all processed tomato food codes in the DPR chronic dietary exposure analysis.

B. Commercial Processing

There was one registrant processing study reviewed that was primarily for pineapple bran; however, it provides information relevant to pineapple juice residue reductions based on the general processing method used. Therefore, this processing reduction factor from the processed commodity measurement was used to modify the default adjustment factor. Residues derived from registrant field studies using the maximum label rates and minimum pre-harvest intervals are considered the appropriate situation on which to apply any commercial processing effect changes to default adjustment values.

Pineapple (Juice)

A 1968 FMC Corporation pineapple bran for animal feed processing study included supplemental processing information relevant to pineapple juice (Hintridge, 1968). The processing method contained information regarding endosulfan residue reduction in pineapple juice. The data indicated that when using maximum application rates that the label allows, the juice endosulfan residues were 77% lower than the whole fruit (Hintridge, 1968). Therefore, the TAS program food form adjustment factor number 1 for pineapple juice and juice concentrate were set to 0.23x from 1.7x and then combined with the DPR monitoring program whole pineapple residues in the dietary exposure analysis.

IV. Dietary Exposure (Summary)

A. Acute Dietary Exposure

The acute dietary exposure values resulting from the use of the endosulfan no-observed-effect-level (NOEL) of 0.7 mg/kg/day (rabbit teratology study) and anticipated residues were examined and the results are presented in Table 2 (TAS, 1996a, USDA, 1989-91). The 95th percentile acute dietary exposures ranged from 0.001365 mg/kg/day, males 13-19 years (endosulfan MOE: 513) to 0.003302 mg/kg/day, children 1-6 years (endosulfan MOE: 212). The complete acute dietary exposure analysis includes all current U.S. EPA label approved endosulfan uses.

B. Seasonal Dietary Exposure for California Workers

Endosulfan, because of its pervasive year around utilization on California crops, does not present a clearly defined sub-chronic use season for workers applying the pesticide. The Worker Health and Safety branch therefore has not calculated a seasonal California worker occupational exposure. The Health Assessment Section (HAS) of the Medical Toxicology branch has also determined that no seasonal exposure by workers would result in a subchronic dietary exposure. Therefore, none was calculated.

C. Chronic Dietary Exposure

The chronic non-oncogenic dietary exposure values obtained by using a NOEL of 0.25 mg/kg/day, derived from a 1 year dog study, were examined (TAS, 1996b, USDA, 1989-91) (Table 2). There were two chronic exposure scenarios. The first scenario consisted of dietary exposure data without the use of any percent of the crop treated adjustments. The second had the chronic dietary exposure data for several

commodities modified with percent of the crop treated adjustments based on registrant, CDFA, DPR and USDA data.

The chronic dietary exposures for unmodified label approved commodities contributions ranged from 0.000105 mg/kg/day, nursing infants (endosulfan MOE: 2,373) to 0.000474 mg/kg/day, children 1-6 years (endosulfan MOE: 528). The chronic dietary exposures for commodities modified by the use of percent of the crop treated (%CT) adjustments ranged from 0.000077 mg/kg/day, nursing infants (MOE: 3,255) to 0.000405 mg/kg/day, children 1-6 years (MOE: 617).

D. Lifetime (Oncogenic) Dietary Exposure

There is no calculated oncogenic potency factor for endosulfan. Therefore, no cancer risk from lifetime (chronic) dietary exposure to endosulfan or any of its degradation products was determined.

Table 2. Dietary Margins of Exposure ^a from Anticipated Endosulfan Residues on Raw Agricultural Commodities.

Population Subgroups	Acute Exposure ^b	Chronic Exposure ^b	
	95 th percentile (Margins of Exposure) ^c	annualized average (MOEs) No %CT ^d	With %CT ^d
US Pop. all seasons	378	1,144	1,320
Western Region	375	1,186	1,390
Pacific Region	377	1,208	1,430
Hispanics	360	1,150	1,320
Non-Hispanic Whites	391	1,152	1,330
Non-Hispanic Blacks	306	1,112	1,250
Non-Hispanic Other	299	1,043	1,250
All infants	227	937	1,140
Infants (nursing, < 1 year)	367	2,373	3,260
Infants (non-nursing, < 1 year)	220	747	890
Children (1-6 years)	212	528	620
Children (7-12 years)	336	749	850
Females (13-19 years, not pregnant, not nursing)	511	1,238	1,400
Females (20+ years, not pregnant, not nursing)	462	1,545	1,790
Females (13-50 years)	504	1,461	1,680
Females (13+ years, pregnant, not nursing)	441	1,467	1,690
Females (13+ years, nursing)	340	1,224	1,510
Males (13-19 years)	513	1,056	1,170
Males (20+ years)	508	1,431	1,630
Seniors (55+ years)	425	1,578	1,810

^a/ MOEs based on all label approved commodities. Exposure levels have been rounded off to 3 significant figures and are based on the 1989-1992 Continuing Survey of Food Intakes of Individuals (CSFII).

^b/ The acute and chronic residue files used anticipated residue values for the commodities.

^c/ MOE = NOEL ÷ Exposure. A MOE of at least 100 is generally considered to be protective of human health when the NOEL (non-oncogenic) is based on animal data. The acute NOEL value of 0.7 mg/kg/day was used (rabbit; teratology). The chronic NOEL value of 0.25 mg/kg/day was used (dog; 1 year; chronic).

^d/ %CT = percent of the crop treated adjustment. The modification is made to adjustment factor 2 in the chronic residue file.

V. Acute Tolerance Assessment

An acute tolerance assessment was performed for endosulfan using the current U.S. EPA tolerances (CFR, 1997). The endosulfan acute NOEL of 0.7mg/kg-body wt was used to calculate margins of exposure based on a rabbit teratology study. There are currently more than 71 human consumption RACs that have endosulfan tolerances (CFR, 1997). A total of 20 commodities, including milk, were analyzed for tolerance level acute dietary exposure.

Five commodities of the 20 analyzed had MOE values greater than 100 for each population subgroup while 15 commodities did not. The 5 commodities with MOE values greater than 100 for all population subgroups were; carrot, corn (sweet), lettuce, milkfat and potato. The RAC carrot tolerance MOE range is nursing infant; 254 (0.002751 mg/kg-bw) - male 20⁺ years; 2,076 (0.000337 mg/kg-bw). The MOE range for the corn (sweet) tolerance is non-nursing infant; 354 (0.001977 mg/kg-bw) - female 13⁺ years (pregnant, not nursing); 1,377 (0.000508 mg/kg-bw). The RAC lettuce tolerance MOE range is children 1-6 years; 139 (0.005027 mg/kg-bw) - non-nursing infants; 410 (0.001707 mg/kg-bw). The MOE range for the milkfat tolerance is non-nursing infant; 363 (0.001929 mg/kg-bw) - Seniors 55⁺ years; 2,383 (0.000294 mg/kg-bw). The potato tolerance MOE range is children 1-6 years; 392 (0.001784 mg/kg-bw) - females 13⁺ years (pregnant, not nursing); 1,029 (0.000680 mg/kg-bw).

Margins of exposure (MOE) were less than 100 for 2 or more population subgroups for 15 different commodities at tolerance when using the endosulfan acute NOEL value of 0.7 mg/kg-bw. The highest acute tolerance residue contribution exposure was 0.154339 mg/kg-bw which occurred in the nursing infants <1 year population subgroup from potential apple (including juice) consumption. The lowest exposure (highest MOE) was obtained from the cauliflower tolerance assessment of the population subgroup non nursing infants with a value of 0.000174 mg/kg/day (4,019). The three commodities (apple, melon and tomato) with 19 or 20 population subgroups with less than 100 margins of exposure will be listed separately (Table 3) from the remaining 15 tolerance evaluations.

The remaining 12 RACs that had 2 or more population subgroups with MOEs of less than 100 are; strawberry (2 subgroups with MOEs of < 100), beans (3), cauliflower (3), spinach (6), peas (6), peach (12), summer squash (13), pear (15), pineapple (15), winter squash (16), broccoli (17) and grape (17 population subgroups).

The RAC strawberry tolerance MOE range is non-Hispanic other; 19 (0.035953 mg/kg-bw) - non nursing infants; 2,239 (0.000313 mg/kg-bw). The MOE range for the beans (all) tolerance is non nursing infants; 40 (0.017500 mg/kg-bw) - females 13⁺ years (pregnant, not nursing); 231 (0.003033 mg/kg-bw). The cauliflower tolerance MOE range is non Hispanic other; 46 (0.015379 mg/kg-bw) - non nursing infants; 4,019 (0.000174 mg/kg-bw). The MOE range for the spinach tolerance is children 1-6 years; 25 (0.028168 mg/kg-bw) - nursing infants; 1,120 (0.000625 mg/kg-bw). The peas tolerance MOE range is nursing infants; 38 (0.018446 mg/kg-bw) - females 13⁺ years (pregnant, not nursing); 164 (0.004270 mg/kg-bw). The MOE range for the peach tolerance is all infants <1 year; 22 (0.031145 mg/kg-bw) - females 13⁺ years (pregnant, not nursing); 187 (0.003748 mg/kg-bw). The summer squash tolerance MOE range is non Hispanic other; 41 (0.017047 mg/kg-bw) - females 13⁺ years (pregnant, not nursing); 130 (0.005381 mg/kg-bw). The MOE range for the pear tolerance is nursing infants; 9 (0.078549 mg/kg-bw) - females 13⁺ years (pregnant, not nursing); 263 (0.002663 mg/kg-bw). The pineapple tolerance MOE range is nursing infants; 15 (0.045339 mg/kg-bw) - females 13⁺ years (pregnant, not nursing); 189 (0.003703 mg/kg-bw). The MOE range for the winter squash tolerance is non-nursing infants; 30 (0.023609 mg/kg-bw) - females 13-19 years (not pregnant or nursing); 200 (0.003497 mg/kg-bw). The broccoli tolerance MOE range is children 1-6 years; 28 (0.025239 mg/kg-bw) - females 13⁺ years (pregnant, not nursing); 168 (0.004170 mg/kg-bw). The MOE

range for the grape tolerance is nursing infants; 12 (0.057697 mg/kg-bw) - females 13⁺ years (pregnant, not nursing); 155 (0.004516 mg/kg-bw).

The RACs apple and melons are the only two commodities with endosulfan tolerances that have all 20 of their analyzed populations result in margins of exposure values of less than 100 (Table 3). The RAC tomato had 19 of its analyzed populations result in MOE values of less than 100 (Table 3). Table 3 is a summary for the 3 commodities with endosulfan tolerances that have MOEs of less than 100 for 19 or more of their population subgroups.

Table 3. Summary of Margins of Exposure Less than 100 For Population Subgroups from Tolerance Levels of Endosulfan.

Commodity Population Subgroup	Acute 95 th Percentile Margins of Exposure ^b		
	Apple ^c	Melons	Tomato
US Pop. all seasons	27	35	73
Western Region	32	36	74
Pacific Region	35	39	76
Hispanics	26	20	58
Non-Hispanic Whites	28	36	76
Non-Hispanic Blacks	25	33	67
Non-Hispanic Other	24	33	71
All Infants	8	12 *	40
Infants (nursing, < 1 year)	5 [#]	None	43
Infants (non-nursing, < 1 year)	9	12 *	54
Children (1-6 years)	13	17	41
Children (7-12 years)	28	29	56
Females (13-19 years; not preg/not nursing)	53	48	73
Females (20+ years; not preg/not nursing)	76	48	95
Females (13-50 years)	61	44	88
Females (13+ years; not nursing)	44	46	91
Females (13+ years; nursing)	22	80	93
Males (13-19 years)	62	28	84
Males (20+ years)	85	52	85
Seniors (55+ years)	88	51	>100

a/ MOEs based on label approved commodities. Exposure levels have been rounded off to 2 significant figures and were based on the 1989-1992 Continuing Survey of Food Intakes of Individuals.

b/ The residue files used tolerance level values for the commodities. The number of user days from the 1989-91 CSFII database generally acceptable. However, for all of the winter squash subpopulations analyzed (all <1% user days) the user days were unacceptable in the acute tolerance assessment.

c/ Commodity population subgroup MOEs with “*” appearing next to them indicate user days of 2% or less. Also, the “#” symbol indicates the lowest MOE reported in the complete acute tolerance assessment.

Endosulfan Dietary Exposure References (July, 1998)

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APPENDIX B.

RESIDUE DATA AND TOLERANCE ASSESSMENT

APPENDIX B.

Residue Data and Tolerance Assessment

Wesley C. Carr, Jr.

HEALTH ASSESSMENT SECTION

MEDICAL TOXICOLOGY BRANCH

CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

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Acute Exposure (EX4) Analysis for Endosulfan Section 3 Registration

RESIDUE FILE NAME: ENDOS1AC ANALYSIS DATE: 06-14-2002

NFCS Combined 89-92 DATA

DPR NOEL (Acute) = 0.7 mg/kg body-wt/day

COMMENT 1: REG, USDA PDP/FSIS, DPR data & USEPA tolerances.

COMMENT 2: Final dietary exposure analysis.

RESIDUE FILE LISTING

TAS Code	CROP Group	FOOD NAME	Residue Adjustment Factors (PPM)	#1	#2	SOURCE CODE
5	N	RASPBERRIES	0.065000	1.00	1.00	PDP96g
7	N	BLUEBERRIES	0.065000	1.00	1.00	PDP96g
13	N	GRAPES	0.065000	1.00	1.00	PDP96
14	N	GRAPES-RAISINS	0.065000	4.30	1.00	PDP96
15	N	GRAPES-JUICE	0.065000	1.20	1.00	PDP96
17	N	STRAWBERRIES	0.180000	1.00	1.00	DPR3Y
40	R	ALMONDS	0.200000	1.00	1.00	REG-f
44	R	FILBERTS (Hazelnuts)	0.200000	1.00	1.00	REG-f
46	R	MACADAMIA NUTS	0.200000	1.00	1.00	REG-f
47	R	PECANS	0.200000	1.00	1.00	REG-f
48	R	WALNUTS	0.200000	1.00	1.00	REG-f
52	L	APPLES	0.021000	1.00	1.00	PDP96
53	L	APPLES-DRIED	0.021000	8.00	1.00	PDP96
54	L	APPLES-JUICE/CIDER	0.002000	1.00	1.00	PDP96j
55	L	CRABAPPLES	0.021000	1.00	1.00	PDP96a
56	L	PEARS	0.077000	1.00	1.00	DPR3Y
57	L	PEARS-DRIED	0.077000	6.25	1.00	DPR3Y
59	M	APRICOTS	0.150000	1.00	1.00	DPR3Y
60	M	APRICOTS-DRIED	0.150000	6.00	1.00	DPR3Y
61	M	CHERRIES	0.180000	1.00	1.00	DPR3Y
62	M	CHERRIES-DRIED	0.180000	4.00	1.00	DPR3Y
63	M	CHERRIES-JUICE	0.180000	1.50	1.00	DPR3Y
64	M	NECTARINES	0.053000	1.00	1.00	PDP96p
65	M	PEACHES	0.053000	1.00	1.00	PDP96
66	M	PEACHES-DRIED	0.053000	7.00	1.00	PDP96
67	M	PLUMS(Damsons)	0.070000	1.00	1.00	DPR3Y
68	M	PLUMS-PRUNES(Dried)	0.160000	5.00	1.00	DPR3Y
69	M	PLUMS/PRUNE-JUICE	0.160000	1.40	1.00	DPR3Y
89	A	Pineapples-peeled fruit	0.090000	1.00	1.00	DPR3Y
90	A	PINEAPPLES-DRIED	0.090000	5.00	1.00	DPR3Y
91	A	PINEAPPLES-JUICE	0.090000	0.23	1.00	DPR3Y
130	A	MUSTARD SEED	0.100000	1.00	1.00	DPR3Yb
139	I	PAPRIKA	0.180000	1.00	1.00	DPR3Yp
141	J	Cantaloupes-nectar	0.570000	1.00	1.00	DPR3Y
142	J	Cantaloupes-pulp	0.570000	1.00	1.00	DPR3Y
143	J	CASABAS	0.570000	1.00	1.00	DPR3Yc
144	J	CRENSHAW	0.570000	1.00	1.00	DPR3Yc
145	J	HONEYDEW MELONS	0.570000	1.00	1.00	DPR3Yc

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RESIDUE FILE NAME: ENDOS1AC

ANALYSIS DATE: 06-14-2002

TAS Code	Crop Group	FOOD NAME	Residue (PPM)	Adjustment #1	Adjustment #2	Source
146	J	PERSIAN MELONS	0.570000	1.00	1.00	DPR3Yc
147	J	WATERMELON	0.570000	1.00	1.00	DPR3Yc
148	J	CUCUMBERS	0.570000	1.00	1.00	DPR3Yc
149	J	PUMPKIN	0.092000	1.00	1.00	DPR3Ys
150	J	SQUASH-SUMMER	0.092000	1.00	1.00	DPR3Y
151	J	SQUASH-WINTER	0.092000	1.00	1.00	DPR3Y
152	J	BITTER MELON	0.092000	1.00	1.00	DPR3Ys
154	I	EGGPLANT	0.092000	1.00	1.00	DPR3Ys
155	I	PEPPERS-SWEET(garden)	0.180000	1.00	1.00	DPR3Y
156	I	CHILI PEPPERS (jalapeno)	0.180000	1.00	1.00	DPR3Yp
157	I	PEPPERS-OTHER	0.180000	1.00	1.00	DPR3Yp
158	I	PIMIENTOS	0.180000	1.00	1.00	DPR3Yp
159	I	TOMATOES-WHOLE	0.048000	1.00	1.00	PDP96
160	I	TOMATOES-JUICE	0.048000	1.50	1.00	PDP96
161	I	TOMATOES-PUREE	0.048000	3.30	1.00	PDP96
162	I	TOMATOES-PASTE	0.048000	5.40	1.00	PDP96
163	I	TOMATOES-CATSUP	0.048000	2.50	1.00	PDP96
166	E	CELERY	0.005000	1.00	1.00	PDP94
168	F	BROCCOLI	0.100000	1.00	1.00	DPR3Y
169	F	BRUSSELS SPROUTS	0.100000	1.00	1.00	DPR3Yb
170	F	CABBAGE-GREEN & RED	0.120000	1.00	1.00	DPR3Y
171	F	CAULIFLOWER	0.100000	1.00	1.00	DPR3Yb
172	F	COLLARDS	0.100000	1.00	1.00	DPR3Yb
173	F	Cabbage-Chinese/celery/bok choy	0.120000	1.00	1.00	DPR3Y
174	F	KALE	0.100000	1.00	1.00	DPR3Yb
176	E	LETTUCE-LEAFY VARIETIES	0.108000	1.00	1.00	PDP96
181	A	ARTICHOKES-GLOBE	0.100000	1.00	1.00	REG-f
182	E	LETTUCE-UNSPECIFIED	0.108000	1.00	1.00	PDP96
183	F	MUSTARD GREENS	0.100000	1.00	1.00	PDP96b
186	E	SPINACH	0.357000	1.00	1.00	PDP96
188	C	TURNIPS-TOPS	0.108000	1.00	1.00	PDP96L
189	A	WATERCRESS	0.108000	1.00	1.00	PDP96L
192	E	LETTUCE-HEAD VARIETIES	0.108000	1.00	1.00	PDP96
198	B	CARROTS	0.008200	1.00	1.00	PDP96
203	B	ARTICHOKES-JERUSALEM	0.100000	1.00	1.00	REG-f
207	B	POTATOES(WHITE)-WHOLE	0.007030	1.00	1.00	PDP96s
208	B	POTATOES(WHITE)-UNSPECIF	0.007030	1.00	1.00	PDP96s
209	B	POTATOES(WHITE)-PEELED	0.007030	1.00	1.00	PDP96s
210	B	POTATOES(WHITE)-DRY	0.007030	1.00	1.00	PDP96s
211	B	POTATOES(WHITE)-peel only	0.007030	1.00	1.00	PDP96s
218	B	SWEET POTATOES & YAMS	0.007030	1.00	1.00	PDP96
227	G	BEANS-DRY-GREAT NORTH	0.010000	1.00	1.00	PDP96b
228	G	BEANS-DRY-KIDNEY	0.010000	1.00	1.00	PDP96b
229	G	BEANS-DRY-LIMA	0.010000	1.00	1.00	PDP96b

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230	G	BEANS-DRY-NAVY (PEA)	0.010000	1.00	1.00	PDP96b
231	G	BEANS-DRY-OTHER	0.010000	1.00	1.00	PDP96b

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RESIDUE FILE NAME: ENDOS1AC ANALYSIS DATE: 06-14-2002

TAS CODE	Crop Group	FOOD NAME	Residue Adjustment Factors			SOURCE CODE
			(PPM)	#1	#2	
232	G	BEANS-DRY-PINTO	0.010000	1.00	1.00	PDP96b
233	G	BEANS-SUCCULENT-LIMA	0.010000	1.00	1.00	PDP96
234	G	BEANS-SUCCULENT-GREEN	0.010000	1.00	1.00	PDP96
235	G	BEANS-SUCCULENT-OTHER	0.010000	1.00	1.00	PDP96
236	G	BEANS-SUCCULENT-YELLOW/WAX	0.010000	1.00	1.00	PDP96
238	O	CORN/SWEET	0.007000	1.00	1.00	PDP96
241	G	PEAS (GARDEN)-GREEN	0.007050	1.00	1.00	PDP96
242	G	LENTILS-WHOLE	0.007050	1.00	1.00	PDP96p
243	G	LENTILS-SPLIT	0.007050	1.00	1.00	PDP96p
244	G	MUNG BEANS (SPROUTS)	0.007050	1.00	1.00	PDP96p
246	A	SUNFLOWER-SEEDS-WITH HULLS	0.050000	1.00	1.00	REGss
249	G	BEANS-DRY-BROADBEANS	0.010000	1.00	1.00	PDP96b
250	G	BEANS-SUCCULENT-BROADBEANS	0.010000	1.00	1.00	PDP96
251	G	BEANS-DRY-PIGEON BEANS	0.010000	1.00	1.00	PDP96b
253	G	BEANS-UNSPECIFIED	0.010000	1.00	1.00	PDP96
256	G	BEANS-DRY-HYACINTH	0.010000	1.00	1.00	PDP96b
257	G	BEANS-SUCCULENT-HYACINTH	0.010000	1.00	1.00	PDP96
258	G	Beans-dry-blackeye peas/cowpea	0.010000	1.00	1.00	PDP96b
259	G	Beans-dry-garbanzo/chick pea	0.010000	1.00	1.00	PDP96b
265	O	BARLEY	0.021000	1.00	1.00	PDP96w
269	O	OATS	0.021000	1.00	1.00	PDP96w
272	O	RYE-ROUGH	0.021000	1.00	1.00	PDP96w
273	O	RYE-GERM	0.021000	1.00	1.00	PDP96w
274	O	RYE-FLOUR	0.021000	1.00	1.00	PDP96w
276	O	WHEAT-ROUGH	0.021000	1.00	1.00	PEP96
277	O	WHEAT-GERM	0.021000	1.00	1.00	PDP96
278	O	WHEAT-BRAN	0.021000	1.00	1.00	PDP96
279	O	WHEAT-FLOUR	0.021000	1.00	1.00	PDP96
282	B	BEET SUGAR	0.008200	1.00	1.00	PDP96c
283	A	CANE SUGAR	0.500000	1.00	1.00	EPA
284	A	SUGAR-MOLASSES	0.500000	1.00	1.00	EPA
290	A	COTTONSEED-OIL	0.030000	1.00	1.00	REG-f
291	A	COTTONSEED-MEAL	0.030000	1.00	1.00	REG-f
294	A	SAFFLOWER-SEED	0.050000	1.00	1.00	REG-f
295	A	SAFFLOWER-OIL	0.050000	1.00	1.00	REG-f
298	A	SUNFLOWER-OIL	0.050000	1.00	1.00	REGss
301	A	CANOLA OIL (RAPE SEED OIL)	0.100000	1.00	1.00	DPR3Yb
315	A	GRAPES-WINE AND SHERRY	0.065000	1.00	1.00	PDP96
318	X	MILK-NONFAT SOLIDS	0.001500	1.00	1.00	PDP96

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319	X	MILK-FAT SOLIDS	0.001500	1.00	1.00	PDP96
320	X	MILK SUGAR (LACTOSE)	0.001500	1.00	1.00	PDP96
321	U	BEEF-MEAT BYPRODUCTS	0.060000	1.00	1.00	FSIS
322	U	BEEF(ORGAN MEATS)-OTHER	0.060000	1.00	1.00	FSIS
323	U	BEEF-DRIED	0.060000	1.00	1.00	FSIS
324	U	BEEF(BONELESS)-FAT	0.060000	1.00	1.00	FSIS
325	U	BEEF(ORGAN MEATS)-KIDNEY	0.060000	1.00	1.00	FSIS

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RESIDUE FILE NAME: ENDOS1AC

ANALYSIS DATE: 06-14-2002

TAS Code	Crop Group	FOOD NAME	Residue (PPM)	Adjustment Factors #1	Adjustment Factors #2	Source
326	U	BEEF(ORGAN MEATS)-LIVER	0.060000	1.00	1.00	FSIS
327	U	BEEF(BONELESS)-LEAN (FAT/FREE)	0.060000	1.00	1.00	FSIS
328	U	GOAT-MEAT BYPRODUCTS	0.060000	1.00	1.00	FSIS
329	U	GOAT(ORGAN MEATS)-OTHER	0.060000	1.00	1.00	FSIS
330	U	GOAT(BONELESS)-FAT	0.060000	1.00	1.00	FSIS
331	U	GOAT(ORGAN MEATS)-KIDNEY	0.060000	1.00	1.00	FSIS
332	U	GOAT(ORGAN MEATS)-LIVER	0.060000	1.00	1.00	FSIS
333	U	GOAT(BONELESS)-LEAN (FAT/FREE)	0.060000	1.00	1.00	FSIS
334	U	HORSE	0.060000	1.00	1.00	FSIS
336	U	SHEEP-MEAT BYPRODUCTS	0.060000	1.00	1.00	FSIS
337	U	SHEEP(ORGAN MEATS)-OTHER	0.060000	1.00	1.00	FSIS
338	U	SHEEP(BONELESS)-FAT	0.060000	1.00	1.00	FSIS
339	U	SHEEP(ORGAN MEATS)-KIDNEY	0.060000	1.00	1.00	FSIS
340	U	SHEEP(ORGAN MEATS)-LIVER	0.060000	1.00	1.00	FSIS
341	U	SHEEP(BONELESS)-LEAN (fat free)	0.060000	1.00	1.00	FSIS
342	U	PORK-MEAT BYPRODUCTS	0.060000	1.00	1.00	FSIS
343	U	PORK(ORGAN MEATS)-OTHER	0.060000	1.00	1.00	FSIS
344	U	PORK(BONELESS)-FAT	0.060000	1.00	1.00	FSIS
345	U	PORK(ORGAN MEATS)-KIDNEY	0.060000	1.00	1.00	FSIS
346	U	PORK(ORGAN MEATS)-LIVER	0.060000	1.00	1.00	FSIS
347	U	PORK(BONELESS)-LEAN (fat free)	0.060000	1.00	1.00	FSIS
377	L	APPLES-JUICE-CONCENTRATE	0.002000	1.00	1.00	PDP96j
379	B	BET SUGAR-MOLASSES	0.008200	1.00	1.00	PDP96c
383	F	CABBAGE-SAVOY	0.120000	1.00	1.00	DPR3Y
384	E	CELERY JUICE	0.005000	1.00	1.00	PDP94
392	N	GRAPES-JUICE-CONCENTRATE	0.065000	3.60	1.00	PDP96
398	X	MILK-BASED WATER	0.001500	1.00	1.00	PDP96
399	O	OATS-BRAN	0.021000	1.00	1.00	PDP96w
402	M	PEACHES-JUICE	0.053000	1.00	1.00	PDP96
404	L	PEARS-NECTAR	0.077000	1.00	1.00	DPR3Y
405	G	Peas-succulent/blackeye/cowpea	0.007050	1.00	1.00	PDP96
406	A	PINEAPPLES-juice-concentrate	0.090000	0.23	1.00	DPR3Y
410	M	APRICOT JUICE OR NECTAR	0.150000	1.00	1.00	DPR3Y
413	G	SNOWPEAS	0.007050	1.00	1.00	PDP96
416	N	STRAWBERRIES-JUICE	0.180000	1.00	1.00	DPR3Y
417	A	SUNFLOWER-SEEDS-HULLED	0.050000	1.00	1.00	REGss
423	I	TOMATOES-DRIED	0.048000	14.30	1.00	PDP96
424	U	VEAL-(BONELESS)-FAT	0.060000	1.00	1.00	FSIS
425	U	VEAL-(BONELESS)-LEAN (fat free)	0.060000	1.00	1.00	FSIS
426	U	VEAL-(ORGAN MEATS)-KIDNEY	0.060000	1.00	1.00	FSIS
427	U	VEAL-(ORGAN MEATS)-LIVER	0.060000	1.00	1.00	FSIS

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428	U	VEAL-(ORGAN MEATS)-OTHER	0.060000	1.00	1.00	FSIS
429	U	VEAL-DRIED	0.060000	1.00	1.00	FSIS
430	U	VEAL-MEAT BYPRODUCTS	0.060000	1.00	1.00	FSIS
431	R	WALNUT OIL	0.200000	1.00	1.00	REG-f
436	J	WATERMELON-JUICE	0.570000	1.00	1.00	DPR3Y
437	O	WHEAT-GERM OIL	0.021000	1.00	1.00	PDP96
439	J	WINTERMELON	0.570000	1.00	1.00	DPR3Y
467	A	CELERY SEED	0.005000	1.00	1.00	PDP94
911	A	MOLASSES-NFS	0.100000	1.00	1.00	EPA

ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration

Residue file name: ENDOS1AC Analysis date: 06-14-2002

1989-92 DATA Adjustment factor #2 NOT used

DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

COMMENT 1: USDA PDP & FSIS, DPR, REG studies & USEPA tolerances

COMMENT 2: Final DPR dietary exposure analysis.

U.S. POP - ALL SEASONS		Daily Exposure Analysis 1/ (mg/kg body-weight/day)	
-----		per Capita	per User
		-----	-----
Mean		0.000661	0.000663
Standard Deviation		0.000799	0.000800
Standard Error		0.000004	0.000004

Percent of Person-Days that are User-Days = 99.69%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE 2/	Percentile	Exposure	MOE

10.00	0.000155	4,528	90.00	0.001299	539
20.00	0.000236	2,970	95.00	0.001854	378
30.00	0.000307	2,278	97.50	0.002578	272
40.00	0.000379	1,846	99.00	0.003721	188
50.00	0.000461	1,519	99.50	0.004874	144
60.00	0.000559	1,252	99.75	0.006492	108
70.00	0.000691	1,013	99.90	0.009318	75
80.00	0.000889	787			

ESTIMATED PERCENTILE OF PER-CAPITA DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg bdy-wt/day and corresponding MOE

Percentile	Exposure	MOE 2/	Percentile	Exposure	MOE

10.00	0.000150	4,659	90.00	0.001298	539

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20.00	0.000234	2,996	95.00	0.001852	378
30.00	0.000306	2,290	97.50	0.002576	272
40.00	0.000378	1,853	99.00	0.003718	188
50.00	0.000459	1,523	99.50	0.004871	144
60.00	0.000558	1,255	99.75	0.006487	108
70.00	0.000690	1,014	99.90	0.009312	75
80.00	0.000888	788			

1/ Analysis based on all participant-days in NFCS 1989-92 survey.
 2/ Margin of Exposure = NOEL/ Dietary Exposure.

ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

WESTERN REGION	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000663	0.000665
Standard Deviation	0.000843	0.000844
Standard Error	0.000010	0.000010

Percent of Person-Days that are User-Days = 99.64%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE 2/	Percentile	Exposure	MOE
10.00	0.000138	5,061	90.00	0.001326	528
20.00	0.000225	3,107	95.00	0.001868	375
30.00	0.000296	2,365	97.50	0.002563	273
40.00	0.000374	1,872	99.00	0.003700	189
50.00	0.000463	1,513	99.50	0.005202	135
60.00	0.000566	1,236	99.75	0.007015	100
70.00	0.000691	1,013	99.90	0.011067	63
80.00	0.000885	791			

ESTIMATED PERCENTILE OF PER-CAPITA DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in
 mg/kg body-wt/day and corresponding MOE

ENDOSULFAN RCD – 5/25/07

Percentile	Exposure	MOE 2/	Percentile	Exposure	MOE
10.00	0.000134	5,232	90.00	0.001324	529
20.00	0.000223	3,143	95.00	0.001866	375
30.00	0.000294	2,379	97.50	0.002560	273
40.00	0.000372	1,880	99.00	0.003698	189
50.00	0.000461	1,518	99.50	0.005197	135
60.00	0.000565	1,240	99.75	0.007008	100
70.00	0.000689	1,015	99.90	0.011057	63
80.00	0.000884	792			

ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration

Residue file name: ENDOS1AC Analysis date: 06-14-2002

DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

HISPANICS	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000658	0.000663
Standard Deviation	0.000923	0.000925
Standard Error	0.000016	0.000016

Percent of Person-Days that are User-Days = 99.24%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE
in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE 2/	Percentile	Exposure	MOE
10.00	0.000120	5,857	90.00	0.001346	520
20.00	0.000204	3,431	95.00	0.001941	361
30.00	0.000270	2,596	97.50	0.002791	251
40.00	0.000340	2,061	99.00	0.003755	186
50.00	0.000432	1,619	99.50	0.005699	123
60.00	0.000531	1,318	99.75	0.009019	78
70.00	0.000674	1,038	99.90	0.013345	52
80.00	0.000894	783			

ENDOSULFAN RCD – 5/25/07

ESTIMATED PERCENTILE OF PER-CAPITA DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE 2/	Percentile	Exposure	MOE
10.00	0.000111	6,288	90.00	0.001343	521
20.00	0.000199	3,520	95.00	0.001936	362
30.00	0.000266	2,630	97.50	0.002784	251
40.00	0.000336	2,081	99.00	0.003750	187
50.00	0.000429	1,632	99.50	0.005685	123
60.00	0.000528	1,325	99.75	0.008993	78
70.00	0.000671	1,043	99.90	0.013323	53
80.00	0.000891	786			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

NON-HISPANIC WHITES -----	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
	-----	-----
Mean	0.000660	0.000661
Standard Deviation	0.000769	0.000770
Standard Error	0.000005	0.000005

Percent of Person-Days that are User-Days = 99.74%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE 2/	Percentile	Exposure	MOE

10.00	0.000165	4,247	90.00	0.001283	546
20.00	0.000245	2,854	95.00	0.001789	391
30.00	0.000317	2,207	97.50	0.002454	285
40.00	0.000390	1,796	99.00	0.003656	191
50.00	0.000469	1,492	99.50	0.004634	151
60.00	0.000567	1,235	99.75	0.006066	115
70.00	0.000695	1,007	99.90	0.008878	79
80.00	0.000889	788			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and
 corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE 2/	Percentile	Exposure	MOE

10.00	0.000161	4,350	90.00	0.001282	546
20.00	0.000244	2,873	95.00	0.001787	392
30.00	0.000316	2,216	97.50	0.002452	285
40.00	0.000389	1,802	99.00	0.003654	192
50.00	0.000468	1,496	99.50	0.004632	151
60.00	0.000566	1,237	99.75	0.006063	115
70.00	0.000694	1,008	99.90	0.008873	79
80.00	0.000888	788			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

NON-HISPANIC BLACKS -----	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
	-----	-----
Mean	0.000654	0.000655
Standard Deviation	0.000840	0.000840
Standard Error	0.000012	0.000012

Percent of Person-Days that are User-Days = 99.82%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE

10.00	0.000124	5,643	90.00	0.001336	524
20.00	0.000198	3,542	95.00	0.002290	306
30.00	0.000271	2,583	97.50	0.002981	235
40.00	0.000338	2,071	99.00	0.003920	179
50.00	0.000407	1,721	99.50	0.005116	137
60.00	0.000517	1,353	99.75	0.007132	98
70.00	0.000657	1,065	99.90	0.009085	77
80.00	0.000865	810			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and
 corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE

10.00	0.000122	5,738	90.00	0.001335	524
20.00	0.000197	3,562	95.00	0.002289	306
30.00	0.000270	2,592	97.50	0.002980	235
40.00	0.000337	2,075	99.00	0.003919	179
50.00	0.000406	1,723	99.50	0.005114	137
60.00	0.000517	1,355	99.75	0.007128	98
70.00	0.000656	1,066	99.90	0.009082	77
80.00	0.000864	810			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day
 =====

NON-HISPANIC OTHER -----	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita -----	per User -----
Mean	0.000758	0.000766
Standard Deviation	0.001021	0.001023
Standard Error	0.000031	0.000031

Percent of Person-Days that are User-Days = 99.06%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE 2/	Percentile	Exposure	MOE

10.00	0.000154	4,535	90.00	0.001560	449
20.00	0.000229	3,062	95.00	0.002343	299
30.00	0.000315	2,222	97.50	0.003016	232
40.00	0.000386	1,811	99.00	0.004674	150
50.00	0.000476	1,472	99.50	0.006655	105
60.00	0.000598	1,170	99.75	0.007721	91
70.00	0.000783	894	99.90	0.010175	69
80.00	0.001119	626			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

Percentile	Exposure	MOE 2/	Percentile	Exposure	MOE

10.00	0.000141	4,959	90.00	0.001556	450
20.00	0.000223	3,139	95.00	0.002336	300
30.00	0.000309	2,264	97.50	0.003009	233
40.00	0.000382	1,830	99.00	0.004664	150
50.00	0.000471	1,485	99.50	0.006636	105
60.00	0.000594	1,179	99.75	0.007711	91
70.00	0.000778	900	99.90	0.010160	69
80.00	0.001112	629			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

NURSING INFANTS (<1 YEAR)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000312	0.000485
Standard Deviation	0.000825	0.000987
Standard Error	0.000067	0.000110

Percent of Person-Days that are User-Days = 64.47%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000013	52,153	90.00	0.001325	528
20.00	0.000027	25,844	95.00	0.001905	367
30.00	0.000078	9,001	97.50	0.004146	169
40.00	0.000088	7,958	99.00	0.004480	156
50.00	0.000110	6,374	99.50	0.004591	152
60.00	0.000157	4,448	99.75	0.004647	151
70.00	0.000274	2,552	99.90	0.004680	150
80.00	0.000615	1,139			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and
 corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000000	>1,000,000	90.00	0.000934	750
20.00	0.000000	>1,000,000	95.00	0.001586	441
30.00	0.000000	>1,000,000	97.50	0.002911	240
40.00	0.000009	75,188	99.00	0.004357	161
50.00	0.000039	17,727	99.50	0.004530	155
60.00	0.000086	8,151	99.75	0.004616	152
70.00	0.000126	5,542	99.90	0.004668	150
80.00	0.000262	2,668			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

NON-NURSING INFANTS (<1)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000990	0.000995
Standard Deviation	0.001194	0.001195
Standard Error	0.000056	0.000057

Percent of Person-Days that are User-Days = 99.44%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000022	31,971	90.00	0.002216	316
20.00	0.000032	22,163	95.00	0.003179	220
30.00	0.000198	3,544	97.50	0.004019	174
40.00	0.000429	1,633	99.00	0.004897	143
50.00	0.000672	1,042	99.50	0.005076	138
60.00	0.000961	728	99.75	0.005165	136
70.00	0.001231	569	99.90	0.005218	134
80.00	0.001926	363			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and
 corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000021	33,685	90.00	0.002214	316
20.00	0.000031	22,474	95.00	0.003174	221
30.00	0.000191	3,666	97.50	0.004014	174
40.00	0.000421	1,664	99.00	0.004894	143
50.00	0.000665	1,052	99.50	0.005075	138
60.00	0.000954	733	99.75	0.005164	136
70.00	0.001226	571	99.90	0.005218	134
80.00	0.001918	365			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

FEMALES (13+/Pregnant/Not Nursing)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000560	0.000560
Standard Deviation	0.000706	0.000706
Standard Error	0.000036	0.000036

Percent of Person-Days that are User-Days =100.00%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE
 in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000143	4,894	90.00	0.000910	769
20.00	0.000218	3,212	95.00	0.001586	441
30.00	0.000275	2,545	97.50	0.003441	203
40.00	0.000326	2,149	99.00	0.003835	183
50.00	0.000376	1,862	99.50	0.004922	142
60.00	0.000443	1,579	99.75	0.005321	132
70.00	0.000516	1,356	99.90	0.005381	130
80.00	0.000670	1,045			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and
 corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000143	4,894	90.00	0.000910	769
20.00	0.000218	3,212	95.00	0.001586	441
30.00	0.000275	2,545	97.50	0.003441	203
40.00	0.000326	2,149	99.00	0.003835	183
50.00	0.000376	1,862	99.50	0.004922	142
60.00	0.000443	1,579	99.75	0.005321	132
70.00	0.000516	1,356	99.90	0.005381	130
80.00	0.000670	1,045			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

FEMALES (13+/NURSING)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000680	0.000680
Standard Deviation	0.000630	0.000630
Standard Error	0.000043	0.000043

Percent of Person-Days that are User-Days =100.00%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000156	4,490	90.00	0.001510	463
20.00	0.000231	3,035	95.00	0.002059	340
30.00	0.000299	2,345	97.50	0.002586	271
40.00	0.000359	1,950	99.00	0.002929	239
50.00	0.000428	1,634	99.50	0.003060	229
60.00	0.000556	1,259	99.75	0.003152	222
70.00	0.000737	950	99.90	0.003264	214
80.00	0.001010	693			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE) in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000156	4,490	90.00	0.001510	463
20.00	0.000231	3,035	95.00	0.002059	340
30.00	0.000299	2,345	97.50	0.002586	271
40.00	0.000359	1,950	99.00	0.002929	239
50.00	0.000428	1,634	99.50	0.003060	229
60.00	0.000556	1,259	99.75	0.003152	222
70.00	0.000737	950	99.90	0.003264	214
80.00	0.001010	693			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

CHILDREN (1-6 YEARS)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.001351	0.001351
Standard Deviation	0.001519	0.001519
Standard Error	0.000025	0.000025

Percent of Person-Days that are User-Days = 99.97%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000395	1,771	90.00	0.002411	290
20.00	0.000548	1,278	95.00	0.003302	212
30.00	0.000694	1,008	97.50	0.005040	139
40.00	0.000842	831	99.00	0.008660	81
50.00	0.000989	708	99.50	0.012620	55
60.00	0.001183	592	99.75	0.014186	49
70.00	0.001400	500	99.90	0.016043	44
80.00	0.001707	410			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000394	1,776	90.00	0.002411	290
20.00	0.000547	1,279	95.00	0.003302	212
30.00	0.000694	1,009	97.50	0.005040	139
40.00	0.000842	831	99.00	0.008659	81
50.00	0.000989	708	99.50	0.012619	55
60.00	0.001183	592	99.75	0.014185	49
70.00	0.001400	500	99.90	0.016042	44
80.00	0.001706	410			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

CHILDREN (7-12 YEARS)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000924	0.000924
Standard Deviation	0.000815	0.000815
Standard Error	0.000014	0.000014

Percent of Person-Days that are User-Days = 99.98%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000327	2,144	90.00	0.001605	436
20.00	0.000439	1,595	95.00	0.002085	336
30.00	0.000543	1,288	97.50	0.002830	247
40.00	0.000638	1,098	99.00	0.004505	155
50.00	0.000742	943	99.50	0.006121	114
60.00	0.000851	823	99.75	0.007285	96
70.00	0.000996	703	99.90	0.008387	83
80.00	0.001226	571			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000326	2,148	90.00	0.001605	436
20.00	0.000439	1,596	95.00	0.002085	336
30.00	0.000543	1,289	97.50	0.002829	247
40.00	0.000638	1,098	99.00	0.004505	155
50.00	0.000742	943	99.50	0.006121	114
60.00	0.000850	823	99.75	0.007284	96
70.00	0.000996	703	99.90	0.008387	83
80.00	0.001226	571			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

MALES (13-19 YEARS)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000630	0.000630
Standard Deviation	0.000582	0.000582
Standard Error	0.000015	0.000015

Percent of Person-Days that are User-Days =100.00%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000211	3,322	90.00	0.001070	654
20.00	0.000302	2,320	95.00	0.001365	513
30.00	0.000373	1,875	97.50	0.001740	402
40.00	0.000450	1,556	99.00	0.003214	218
50.00	0.000511	1,370	99.50	0.004045	173
60.00	0.000601	1,165	99.75	0.004759	147
70.00	0.000699	1,002	99.90	0.007916	88
80.00	0.000835	838			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000211	3,322	90.00	0.001070	654
20.00	0.000302	2,320	95.00	0.001365	513
30.00	0.000373	1,875	97.50	0.001740	402
40.00	0.000450	1,556	99.00	0.003214	218
50.00	0.000511	1,370	99.50	0.004045	173
60.00	0.000601	1,165	99.75	0.004759	147
70.00	0.000699	1,002	99.90	0.007916	88
80.00	0.000835	838			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

FEMALES (13-19 Years/Non Pregnant/Not Nursing)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000574	0.000576
Standard Deviation	0.000632	0.000632
Standard Error	0.000015	0.000015

Percent of Person-Days that are User-Days = 99.80%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000170	4,113	90.00	0.000967	724
20.00	0.000244	2,874	95.00	0.001371	511
30.00	0.000306	2,287	97.50	0.001851	378
40.00	0.000370	1,894	99.00	0.003612	194
50.00	0.000439	1,595	99.50	0.004435	158
60.00	0.000530	1,321	99.75	0.005433	129
70.00	0.000615	1,137	99.90	0.006727	104
80.00	0.000755	927			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/ day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000167	4,187	90.00	0.000966	725
20.00	0.000242	2,888	95.00	0.001370	511
30.00	0.000305	2,293	97.50	0.001850	378
40.00	0.000369	1,898	99.00	0.003610	194
50.00	0.000438	1,597	99.50	0.004434	158
60.00	0.000529	1,323	99.75	0.005431	129
70.00	0.000615	1,138	99.90	0.006725	104
80.00	0.000754	928			

ENDOSULFAN RCD – 5/25/07

ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration

Residue file name: ENDOS1AC Analysis date: 06-14-2002

DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

MALES (20+ YEARS)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000539	0.000539
Standard Deviation	0.000533	0.000533
Standard Error	0.000005	0.000005

Percent of Person-Days that are User-Days = 99.86%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000146	4,789	90.00	0.001007	695
20.00	0.000222	3,155	95.00	0.001378	508
30.00	0.000284	2,461	97.50	0.001962	357
40.00	0.000342	2,047	99.00	0.002911	240
50.00	0.000405	1,727	99.50	0.003555	197
60.00	0.000485	1,444	99.75	0.004072	172
70.00	0.000582	1,203	99.90	0.005061	138
80.00	0.000727	963			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000144	4,850	90.00	0.001007	695
20.00	0.000221	3,167	95.00	0.001377	508
30.00	0.000284	2,466	97.50	0.001962	357
40.00	0.000341	2,050	99.00	0.002910	241
50.00	0.000405	1,729	99.50	0.003554	197
60.00	0.000484	1,445	99.75	0.004071	172
70.00	0.000581	1,204	99.90	0.005061	138
80.00	0.000726	964			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

FEMALES (20+ Years/Non Pregnant/Not Nursing)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000536	0.000537
Standard Deviation	0.000620	0.000620
Standard Error	0.000005	0.000005

Percent of Person-Days that are User-Days = 99.75%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000129	5,414	90.00	0.001031	679
20.00	0.000196	3,569	95.00	0.001514	462
30.00	0.000254	2,755	97.50	0.002207	317
40.00	0.000315	2,221	99.00	0.003173	221
50.00	0.000382	1,831	99.50	0.003922	178
60.00	0.000457	1,531	99.75	0.004883	143
70.00	0.000554	1,263	99.90	0.005747	122
80.00	0.000706	991			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000126	5,541	90.00	0.001030	680
20.00	0.000195	3,594	95.00	0.001513	463
30.00	0.000253	2,766	97.50	0.002206	317
40.00	0.000314	2,228	99.00	0.003171	221
50.00	0.000381	1,835	99.50	0.003920	179
60.00	0.000457	1,533	99.75	0.004881	143
70.00	0.000553	1,265	99.90	0.005746	122
80.00	0.000705	992			

ENDOSULFAN RCD – 5/25/07

ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration

Residue file name: ENDOS1AC Analysis date: 06-14-2002

DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

SENIORS (55+)

Daily Exposure Analysis
(mg/kg body-weight/day)
per Capita per User

	per Capita	per User
Mean	0.000550	0.000551
Standard Deviation	0.000659	0.000659
Standard Error	0.000007	0.000007

Percent of Person-Days that are User-Days = 99.84%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000130	5,389	90.00	0.001108	632
20.00	0.000194	3,600	95.00	0.001648	425
30.00	0.000251	2,787	97.50	0.002273	308
40.00	0.000309	2,264	99.00	0.003226	217
50.00	0.000374	1,869	99.50	0.004101	171
60.00	0.000450	1,556	99.75	0.005011	140
70.00	0.000558	1,255	99.90	0.007106	99
80.00	0.000720	972			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000128	5,465	90.00	0.001107	632
20.00	0.000194	3,615	95.00	0.001647	425
30.00	0.000251	2,794	97.50	0.002272	308
40.00	0.000309	2,268	99.00	0.003225	217
50.00	0.000374	1,872	99.50	0.004099	171
60.00	0.000449	1,558	99.75	0.005010	140
70.00	0.000557	1,256	99.90	0.007104	99
80.00	0.000720	973			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

PACIFIC REGION -----	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000656	0.000657
Standard Deviation	0.000855	0.000856
Standard Error	0.000012	0.000012

Percent of Person-Days that are User-Days = 99.73%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000134	5,241	90.00	0.001296	540
20.00	0.000222	3,149	95.00	0.001857	377
30.00	0.000292	2,395	97.50	0.002549	275
40.00	0.000367	1,906	99.00	0.003805	184
50.00	0.000453	1,544	99.50	0.005215	134
60.00	0.000558	1,255	99.75	0.007024	100
70.00	0.000678	1,033	99.90	0.011322	62
80.00	0.000871	804			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000130	5,374	90.00	0.001295	541
20.00	0.000220	3,177	95.00	0.001855	377
30.00	0.000291	2,406	97.50	0.002547	275
40.00	0.000366	1,912	99.00	0.003803	184
50.00	0.000452	1,548	99.50	0.005211	134
60.00	0.000556	1,258	99.75	0.007019	100
70.00	0.000677	1,034	99.90	0.011314	62
80.00	0.000870	805			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

ALL INFANTS -----	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000789	0.000886
Standard Deviation	0.001140	0.001172
Standard Error	0.000046	0.000051

Percent of Person-Days that are User-Days = 89.08%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000022	31,572	90.00	0.002268	309
20.00	0.000031	22,508	95.00	0.003080	227
30.00	0.000101	6,902	97.50	0.004185	167
40.00	0.000256	2,737	99.00	0.004568	153
50.00	0.000495	1,414	99.50	0.004696	149
60.00	0.000781	896	99.75	0.004760	147
70.00	0.001158	604	99.90	0.004798	146
80.00	0.001470	476			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000000	>1,000,000	90.00	0.002170	323
20.00	0.000022	31,327	95.00	0.002980	235
30.00	0.000041	17,039	97.50	0.004050	173
40.00	0.000142	4,921	99.00	0.004537	154
50.00	0.000348	2,009	99.50	0.004680	150
60.00	0.000641	1,092	99.75	0.004752	147
70.00	0.001020	687	99.90	0.004795	146
80.00	0.001394	502			

ENDOSULFAN RCD – 5/25/07

 ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration
 Residue file name: ENDOS1AC Analysis date: 06-14-2002
 DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

FEMALES (13-50 YEARS)	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
Mean	0.000537	0.000538
Standard Deviation	0.000593	0.000593
Standard Error	0.000006	0.000006

Percent of Person-Days that are User-Days = 99.74%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000139	5,038	90.00	0.000990	707
20.00	0.000209	3,346	95.00	0.001389	504
30.00	0.000271	2,580	97.50	0.002049	342
40.00	0.000334	2,097	99.00	0.003224	217
50.00	0.000400	1,752	99.50	0.004060	172
60.00	0.000474	1,476	99.75	0.004988	140
70.00	0.000569	1,230	99.90	0.005867	119
80.00	0.000707	991			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000136	5,159	90.00	0.000990	707
20.00	0.000208	3,370	95.00	0.001388	504
30.00	0.000270	2,591	97.50	0.002047	342
40.00	0.000333	2,103	99.00	0.003222	217
50.00	0.000399	1,755	99.50	0.004057	173
60.00	0.000474	1,478	99.75	0.004986	140
70.00	0.000568	1,231	99.90	0.005866	119
80.00	0.000706	992			

ENDOSULFAN RCD – 5/25/07

ACUTE EXPOSURE (EX4) ANALYSIS FOR ENDOSULFAN Section 3 Registration

Residue file name: ENDOS1AC Analysis date: 06-14-2002

DPR NOEL (Acute) = 0.700000 mg/kg body-wt/day

CUSTOM DEMOGRAPHICS 1: U.S. Population 16+ Years

All Seasons, All Regions, Sex: M/F-all/, All Races

Age-Low: 16 yrs High: 110 yrs

Daily Exposure Analysis
(mg/kg body-weight/day)
per Capita per User

	per Capita	per User
Mean	0.000540	0.000541
Standard Deviation	0.000583	0.000583
Standard Error	0.000004	0.000004

Percent of Person-Days that are User-Days = 99.81%

ESTIMATED PERCENTILE OF USER-DAYS LESS THAN/EQUAL TO CALCULATED EXPOSURE in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000140	5,002	90.00	0.001017	688
20.00	0.000210	3,330	95.00	0.001441	486
30.00	0.000272	2,572	97.50	0.002065	339
40.00	0.000332	2,109	99.00	0.003101	226
50.00	0.000397	1,763	99.50	0.003811	184
60.00	0.000474	1,478	99.75	0.004520	155
70.00	0.000574	1,220	99.90	0.005959	117
80.00	0.000718	975			

Estimated Percentile of Per-Capita Days Less Than/Equal to Calculated Exposure in mg/kg body-wt/day and corresponding Margin of Exposure (MOE)

PERCENTILE	EXPOSURE	MOE 2/	PERCENTILE	EXPOSURE	MOE
10.00	0.000138	5,089	90.00	0.001016	689
20.00	0.000209	3,348	95.00	0.001440	486
30.00	0.000271	2,580	97.50	0.002063	339
40.00	0.000331	2,113	99.00	0.003099	226
50.00	0.000396	1,766	99.50	0.003810	184
60.00	0.000473	1,479	99.75	0.004518	155
70.00	0.000573	1,221	99.90	0.005957	118
80.00	0.000717	976			

ENDOSULFAN RCD – 5/25/07

Chronic Exposure (EX1) Analysis for Endosulfan Section 3 Registration

RESIDUE FILE NAME: ENDOS1CH ANALYSIS DATE: 06-14-2002

NFCS Combined 89-92 DATA

EPA Reference dose (RfD, chronic) = 0.006000 mg/kg body-wt/day

DPR NOEL (Chronic) = 0.610000 mg/kg body-wt/day

COMMENT 1: REG, USDA PDP/FSIS, DPR data & USEPA tolerances. %CT

COMMENT 2: Final dietary exposure analysis.

RESIDUE FILE LISTING

TAS Code	Crop Group	FOOD NAME	Residue (PPM)	Adjusted #1	Factors #2	SOURCE CODE
5	N	RASPBERRIES	0.007700	1.00	1.00	PDP96g
7	N	BLUEBERRIES	0.007700	1.00	1.00	PDP96g
13	N	GRAPES	0.007700	1.00	0.07	PDP96
14	N	GRAPES-RAISINS	0.007700	4.30	0.07	PDP96
15	N	GRAPES-JUICE	0.007700	1.20	0.07	PDP96
17	N	STRAWBERRIES	0.060300	1.00	0.14	DPR3Y
40	R	ALMONDS	0.100000	1.00	1.00	REG-f
44	R	FILBERTS (HAZELNUTS)	0.100000	1.00	1.00	REG-f
46	R	MACADAMIA NUTS (BUSH NUTS)	0.100000	1.00	1.00	REG-f
47	R	PECANS	0.100000	1.00	1.00	REG-f
48	R	WALNUTS	0.100000	1.00	1.00	REG-f
52	L	APPLES	0.006400	1.00	0.33	PDP96
53	L	APPLES-DRIED	0.006400	8.00	0.33	PDP96
54	L	APPLES-JUICE/CIDER	0.002000	1.00	0.33	PDP96j
55	L	CRABAPPLES	0.006400	1.00	0.33	PDP96a
56	L	PEARS	0.020200	1.00	0.54	DPR3Y
57	L	PEARS-DRIED	0.020200	6.25	0.54	DPR3Y
59	M	APRICOTS	0.031000	1.00	1.00	DPR3Y
60	M	APRICOTS-DRIED	0.031000	6.00	1.00	DPR3Y
61	M	CHERRIES	0.033000	1.00	1.00	DPR3Y
62	M	CHERRIES-DRIED	0.033000	4.00	1.00	DPR3Y
63	M	CHERRIES-JUICE	0.033000	1.50	1.00	DPR3Y
64	M	NECTARINES	0.009000	1.00	0.06	PDP96p
65	M	PEACHES	0.009000	1.00	0.06	PDP96
66	M	PEACHES-DRIED	0.009000	7.00	0.06	PDP96
67	M	PLUMS(DAMSONS)	0.030200	1.00	1.00	DPR3Y
68	M	PLUMS-PRUNES(DRIED)	0.046000	5.00	1.00	DPR3Y
69	M	PLUMS/PRUNE-JUICE	0.046000	1.40	1.00	DPR3Y
89	A	PINEAPPLES-PEELED FRUIT	0.045400	1.00	1.00	DPR3Y
90	A	PINEAPPLES-DRIED	0.045400	5.00	1.00	DPR3Y
91	A	PINEAPPLES-JUICE	0.045400	0.23	1.00	DPR3Y
130	A	MUSTARD SEED	0.030300	1.00	1.00	DPR3Yb

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139 I PAPRIKA 0.037000 1.00 1.00 DPR3Yp

RESIDUE FILE LISTING (continued)

TAS Code	Crop Group	FOOD NAME	Residue (PPM)	Adjusted #1	Factors #2	SOURCE CODE
141	J	CANTALOUPE-NECTAR	0.049000	1.00	1.00	DPR3Y
142	J	Cantaloupes-Pulp (Muskmelon)	0.049000	1.00	1.00	DPR3Y
143	J	CASABAS	0.049000	1.00	1.00	DPR3Yc
144	J	CRENSHAW	0.049000	1.00	1.00	DPR3Yc
145	J	HONEYDEW MELONS	0.049000	1.00	1.00	DPR3Yc
146	J	PERSIAN MELONS	0.049000	1.00	1.00	DPR3Yc
147	J	WATERMELON	0.049000	1.00	1.00	DPR3Yc
148	J	CUCUMBERS	0.049000	1.00	1.00	DPR3Yc
149	J	PUMPKIN	0.027000	1.00	1.00	DPR3Ys
150	J	SQUASH-SUMMER	0.027000	1.00	1.00	DPR3Y
151	J	SQUASH-WINTER	0.027000	1.00	1.00	DPR3Y
152	J	BITTER MELON	0.027000	1.00	1.00	DPR3Ys
154	I	EGGPLANT	0.027000	1.00	1.00	DPR3Ys
155	I	PEPPERS-SWEET(GARDEN)	0.037000	1.00	1.00	DPR3Y
156	I	CHILI PEPPERS (JALAPENO)	0.037000	1.00	1.00	DPR3Yp
157	I	PEPPERS-OTHER	0.037000	1.00	1.00	DPR3Yp
158	I	PIMIENTOS	0.037000	1.00	1.00	DPR3Yp
159	I	TOMATOES-WHOLE	0.010500	1.00	0.46	PDP96
160	I	TOMATOES-JUICE	0.010500	1.50	0.10	PDP96
161	I	TOMATOES-PUREE	0.010500	3.30	0.10	PDP96
162	I	TOMATOES-PASTE	0.010500	5.40	0.10	PDP96
163	I	TOMATOES-CATSUP	0.010500	2.50	0.10	PDP96
166	E	CELERY	0.001530	1.00	1.00	PDP94
168	F	BROCCOLI	0.030300	1.00	0.12	DPR3Y
169	F	BRUSSELS SPROUTS	0.030300	1.00	1.00	DPR3Yb
170	F	CABBAGE-GREEN AND RED	0.045000	1.00	1.00	DPR3Y
171	F	CAULIFLOWER	0.030300	1.00	1.00	DPR3Yb
172	F	COLLARDS	0.030300	1.00	1.00	DPR3Yb
173	F	Cabbage-Chinese/Celery/Bok Choy	0.045000	1.00	1.00	DPR3Y
174	F	KALE	0.030300	1.00	1.00	DPR3Yb
176	E	LETTUCE-LEAFY VARIETIES	0.014000	1.00	1.00	PDP96
181	A	ARTICHOKES-GLOBE	0.050000	1.00	1.00	REG-f
182	E	LETTUCE-UNSPECIFIED	0.014000	1.00	1.00	PDP96
183	F	MUSTARD GREENS	0.030300	1.00	1.00	PDP96b
186	E	SPINACH	0.026000	1.00	1.00	PDP96
188	C	TURNIPS-TOPS	0.014000	1.00	1.00	PDP96L

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189	A	WATERCRESS	0.014000	1.00	1.00	PDP96L
192	E	LETTUCE-HEAD VARIETIES	0.014000	1.00	1.00	PDP96
198	B	CARROTS	0.004200	1.00	1.00	PDP96
203	B	ARTICHOKES-JERUSALEM	0.050000	1.00	1.00	REG-f
207	B	POTATOES(WHITE)-WHOLE	0.003600	1.00	1.00	PDP96s
208	B	Potatoes (white) unspecified	0.003600	1.00	1.00	PDP96s
209	B	POTATOES(WHITE)-PEELED	0.003600	1.00	1.00	PDP96s

RESIDUE FILE LISTING (continued)

TAS Code	Crop Group	FOOD NAME	Residue (PPM)	Adjusted #1	Adjusted #2	SOURCE CODE
210	B	POTATOES(WHITE)-DRY	0.003600	1.00	1.00	PDP96s
211	B	POTATOES(WHITE)-PEEL ONLY	0.003600	1.00	1.00	PDP96s
218	B	Sweet Potatoes (including yams)	0.003600	1.00	1.00	PDP96
227	G	BEANS-DRY-GREAT NORTHERN	0.004000	1.00	1.00	PDP96b
228	G	BEANS-DRY-KIDNEY	0.004000	1.00	1.00	PDP96b
229	G	BEANS-DRY-LIMA	0.004000	1.00	1.00	PDP96b
230	G	BEANS-DRY-NAVY (PEA)	0.004000	1.00	1.00	PDP96b
231	G	BEANS-DRY-OTHER	0.004000	1.00	1.00	PDP96b
232	G	BEANS-DRY-PINTO	0.004000	1.00	1.00	PDP96b
233	G	BEANS-SUCCULENT-LIMA	0.004000	1.00	1.00	PDP96
234	G	BEANS-SUCCULENT-GREEN	0.004000	1.00	1.00	PDP96
235	G	BEANS-SUCCULENT-OTHER	0.004000	1.00	1.00	PDP96
236	G	Beans-Succulent-Yellow/wax	0.004000	1.00	1.00	PDP96
238	O	CORN/SWEET	0.003500	1.00	1.00	PDP96
241	G	PEAS (GARDEN)-GREEN	0.003710	1.00	1.00	PDP96
242	G	LENTILS-WHOLE	0.003710	1.00	1.00	PDP96p
243	G	LENTILS-SPLIT	0.003710	1.00	1.00	PDP96p
244	G	MUNG BEANS (SPROUTS)	0.003710	1.00	1.00	PDP96p
246	A	Sunflower seeds with hulls	0.008000	1.00	1.00	REGss
249	G	BEANS-DRY-BROADBEANS	0.004000	1.00	1.00	PDP96b
250	G	Beans-Succulent-Broadbeans	0.004000	1.00	1.00	PDP96
251	G	BEANS-DRY-PIGEON BEANS	0.004000	1.00	1.00	PDP96b
253	G	BEANS-UNSPECIFIED	0.004000	1.00	1.00	PDP96
256	G	BEANS-DRY-HYACINTH	0.004000	1.00	1.00	PDP96b
257	G	BEANS-SUCCULENT-HYACINTH	0.004000	1.00	1.00	PDP96
258	G	Beans-Dry-Blackeye Peas/Cowpeas	0.004000	1.00	1.00	PDP96b
259	G	Beans-Dry-Garbanzo/Chickpea	0.004000	1.00	1.00	PDP96b
265	O	BARLEY	0.010500	1.00	1.00	PDP96w
269	O	OATS	0.010500	1.00	1.00	PDP96w
272	O	RYE-ROUGH	0.010500	1.00	1.00	PDP96w
273	O	RYE-GERM	0.010500	1.00	1.00	PDP96w

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274	O	RYE-FLOUR	0.010500	1.00	1.00	PDP96w
276	O	WHEAT-ROUGH	0.010500	1.00	1.00	PEP96
277	O	WHEAT-GERM	0.010500	1.00	1.00	PDP96
278	O	WHEAT-BRAN	0.010500	1.00	1.00	PDP96
279	O	WHEAT-FLOUR	0.010500	1.00	1.00	PDP96
282	B	BEET SUGAR	0.004200	1.00	1.00	PDP96c
283	A	CANE SUGAR	0.250000	1.00	1.00	EPA1/2
284	A	SUGAR-MOLASSES	0.250000	1.00	1.00	EPA1/2
290	A	COTTONSEED-OIL	0.015000	1.00	1.00	REG-f
291	A	COTTONSEED-MEAL	0.015000	1.00	1.00	REG-f
294	A	SAFFLOWER-SEED	0.008000	1.00	1.00	REG-f
295	A	SAFFLOWER-OIL	0.008000	1.00	1.00	REG-f

RESIDUE FILE LISTING (continued)

TAS Code	Crop Group	FOOD NAME	Residue (PPM)	Adjusted #1	Factors #2	SOURCE CODE
298	A	SUNFLOWER-OIL	0.008000	1.00	1.00	REGss
301	A	CANOLA OIL (RAPE SEED OIL)	0.030300	1.00	1.00	DPR3Yb
315	A	GRAPES-WINE AND SHERRY	0.007700	1.00	0.07	PDP96
318	X	MILK-NONFAT SOLIDS	0.001500	1.00	1.00	PDP96
319	X	MILK-FAT SOLIDS	0.001500	1.00	1.00	PDP96
320	X	MILK SUGAR (LACTOSE)	0.001500	1.00	1.00	PDP96
321	U	BEEF-MEAT BYPRODUCTS	0.030000	1.00	1.00	FSIS
322	U	BEEF(ORGAN MEATS)-OTHER	0.030000	1.00	1.00	FSIS
323	U	BEEF-DRIED	0.030000	1.00	1.00	FSIS
324	U	BEEF(BONELESS)-FAT	0.030000	1.00	1.00	FSIS
325	U	BEEF(ORGAN MEATS)-KIDNEY	0.030000	1.00	1.00	FSIS
326	U	BEEF(ORGAN MEATS)-LIVER	0.030000	1.00	1.00	FSIS
327	U	Beef (boneless) Lean (fat/free)	0.030000	1.00	1.00	FSIS
328	U	GOAT-MEAT BYPRODUCTS	0.030000	1.00	1.00	FSIS
329	U	GOAT(ORGAN MEATS)-OTHER	0.030000	1.00	1.00	FSIS
330	U	GOAT(BONELESS)-FAT	0.030000	1.00	1.00	FSIS
331	U	GOAT(ORGAN MEATS)-KIDNEY	0.030000	1.00	1.00	FSIS
332	U	GOAT(ORGAN MEATS)-LIVER	0.030000	1.00	1.00	FSIS
333	U	Goat (boneless) Lean (fat free)	0.030000	1.00	1.00	FSIS
334	U	HORSE	0.030000	1.00	1.00	FSIS
336	U	SHEEP-MEAT BYPRODUCTS	0.030000	1.00	1.00	FSIS
337	U	SHEEP(ORGAN MEATS)-OTHER	0.030000	1.00	1.00	FSIS
338	U	SHEEP(BONELESS)-FAT	0.030000	1.00	1.00	FSIS
339	U	SHEEP(ORGAN MEATS)-KIDNEY	0.030000	1.00	1.00	FSIS
340	U	SHEEP(ORGAN MEATS)-LIVER	0.030000	1.00	1.00	FSIS
341	U	Sheep (boneless) Lean (fat free)	0.030000	1.00	1.00	FSIS
342	U	PORK-MEAT BYPRODUCTS	0.030000	1.00	1.00	FSIS
343	U	PORK(ORGAN MEATS)-OTHER	0.030000	1.00	1.00	FSIS
344	U	PORK(BONELESS)-FAT	0.030000	1.00	1.00	FSIS

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345	U	PORK(ORGAN MEATS)-KIDNEY	0.030000	1.00	1.00	FSIS
346	U	PORK(ORGAN MEATS)-LIVER	0.030000	1.00	1.00	FSIS
347	U	Pork (Boneless) Lean (fat free)	0.030000	1.00	1.00	FSIS
377	L	APPLES-JUICE-CONCENTRATE	0.002000	1.00	0.33	PDP96j
379	B	BEET SUGAR-MOLASSES	0.004200	1.00	1.00	PDP96c
383	F	CABBAGE-SAVOY	0.045000	1.00	1.00	DPR3Y
384	E	CELERY JUICE	0.001530	1.00	1.00	PDP94
392	N	GRAPES-JUICE-CONCENTRATE	0.007700	3.60	0.07	PDP96
398	X	MILK-BASED WATER	0.001500	1.00	1.00	PDP96
399	O	OATS-BRAN	0.010500	1.00	1.00	PDP96w
402	M	PEACHES-JUICE	0.009000	1.00	0.06	PDP96
404	L	PEARS-NECTAR	0.020200	1.00	0.54	DPR3Y
405	G	Peas-Succulent/Blackeye/Cowpea	0.003710	1.00	1.00	PDP96
406	A	Pineapples-Juice-Concentrate	0.045400	0.23	1.00	DPR3Y
410	M	APRICOT JUICE OR NECTAR	0.031000	1.00	1.00	DPR3Y
413	G	SNOWPEAS	0.003710	1.00	1.00	PDP96
416	N	STRAWBERRIES-JUICE	0.060300	1.00	0.14	DPR3Y
417	A	SUNFLOWER-SEEDS-HULLED	0.008000	1.00	1.00	REGss
423	I	TOMATOES-DRIED	0.010500	14.30	0.46	PDP96
424	U	VEAL-(BONELESS)-FAT	0.030000	1.00	1.00	FSIS
425	U	Veal (Boneless) Lean (Fat free)	0.030000	1.00	1.00	FSIS
426	U	VEAL-(ORGAN MEATS)-KIDNEY	0.030000	1.00	1.00	FSIS
427	U	VEAL-(ORGAN MEATS)-LIVER	0.030000	1.00	1.00	FSIS
428	U	VEAL-(ORGAN MEATS)-OTHER	0.030000	1.00	1.00	FSIS
429	U	VEAL-DRIED	0.030000	1.00	1.00	FSIS
430	U	VEAL-MEAT BYPRODUCTS	0.030000	1.00	1.00	FSIS
431	R	WALNUT OIL	0.100000	1.00	1.00	REG-f
436	J	WATERMELON-JUICE	0.049000	1.00	1.00	DPR3Y
437	O	WHEAT-GERM OIL	0.010500	1.00	1.00	PDP96
439	J	WINTERMELON	0.049000	1.00	1.00	DPR3Y
467	A	CELERY SEED	0.001530	1.00	1.00	PDP94
911	A	MOLASSES-NFS	0.050000	1.00	1.00	EPA1/2

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Chronic Exposure (EX1) Analysis for Endosulfan Section 3 Registration

RESIDUE FILE NAME: ENDOS1CH ANALYSIS DATE: 06-14-2002

NFCS Combined 89-92 DATA

EPA Reference dose (RfD, chronic) = 0.006000 mg/kg body-wt/day

DPR NOEL (Chronic) = 0.570000 mg/kg body-wt/day

COMMENT 1: REG, USDA PDP/FSIS, DPR data & USEPA tolerances. %CT

COMMENT 2: Final dietary exposure analysis.

 TOTAL EXPOSURE BY POPULATION SUBGROUP

TOTAL EXPOSURE

POPULATION SUBGROUP	mg/kg body-wt/day	Margin of Exposure ^a	Percent of RfD
U.S. POP - 48 STATES - ALL SEASONS	0.000190	3,001	3.2%
U.S. POPULATION - SPRING SEASON	0.000187	3,041	3.1%
U.S. POPULATION - SUMMER SEASON	0.000206	2,769	3.4%
U.S. POPULATION - AUTUMN SEASON	0.000188	3,031	3.1%
U.S. POPULATION - WINTER SEASON	0.000177	3,220	3.0%
NORTHEAST REGION	0.000192	2,976	3.2%
MIDWEST REGION	0.000192	2,970	3.2%
SOUTHERN REGION	0.000193	2,946	3.2%
WESTERN REGION	0.000180	3,167	3.0%
PACIFIC REGION	0.000175	3,252	2.9%
HISPANICS	0.000190	3,004	3.2%
NON-HISPANIC WHITES	0.000188	3,034	3.1%
NON-HISPANIC BLACKS	0.000201	2,838	3.3%
NON-HISPANIC OTHER	0.000200	2,847	3.3%
ALL INFANTS	0.000219	2,597	3.7%
NURSING INFANTS (<1 YEAR OLD)	0.000077	7,421	1.3%
NON-NURSING INFANTS (<1 YEAR OLD)	0.000280	2,039	4.7%
CHILDREN (1-6 YEARS)	0.000405	1,407	6.8%
CHILDREN (7-12 YEARS)	0.000293	1,943	4.9%
FEMALES (13-19 Years/not pregnant, nursing)	0.000179	3,187	3.0%
FEMALES (20+ Years/not pregnant, nursing)	0.000140	4,082	2.3%
FEMALES (13-50 YEARS)	0.000148	3,840	2.5%
FEMALES (13+/Pregnant/not nursing)	0.000148	3,846	2.5%
FEMALES (13+/Nursing)	0.000165	3,448	2.8%
MALES (13-19 YEARS)	0.000214	2,668	3.6%
MALES (20+ YEARS)	0.000153	3,725	2.6%
SENIORS (55+)	0.000138	4,132	2.3%

 a - Margin of Exposure = DPR NOEL / Dietary Exposure

ENDOSULFAN RCD – 5/25/07

Chronic Exposure (EX1) Analysis for Endosulfan Section 3 Registration

RESIDUE FILE NAME: ENDOS1CH ANALYSIS DATE: 06-14-2002 NFCS Combined 89-92 DATA

EPA Reference dose (RfD, chronic) = 0.006000 mg/kg body-wt/day DPR NOEL (Chronic) = 0.570000 mg/kg body-wt/day

COMMENT 1: REG, USDA PDP/FSIS, DPR data & USEPA tolerances. %CT; COMMENT 2: Final dietary exposure analysis.

Critical Commodity Contribution Analyses

Crop Group ^a Food/Food Form ^b	Exposure Analysis			
	mg/kg body wt/d	% of Total Exposure	MOE ^c	% RfD
Non-Nursing Infants (< 1 year old) Total Exposure = 0.0002795 mg/kg Body Weight/day				
Group Unspecified				
Cane Sugar	0.0001	35.78%	5,699	1.7%
Total for Crop Group	0.0001	36.55%	5,578	1.7%
Fruiting Vegetables (Cucurbits)				
Squash-Winter	0.0002	8.31%	24,546	0.4%
Total for Crop Group	0.0002	9.07%	22,480	0.4%
Pome Fruits				
Total for Crop Group	0.000025	9.00%	22,480	0.4%
Stone Fruits				
Plums-Prunes (Dried)	0.000035	12.76%	15,986	0.6%
Total for Crop Group	0.000049	17.42%	11,705	0.8%
Red Meat				
Total for Crop Group	0.000018	6.53%	31,222	0.3%
Dairy Products				
Milk-Based Water	0.000015	5.46%	37,346	0.3%
Total for Crop Group	0.000029	10.25%	19,897	0.5%
Total Listed Crop Groups	0.00025	88.82%	2,296	4.1%
Children (1 - 6 years) Total Exposure = 0.00041 mg/kg Body Weight/day				
Group Unspecified				
Cane Sugar	0.0002	40.19%	3,502	2.7%
Total for Crop Group	0.0002	42.57%	3,306	2.9%
Cereal Grains				
Wheat-Flour	0.000033	8.06%	17,461	0.5%
Total for Crop Group	0.000041	10.04%	14,022	0.7%
Red Meat				
Beef (Boneless) - Lean (Fat/FR)	0.000045	11.03%	12,764	0.7%
Total for Crop Group	0.000084	20.63%	6,822	1.4%
Dairy Products				
Milk-Based Water	0.000035	8.53%	16,505	0.6%
Total for Crop Group	0.000040	9.94%	14,160	0.7%
Total Listed Crop Groups	0.00034	83.17%	1,692	5.6%

a - Crop groups with total exposure contribution > 5%

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b - Foods/food forms with exposure contribution > 5%

c - Margin of Exposure = DPR/Dietary Exposure

APPENDIX C.

**ESTIMATION OF EXPOSURE OF PERSONS IN CALIFORNIA TO PESTICIDE
PRODUCTS THAT CONTAIN ENDOSULFAN**

APPENDIX C

ENDOSULFAN (Thiodan™)

**DIETARY EXPOSURE ASSESSMENT
ADDENDUM**

Wesley C. Carr, Jr.

HEALTH ASSESSMENT SECTION

MEDICAL TOXICOLOGY BRANCH

CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

September 29, 2006

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I. INTRODUCTION

Dietary exposure to the pesticide endosulfan (6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide) and its metabolites has been previously assessed. The dietary exposure assessment, based on anticipated residues of endosulfan, was completed during July 1998 by Medical Toxicology Branch staff. The 1998 assessment used the TAS, Inc EXTM acute and chronic dietary exposure software (TAS, 1996). All of the acute and chronic dietary margins-of-exposure (MOEs) were greater than 100. As of August 2006, the Department of Pesticide Regulation (DPR) draft Endosulfan Risk Characterization document (RCD), which includes a dietary exposure assessment, is not final. The need for a complete revision of the 1998 dietary exposure assessment for the draft endosulfan RCD is evaluated in this addendum.

II. TOLERANCES AND APPLICATION RATES

There were 72 commodities with human consumption that had U.S. EPA endosulfan tolerances in 1998 (U.S. EPA, 1999). The same 72 commodities with U.S. EPA tolerances were still registered in 2001 (U.S. EPA, 2001a). However, 9 commodity tolerances have either been canceled or proposed for cancellation by the registrants of technical endosulfan (U.S. EPA, 2002). The unsupported or canceled tolerances are for artichoke, canola, mustard seed, raspberry, safflower seed, sugar beet, sugarcane, sunflower seed, and watercress (U.S. EPA, 2001a,b, 2002). Sugarcane is the only one of the unsupported tolerances that has any significant consumption reported in the USDA Continuing Survey of Food Intake by Individuals (CSFII) consumption databases (USDA, 1989-92, 1994-98a). A proposed rule by U.S. EPA in the April 26th 2006 Federal Register proposes to make final the tolerance changes presented in the 2002 RED (U.S. EPA, 2002, 2006a).

The U.S. EPA July 2002 draft endosulfan re-registration eligibility decision (RED) document proposed that the tolerances for 5 commodities should be revoked (U.S. EPA, 2002). Several of these commodities are sources of frequent consumption by infants and children. The proposed tolerance revocations are for beans (succulent), grape (including juice and raisin), peas (succulent), pecan, and spinach. Pecan is the only one of the 5 proposed for revocation that is not a frequently consumed commodity by infants and children. Succulent beans, succulent peas, and grapes are very frequently consumed commodities by infants and children. The U.S. EPA concluded that the revocation of tolerances for succulent beans and peas, grapes, and spinach would mitigate acute dietary exposure concerns to acceptable levels for infants and children (U.S. EPA, 2002). There were no chronic dietary exposure concerns cited by the EPA RED (U.S. EPA, 2002). There will be only 58 remaining tolerances after the registrants' voluntary cancellations and the U.S. EPA proposed tolerance revocations are implemented (U.S. EPA, 2001b, 2002). The U.S. EPA proposed rule in the Federal Register finalizes the 2002 RED tolerance actions (U.S. EPA, 2006a).

The U.S. EPA draft endosulfan RED also decreased the maximum label application rates for a number of commodities that will still have tolerances. The maximum annual application rates for pome fruits, stone fruits, and citrus will be decreased. The maximum rates will decrease from 3.0

pounds (lbs.) active ingredient (a.i.) per acre to 2.5 lbs. a.i./acre (U.S. EPA, 2002). This represents a decrease of approximately 17%. The draft RED also lowered the maximum annual application rates for Brassica species, carrots, cucurbits, fruiting vegetables, dry beans, dry peas, nuts, and strawberries (U.S. EPA, 2002). The revised maximum annual rates for these commodities will decrease from 3.0 lbs. a.i./acre to 2.0 lbs. a.i./acre (U.S. EPA, 2002). These label changes represent a decrease of approximately 33%. The reduction in maximum annual application rates for the above mentioned commodities could also result in a corresponding percentage decrease in the magnitude of the residues detected on endosulfan treated commodities.

III. ENDOSULFAN USE

There were approximately 50 products containing endosulfan actively registered with the U.S. EPA in 1998, 42 were active in 2002, and 13 remain in 2006 (U.S. EPA, 2001b, 2006, DPR, 2002, 2006). The reduction in product registrations with the U.S. EPA since 1998 did not have a significant impact on the amount of endosulfan used nationally through 2001 preceding the release of the draft endosulfan RED. The most recent U.S. EPA pesticide use publication dates from 2004 and reports 2000 and 2001 estimates (U.S. EPA, 2004). No specific endosulfan information was available in the 2004 publication. However, national endosulfan use would be less than 1-3 million pounds annually as this was the lowest total reported for an insecticide (malathion). Unfortunately, more recent U.S. EPA data are not available.

There were 14 active endosulfan products registered with the DPR in 1998 (Carr, 1998). In 2002, there were 15 endosulfan products with active DPR registrations (DPR, 2002). While there was an increase of 1 in the number of DPR registered products between 1998 and 2002, the total amount of endosulfan used in California decreased. Currently, there are 8 active DPR registered endosulfan products in California (DPR, 2006). California use in 2004, the most recent year available, was lower than either 2002 or 1998 (DPR, 2006).

The estimated national average annual usage of endosulfan in 1998 was 1.4 million pounds (U.S. EPA, 2001b). This was also the national average annual usage for the period between 1987 - 1998 (U.S. EPA, 2001b). The multi-year 1.4 million pounds national annual average through 1998 represents the most recent endosulfan specific information (U.S. EPA, 2001b, 2002).

According to the draft 2002 U.S. EPA endosulfan RED, the top 4 national commodities, based on lbs. of endosulfan active ingredient used annually, are cotton (286,000 lbs.), tomatoes (194,000 lbs.), potatoes (120,000 lbs.), and apples (110,000 lbs.) (U.S. EPA, 2001b). Pear, a frequently consumed commodity by infants and children, averaged approximately 35,000 lbs. of endosulfan applied per year nationally. National endosulfan use on pears ranked 12th, just below the average annual use on cantaloupe (39,000 lbs./year) (U.S. EPA, 2001b, 2002). Overall, national endosulfan use remained fairly stable during the 1992-2001 period.

The United States Department of Agriculture (USDA) National Agricultural Statistics Service (NASS) conducts annual national crop and pesticide use surveys. The USDA NASS crop surveys are

used to estimate national endosulfan use since the release of the draft 2002 U.S. EPA RED. The most recent USDA NASS information for the 5 crops (cotton, tomato, potato, apple, and pear) previously noted in the draft 2002 U.S. EPA endosulfan RED are summarized. The NASS survey results for cotton indicates approximately 7,000 lbs. was used nationally in 2005 (USDA, 2006a). The NASS results for tomato (fresh and processing) shows approximately 99,000 lbs. was used nationally in 2004 (USDA, 2005a). The results for potato indicates that approximately 14,000 lbs. was used nationally in 2005 (USDA, 2006a). Survey results for apple indicates approximately 59,000 lbs. was used nationally in 2005 (USDA, 2006b). The NASS results for pear shows that approximately 54,000 lbs. was used nationally in 2005 (USDA, 2006b). Compared to the estimates in the draft 2002 U.S. EPA RED, USDA NASS statistics indicate that recent national endosulfan use is lower for 4 crops (cotton, tomato, potato, and apple) and higher for pear. Based on the NASS statistics, the combined use of endosulfan nationally on cotton, tomato, potato, apple and pear declined by 69% (233,000 lbs. vs. 745,000 lbs.) from the total reported in the draft 2002 U.S. EPA RED.

Average annual use of endosulfan in California is summarized in Table 1. The 1996 - 2000 California annual average use was 187,900 lbs. of endosulfan active ingredient (DPR, 2002). The most current 4 years (2001 - 2004) of endosulfan annualized use in California averaged 147,968 lbs. per year (DPR, 2006). The top 4 crops receiving endosulfan applications in California are alfalfa, cotton, head lettuce, and tomato (Table 1). The top 4 crops for endosulfan applications comprise about 77% of the total California use (2001-2004 average). California applications represent about 13 percent of the total national average. Cotton and tomato are on both the national and California top 4 commodity use lists. Applications on California cotton represent about 13% of the national use on cotton. California accounts for approximately 8% of the national endosulfan tomato applications. In California, the 2001-2004 average annualized use is ca. 78% of the 1996-2000 period and ca. 41% of 1993-1995 period. Total endosulfan use in California has decreased ca. 42% over the last 12 years (1993: 366,008 lbs. vs. 2004: 153,339 lbs.). Pear had very little California acreage treated with endosulfan during either the 1996-2000 or 2001-2004 periods (Table 1, footnote #2). A measurable downward trend in California endosulfan use is apparent even when considering annual variability due to weather and pest pressure.

Table 1. Average Annual Endosulfan Use In California

Time Period	Average Annual Use ¹	Highest Use Crops ²
1993 - 1995	356,970 lbs.	Cotton (192,000 lbs.), grapes (47,000 lbs), cantaloupe (20,000 lbs), and head lettuce (20,000 lbs.)
1996 - 2000	187,900 lbs.	Alfalfa (46,420 lbs.), cotton (36,700 lbs.), head-lettuce (23,800 lbs.), and tomato (15,900 lbs.)
2001-2004 ³	147,968 lbs.	Cotton (61,460 lbs.), tomato (19,850 lbs.), head lettuce (17,675 lbs.), and alfalfa (14,470 lbs.)

1. Average of California DPR Pesticide Use Report (PUR) data.

2. The top 4 crops for each time period based on average annualized pounds used from DPR PUR. Endosulfan use on California pears averaged 1,197 lbs./years (1993-95), 259 lbs./year (1996-2000), and 59 lbs/yr. during 2001-2004.

3. 2004 is the most recent year for complete data.

IV. TOXICOLOGY

The toxicology data used to characterize the risk for the dietary exposure has been established in the draft DPR Endosulfan Risk Characterization document (RCD)(Silva, draft 2006). A no-observed-effect-level (NOEL) of 0.7 mg/kg body weight/day based on death (1/26 does) and neurotoxic effects reported at the lowest-observed-effect-level (LOEL) of 1.8 mg/kg body-weight from a rabbit teratology study was used to calculate acute dietary risk in the DPR RCD. A NOEL of 1.5 mg/kg body weight/day, based on neurotoxic effects reported at the LOEL of 3.0 mg/kg bd-wt from a rat acute neurotoxicity study, was used to calculate acute dietary risk by the U.S. EPA. A NOEL of 0.57 mg/kg (females) based on violent upper abdominal contractions, neurotoxicity, and decreased food consumption reported at the LOEL of 1.98 mg/kg body (females) from a 1 year dog study was used to calculate chronic dietary risk (Silva, draft 2006). The U.S. EPA used a NOEL of 0.6 mg/kg-bw/day, based on enlarged kidneys, nephritis and blood vessel aneurysms reported in males at the LOEL of 2.9 mg/kg bd-wt/day from a rat 2-year feeding study, to calculate chronic dietary risk.

V. RESIDUE DATA

A complete reassessment of the previous (1998) dietary exposure would require an extensive revision of the endosulfan residue database. However, a complete reassessment is unnecessary for three reasons: 1. The existing 1998 dietary exposure assessment resulted in acceptable margins of exposure (MOEs) for both the acute and chronic scenarios, 2. A revised dietary exposure assessment would also result in acceptable MOEs because of post-1998 U.S. EPA endosulfan product label changes, commodity tolerance revocations, decreased use, and residue data changes. 3. The U.S. EPA draft 2002 RED presented a dietary exposure assessment using methodology similar to current DPR guidelines. The U.S. EPA draft RED assessment resulted in acceptable acute and chronic dietary exposure. The changes in residue determination methodology in the current DPR guidelines and the differences between the residue databases since the 1998 DPR dietary exposure assessment are presented in Section V.

The majority of the endosulfan residue data for the 1998 dietary exposure assessment was taken from either the DPR market basket or the USDA Pesticide Data Program (PDP) monitoring programs. The PDP program analyzes residues with the intent to provide residue information for dietary risk assessment. The primary mission of the DPR pesticide residue program is enforcement of U.S. EPA tolerances. These dissimilar mandates result in two main programmatic differences between the PDP and DPR residues. Commodities in the PDP program are prepared into a ready-to-eat form (inedible rinds removed, fruit destemmed, etc.) before the pesticide analysis is conducted. The DPR program includes rinds and peels. Also, the PDP's limit-of-detection (LOD) levels are generally much lower by design than the DPR market basket program. A revised DPR dietary exposure assessment would preferentially use PDP data for distributional analyses when appropriate. A distributional analysis holds the potential to significantly refine the dietary exposure assessment to more accurately reflect

the actual commodity residue. Only high value deterministic estimates were used to represent commodity residues in the previous 1998 dietary exposure assessment.

The raw agricultural commodity cantaloupe illustrates the preparation differences between the DPR market basket and USDA PDP analytical programs. The DPR analysis cuts a number of melons into slices with the outer rind attached before analysis of the composite sample. The PDP program cuts cantaloupes in half with the seeds and outer rind removed from each melon before the composite sample is analyzed. For non-systemic pesticides, discarding inedible rinds prior to commodity pesticide analysis reduces and more accurately reflects the actual residues likely to be consumed. The current DPR guidelines recommend using ready-to-eat residue data when available. This was not a criterion in the earlier 1998 dietary exposure assessment.

The raw agricultural commodity pear provides another example of preparation differences between the DPR and PDP programs. The DPR analysis uses the entire pear including the outer peel and attached stem for each analyzed composite sample. The PDP program washes, cores and removes the stem from each pear before the sample is analyzed. Commodity processing studies have demonstrated that many non-systemic pesticide residues can be significantly lower by removal through washing prior to consumption (e.g. Elkins, 1989, Hamilton et al., 2004). Current DPR guidelines prioritize using ready-to-eat residue data which includes washing and de-stemming as minimal processing efforts.

The PDP preparation methods would have the potential to remove residues of non-systemic pesticides but also better reflect how people eat cantaloupes and pears. The typically lower PDP analytical method LODs would have a greater impact on chronic rather than acute dietary residues. This occurs because the chronic non-detect values contribute directly into the overall commodity mean residues. The lower LODs for the non-detected residues would not have a meaningful impact on upper bound deterministic acute values. The lower LODs would mainly affect acute residues in a distributional assessment. A revised DPR dietary exposure assessment would likely use a distributional analysis and combine the lower LOD values with the detected residues. This would probably result in a lower distributional residue than the deterministic value. This was not done in the 1998 assessment.

There were 56 separate residue values listed in the 1998 DPR dietary commodity file. The commodity sources were as follows: 20 commodity residues obtained from DPR, 6 residues from the endosulfan registrants, the USDA (PDP and FSIS) provided 29 residue values, and 1 U.S. EPA tolerance was used.

If the endosulfan dietary exposure assessment was revised, there would be an almost complete replacement of DPR residue data with USDA PDP data. This is because the statistically valid PDP data are more valid, and therefore more suitable, for use in distributional analysis. The USDA PDP annual summaries published since the 1998 endosulfan dietary exposure assessment contain residue data representing all 20 commodities that had previously used DPR data (USDA, 1998b, 2000 - 2006). The 20 commodity residues originating from the DPR monitoring program would be replaced by PDP values. This could have a meaningful impact on detected residue values primarily due to the differences in PDP sample preparation versus the DPR methods. The following commodities

currently use DPR origin data and could be replaced by USDA PDP residue data in an updated dietary exposure analysis. The commodities are broccoli, cantaloupe, cherry, cucumbers, pear, peppers, pineapple, squash, and strawberry. In addition, broccoli would be used as a surrogate to represent 5 other Brassica varieties with tolerances, cantaloupe would be a surrogate for all melons, squash would represent pumpkins, and cherry could serve as a surrogate for apricot, plum, and prune. Several of these commodities recorded frequent consumption by infants and children in the CSFII databases. The current DPR dietary exposure guidelines allow for use of representative surrogate residue data. The 1998 dietary exposure assessment did not use this currently accepted DPR and U.S. EPA method. Instead, marginal, and possibly non-representative residues or tolerance values were used, leading to greater exposure.

The complete distribution of the new, replacement PDP commodity residues is unknown. Their impact on the commodity residue contribution is also unknown unless a revised dietary exposure assessment is conducted. However, the commodities that previously used DPR residues in the 1998 dietary exposure assessment are compared with replacement PDP residues (Table 2). Table 2 presents the maximum measured value (non-distributional) for each monitoring program.

Cantaloupe and pear are used to illustrate the DPR and PDP residue monitoring program comparisons. Both cantaloupe and pear are frequently consumed commodities each with significant national percent crop treated rates (USDA, 1994-98, U.S. EPA, 2001b). Both of these commodities were represented by deterministic values in the 1998 DPR acute dietary exposure assessment but in a revised assessment would be replaced by distributional estimates using PDP data, thus reducing exposure.

The U.S. EPA endosulfan RED reported that nationally on average, 31% of the cantaloupe and 20% of the pear acreage were treated (U.S. EPA, 2002). The 1998 DPR value of 0.57 ppm represents the maximum measured from the detected cantaloupe residues (Table 2). The residue of 0.091 ppm represents the maximum measured PDP cantaloupe value (Table 2). The maximum PDP cantaloupe residue is 6 fold lower than the DPR maximum value. The 1998 DPR value of 0.25 ppm represents the maximum measured pear residue (Table 2). The 0.16 ppm pear residue represents the maximum measured PDP value. The maximum PDP pear residue is 36% lower than the DPR maximum value (Table 2).

Both of the PDP cantaloupe and pear endosulfan maximum residues are lower than the 1998 DPR values they would replace. All but three of the commodity residues in Table 2 are lower when PDP data replace the 1998 DPR values. Broccoli, pepper and strawberry are the 3 out of nine PDP residues that are higher (Table 2). If the screening level deterministic estimate margins of exposure (MOEs) were inadequate at the 95th% level of exposure in a revised dietary exposure assessment, then a distributional analysis (Monte Carlo) would be performed to better characterize the acute anticipated residues. These new data would most likely consist of PDP data. This is because the commodity sampling protocol for the PDP program is statistically more representative of residues found in grocery stores in both California and nationally. Refined Monte Carlo iterations using PDP data at the same 95th% of exposure as the 1998 assessment would result in lower dietary exposures.

However, the 99.9th% level of exposure Monte Carlo iterations for the replaced residue data sets could be lower, equal, or higher than the 95th% level exposure point estimate values from the 1998 dietary exposure assessment they replace. That determination can only be made if a revised acute dietary exposure assessment is done. Based on the Table 2 examples and previous residue comparisons between PDP and DPR data for other pesticides, the PDP residues would be lower than the DPR values the majority of the time.

The PDP data reported in the 1998 DPR dietary exposure assessment could also be revised using food form data. Both the deterministic and distributional processes allow for the incorporation of specific food form data (i.e. canned tomato versus raw, whole tomato) when available. Such PDP data now exist and a revised DPR acute dietary exposure assessment would use these food forms in a similar manner to the U.S. EPA methodology (Table 2). Specific food form data were not used in the 1998 DPR dietary exposure assessment.

Table 2. Comparative DPR and PDP Maximum Measured Endosulfan Residues

Commodity	Regulatory Monitoring Program Residue (in PPM) ¹		
	DPR ²	USDA PDP ²	Comparison
Broccoli ³	0.1	0.19	PDP residue is higher
Cantaloupe ³	0.57	0.091	DPR residue is higher
Cherry	0.18	0.041	DPR residue is higher
Cucumber ³	0.57	0.44	DPR residue is higher
Pear ³	0.25	0.16	DPR residue is higher
Pepper ³	0.71	1.1	PDP residue is higher *
Pineapple	0.09	0.005	Non-detect for each program
Squash ³	0.31	Fresh: 0.048	DPR residue is higher
	N.A. ⁴	Processed: 0.02	
Strawberry ³	0.18	Fresh: 0.68	PDP fresh value higher *
	N.A.	Processed: 0.008	

1. Maximum detected deterministic values represent both monitoring program's residues.
 2. DPR = California Department of Pesticide Regulation. PDP = USDA Pesticide Data Program. The DPR residues used in the 1998 analysis came from the 1993 -1995 market basket program. The PDP data are from the 1994 (broccoli only) and 1997- 2004 annual summaries.
 3. Frequently consumed commodity and a primary candidate for a distributional analysis.
 4. N.A. - not applicable. The DPR program analyzed only raw agricultural commodities.

Recent PDP data include both whole and canned tomato food form residue data. The whole tomato food form residue was used to represent the other tomato food forms in the 1998 DPR dietary exposure assessment. The whole tomato deterministic residue used in the assessment was 0.048 ppm (95th% of the detected residues). The maximum detected whole tomato residue value was 0.132 ppm. The canned tomato Monte Carlo estimation residue would be based on a distribution of several

hundred samples with the maximum detected value of 0.008 ppm. The canned tomato maximum value is 6 fold lower than the tomato value used in the 1998 dietary assessment and 16.5 fold lower than the maximum whole tomato residue. In a revised DPR assessment, canned tomato residue values would be used to represent commercially prepared canned juice, ketchup, paste, puree, and canned whole tomatoes. This method would be used for additional PDP origin commodities with both raw and processed residue data in a revised DPR dietary exposure assessment.

The Biological and Economic Analysis Division of the U.S. EPA (U.S. EPA BEAD) can generate percent-of-the-crop-treated (%CT) estimates based on USDA NASS and registrant product use and sales information (U.S. EPA, 2001b). When appropriate, commodity residue values in a dietary exposure analysis that come from registrant field trial data, state, or federal residue monitoring programs can be considered for %CT adjustments.

A commodity that has distributional residue data can be considered for modification by acute %CT information (DPR, 2002b). Unless specifically modified by an acute %CT adjustment, all other commodities in a DPR acute dietary exposure analysis will use the default assumption that 100% of the commodity has been treated with the pesticide active ingredient. The U.S. EPA BEAD estimate can be factored into the acute residue distribution to represent untreated commodity (true zeros) instead of the limit of detection (LOD). Incorporation of %CT estimates into a distributional estimate would likely result in lower exposure than a deterministic estimate using a 100 %CT assumption. The %CT treated method was not used for any acute residues in the 1998 DPR dietary exposure assessment. A revised DPR dietary exposure assessment would extensively use U.S. EPA BEAD data for both the acute and chronic duration scenarios.

VI. CONSUMPTION DATABASES

The United States Department of Agriculture (USDA) 1989-92 and 1994-98 Continuing Survey of Food Intake by Individuals (CSFII) consumption databases constitute 2 of the dietary consumption surveys available (USDA, 1989-92, 1994-98). The TAS Exposure TM program used residue data, acute/chronic NOELs, and the 1989-92 CSFII consumption database to estimate dietary exposure and MOEs (TAS, 1996). The TAS Exposure TM program is inactive and not currently supported by any organization. However, the 1989-92 CSFII consumption data within the TAS program are still relevant and available in other dietary exposure software. The 1998 DPR dietary exposure assessment used the 1989-92 CSFII consumption data from the TAS Exposure TM program.

The DEEM TM program was the standard dietary exposure software used by DPR in 2002 when the U.S. EPA draft endosulfan RED was released (Novigen, 2001, U.S. EPA 2002). The DEEM TM program can access either the 1989-92 or the 1994-98 CSFII databases. The U.S. EPA also used the DEEM TM dietary exposure software. The U.S. EPA 2002 draft endosulfan RED used the DEEM TM 1989-92 CSFII consumption database.

The DEEM-FCID™ program is the current standard dietary exposure software used by the California DPR (Exponent, 2004b). In August 2003, the DPR adopted the 1994-98 CSFII consumption database within the DEEM-FCID™ program for all new or revised dietary exposure assessments. The DEEM-FCID™ program contains just the 1994-98 CSFII database. The U.S. EPA also currently uses the DEEM-FCID™ dietary exposure software. The U.S. EPA 2002 draft endosulfan RED used the DEEM™ 1989-92 CSFII consumption database. The U.S. EPA underwent a transition to the 1994-98 CSFII from the 1989-92 consumption database within DEEM™ software between 2000 and 2002. The U.S. EPA converted to the DEEM-FCID™ dietary exposure software and the 1994-98 CSFII consumption database in 2003 (Exponent 2004 a,b). Primarily, the U.S. EPA did this to use the revised and better organized U.S. EPA commodity and individual food form codes.

The USDA 1989-92 CSFII database contains the consumption survey results from 10,383 participants over 3 complete days of dietary intake. There were a total of 3,132 individuals between the ages of 0 and 11 surveyed for the 1989-92 CSFII (Exponent, 2004a, USDA, 1989-92). The 1994-96 and 1998 (1994-98 CSFII) USDA survey reflects the results from 15,303 participants during the 1994-96 period plus an additional 5,304 children (0-9 years of age) surveyed in 1998 (Exponent, 2004b, USDA, 1994-98). The 1994-98 CSFII is a 2 day complete consumption intake survey. The 1994-96 CSFII surveyed the dietary intake of 4,253 children between birth and 9 years of age. Therefore, the combined total of infants and children between the ages of 0 and 9 surveyed for the 1994-98 CSFII was 9,557. The 1994-98 CSFII represents a 2 fold increase in the number of infants and children surveyed in the 1989-92 CSFII (Exponent, 2004b, USDA, 1994-98). Infants and children constitute ca. 46% of the 1994-98 participants.

There are two main differences between the CSFII databases besides the total number of participants and survey days. First, the 1994-98 CSFII reflects the most recent regional, gender, and ethnic commodity consumption patterns. Second, the survey contains additional targeted infants and children consumption information to address USDA concerns regarding statistically valid population sampling (USDA, 1994-98). These concerns arose during evaluations of the preceding 1987-88 National-Food-Consumption-Survey (NFCS) and the 1989-92 CSFII survey by the National Research Council (USDA, 1994-98, NRC, 1993). After review by governmental statisticians, the 1994-98 CSFII survey was deemed more statistically reliable and reflective of current consumption patterns by the USDA and the Government Accounting Office (GAO) than either the 1987-88 NFCS or the 1989-92 CSFII (USDA, 1994-98, Exponent, 2004a). The 1998 DPR assessment used the 1989-92 CSFII with its GAO and NRC identified sampling deficiencies. DPR currently uses the 1994-98 CSFII consumption database associated with the DEEM-FCID™ dietary exposure software (USDA, 1994-98, Exponent, 2004b).

The 1989-92 CSFII survey results were determined using the DEEM™ program while the 1994-98 CSFII consumption results were obtained using the DEEM-FCID™ software. The children 1-2 years of age population subgroup available in the 1994-98 CSFII of the DEEM-FCID™ software

was not used. This exclusion from the 1994-98 CSFII was done because a standard Children 1-2 years population subgroup is unavailable in the 1989-92 CSFII consumption survey. The consumption rates for the 4 highest use crops treated with endosulfan nationwide were analyzed. Pear was also included because it is a frequently consumed commodity by infants and children. When the 2002 U.S. EPA draft RED was published, the 4 crops with the highest endosulfan use at the national level were cotton, tomato, potato, and apple (U.S. EPA, 2001b, 2002). Pear had the 12th highest use nationally. The consumption rates for cottonseed are not discussed since there was very low intake and also little difference in mean consumption between the two CSFII surveys¹. Consumption rates based on age, gender, and ethnicity for each of the 3 highest use crops plus pears were compared for the 1989-92 and 1994-98 CSFII surveys. The consumption rates of apple, pear, potato, and tomato from the population subgroups western United States (western U.S.), children 1-6 years, nursing, and non nursing infants < 1 year for both the 1989-92 and 1994-98 CSFII are summarized. There are significant differences in mean consumption rates between the two CSFII surveys (1989-92 and 1994-98) for the selected commodities and infant/children combinations. The differences between the 2 surveys' consumption rates ranged from a 63% decrease in tomato consumption by nursing infants from the 1989-92 group levels to a 71% increase in potato consumption by non-nursing infants relative to the 1989-92 rates.

Apple: The mean consumption of apple from the 1994-98 CSFII survey ranged from a 39% decrease from 1989-92 levels to a 37% increase over 1989-92 levels depending on the population subgroup. The 1994-98 CSFII consumption by the western U.S. population subgroup was 4% higher than rates from the 1989-92 survey. The 1994-98 consumption by the nursing infants sub-group was 39% lower than the 1989-92 rate. The 1994-98 CSFII consumption by the non-nursing infants subgroup was 37% higher than the 1989-92 rate. The 1994-98 CSFII consumption by the children 1-6 years population was 9% lower than the 1989-92 rate.

Pear: Mean pear consumption from the 1994-98 CSFII survey ranged between decreases of 45% to 60% when compared to the 1989-92 levels. The 1994-98 CSFII consumption by the western U.S. population subgroup was 54% lower than the 1989-92 rate. The 1994-98 consumption by the nursing infants sub-group was 60% lower than 1989-92 rate. The 1994-98 consumption by non-nursing infants was 51% lower than 1989-92 rates. The 1994-98 CSFII consumption by the children 1-6 years population was 45% lower than 1989-92 rate.

Potato: Overall mean potato consumption from the 1994-98 CSFII survey ranged from a 37% decrease to a 77% increase over 1989-92 levels. The 1994-98 CSFII consumption by the western U.S. population was 37% lower than 1989-92 rate. The 1994-98 consumption by the nursing infants subgroup was 24% lower than the 1989-92 CSFII level. The 1994-98 CSFII consumption by the non-nursing infants population was 77% higher than the 1989-92 level. The 1994-98 CSFII potato consumption level by the children 1-6 years sub-group was 32% lower than the 1989-92 rate.

¹Western U.S. population mean cottonseed consumption rates were 0.03 grams \pm 0.05 g for the 1989-92 survey and 0.04 g \pm 0.07 g for the 1994-98 CSFII. Cottonseed consumption rates were similar for the other groups.

Tomato: The mean consumption of tomato from the 1994-98 CSFII survey ranged from a 63% increase from 1989-92 levels to a 71% increase over the 1989-92 levels. The 1994-98 CSFII consumption by the western U.S. population sub-group was 7% lower than the 1989-92 rate. The 1994-98 consumption by the nursing infants subgroup was 63% lower than the 1989-92 rate. The 1994-98 CSFII consumption by the non-nursing infants subgroup was 71% higher than the 1989-92 rate. Finally, 1994-98 tomato consumption by the children 1-6 years population subgroup was 18% lower than the 1989-92 CSFII rate.

The increased number of surveyed infants and children included in the 1994-98 CSFII database appears to have had an impact on percent user day rates. The percent user day rate is the ratio of actual consumers divided by *per capita* consumption for each commodity. *Per capita* consumption includes both consumers and non-consumers. Therefore, percent user day basis consumption reports only active consumers. The higher the percentage of active consumers relative to *per capita* consumption, the lower the variability and higher the reliability of the survey commodity consumption rates. *Per capita* consumption can often result in lower exposure in individual commodities when compared with active consumers (user days). The differences between *per capita* and active consumer consumption results become less relevant in frequently eaten, ubiquitous commodities (i.e., corn and other grain products, milk, soybean, and refined sugar). Therefore, there is no difference between the intake rate of *per capita* and active consumers (user days) when consumption approaches 100% of the total person days. Over-all, the percent user day rates for the four surveyed groups in the 1994-98 CSFII database were generally equal to or higher than the consumption rates seen in the 1989-92 populations (Table 3). The exception was the non-nursing infants subgroup (apple and tomato only).

Table 3. Comparison of Percent User Day Rates Between The 1989-92 and 1994-98 CSFII ¹

RAC ----- Population	Apple		Pear		Potato		Tomato	
	1989 ²	1994 ²	1989	1994	1989	1994	1989	1994
West U.S. ³	33%	34%	7%	11%	43%	71%	60%	67%
Child 1-6	46	61	8	22	48	78	54	64
Nur. Inf.	15	25	5	8	11	17	5	8
N.N. Inf	47	44	15	15	30	35	24	17

1. A Percent User Day is the ratio of actual consumers divided by the combination of consumers and non-consumers (*per capita*) for each population subgroup.

2. The 1989-92 CSFII survey used DEEM TM and the 1994-98 CSFII used the DEEM-FCID TM program.

3. West U.S. = Western United States; Child 1-6 = Children 1-6 years of age; Nur. Inf. = Nursing infants; N.N. Inf. = Non-nursing infants population subgroups.

VII. CONCLUSION

A review of the tolerance, usage, residue, consumption, prior MOEs, and CSFII survey information indicate that an update of the 1998 DPR endosulfan dietary exposure assessment is not necessary.

While the average consumption rates increased for some commodity / population subgroup combinations in the 1994-98 CSFII survey when compared to the 1989-92 CSFII, this would likely be mitigated by existing tolerance cancellations and proposed revocations and reduced annual maximum applications. In addition, if the DPR acute dietary exposure analysis was updated there would be a change to Monte Carlo distributional iterations for many commodities where acute %CT estimates could be incorporated. Using updated residue, consumption and the U.S. EPA endosulfan RED tolerance and use information, the DPR acute dietary exposure assessment would likely be lower. This conclusion would hold even though MOEs at the 99.9th% level of acute exposure would be reported instead of the 95th% level of exposure MOEs used in the existing point estimate DPR dietary analysis. This conclusion is supported by the acceptable acute MOEs reported in the 2002 U.S. EPA draft endosulfan RED.

A new DPR acute dietary exposure analysis would: 1) update the residue data of the remaining commodities with tolerances, 2) delete the 9 commodity tolerances from the dietary residue file that have been canceled by the registrants since 1998, 3) delete the U.S. EPA draft endosulfan RED proposed tolerance revocations (succulent bean and pea, grape, pecan, and spinach), 4) use more realistic residue data (e.g. exclude melon rinds), 5) use processed food forms when available instead of the raw forms as surrogates (e.g. apple juice instead of raw apples representing apple juice) for processed forms, 6) use Monte Carlo distributional iterations to replace point estimates whenever appropriate, and 7) incorporate acute %CT data into any distributional analysis (Monte Carlo). The updated DPR acute dietary exposure analysis would be very similar to the acute dietary analysis referenced in the 2002 U.S. EPA endosulfan RED (U.S. EPA, 2002).

The existing DPR 1998 endosulfan dietary exposure assessment reports MOEs greater than 100 for both the acute and chronic scenarios (Carr, 1998). The acute MOEs at the 95th% level of exposure ranged from 212 for children 1-6 years to 513 for the males 13-19 years population subgroups. The chronic MOEs ranged from 1,407 for children 1-6 years to 7,421 for nursing infants \bar{y} 1 year old.

The U.S. EPA 2002 draft endosulfan RED concluded that infants and children acute dietary exposure risk is mitigated by their tolerance revocations and proposed label changes and therefore are no longer a concern. The U.S. EPA endosulfan RED concluded that adult acute and chronic dietary exposures are also not a concern. The conclusions resulting from an updated DPR dietary exposure assessment would likely be similar to those reported in the U.S. EPA 2002 endosulfan RED. Therefore, a complete revision of the DPR 1998 dietary exposure assessment would appear unnecessary and the 2006 dietary exposure addendum suffices when combined with the prior 1998 DPR dietary exposure assessment.

VII. CONCLUSION – POST SCRIPT (October 3, 2006)

The April 26th 2006 Federal Register proposed rule, discussed in Section II, which would codify tolerance changes presented in the 2002 U.S. EPA RED, was made final on September 15th 2006 (U.S. EPA, 2002, 2006a, b). The two U.S. EPA rules were the same except that the September version contained a nomenclature change (filbert to hazelnut) that did not appear in the April

proposal. It should be noted that the September 15th 2006 final rule in the Federal Register did not contain all of the tolerance actions listed in the 2002 U.S. EPA RED. Additional tolerance actions may appear in a future Federal Register notice. However, these results do not change the conclusions discussed in the current DPR dietary exposure addendum.

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APPENDIX D.
SUMMARY OF TOXICOLOGY DATA

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA

ENDOSULFAN (THIODAN)

Chemical Code # 000259, Tolerance # 182
SB 950-052,
November 14, 1986
Revised 9/19/88; 3/15/90; 3/5/99, 11/28/06

I. DATA GAP STATUS

Combined (chronic/onco), rat:	No data gap, possible adverse effect.
Chronic, dog:	No data gap, no adverse effect.
Oncogenicity, mouse:	No data gap, no adverse effect.
Reproduction, rat:	No data gap, no adverse effect.
Teratogenicity, rat:	No data gap, no adverse effect.
Teratogenicity, rabbit:	No data gap, no adverse effect.
Gene mutation:	No data gap, no adverse effect.
Chromosome aberration:	No data gap, no adverse effect.
DNA damage:	No data gap, no adverse effect.
Neurotoxicity, hen & rat:	No data gap, no adverse effect.

Note, Toxicology one-liners are attached

** indicates acceptable study

Bold face indicates possible adverse effect

File name: T061128

Revised: 11/28/06, T. Moore.

All volumes through 182-0122 and record numbers through 228573 have been examined.

II. TOXICOLOGY SUMMARY

COMBINED, RAT

Subchronic Study:

032 035803, "13 Week Toxicity Study in Rats Followed by a 4-week Withdrawal Period (Final Report)", (Huntingdon Research Centre plc, Huntingdon, Cambridgeshire, England, report # HST 230/84176, 3/25/85). Endosulfan technical (97.2% pure) was fed in the diet for 13 weeks at 0, 10, 30, 60, and 360 ppm (actual) with 25/sex/group. Following 13-weeks of treatment, 5/sex/group underwent a 4-week withdrawal (off treatment) period. NOEL \leq 10 ppm (significantly lower red blood cell parameters were observed in both sexes at \geq 60 ppm; females at 360 ppm had significantly lower plasma and RBC cholinesterase values; dark urine with increased ketones was reported at 13 weeks in males at \geq 60 ppm. Histopathology revealed traces of yellowish discolored cells (proximal convoluted tubules) at \geq 10 ppm but no cell death was reported). NOAEL \leq 30 ppm (increased liver weights at 360 ppm; increased kidney weights at \geq 60 ppm (males) and 360 ppm in females). **No adverse effect** indicated. **Supplemental to 074851**. (H. Green & M. Silva, 3/7/90).

Combined Study:

**** 066 074851**, "Combined Chronic Toxicity/Carcinogenicity Study 104-Week Feeding in Rats", (Huntingdon Research Centre Ltd., England, report # HST 289/881067, 4/1/89). Endosulfan technical (96.7% pure; batch 381 (A-D)) was fed in the diet for 104 weeks at 0 (vehicle = acetone to dissolve, then corn oil to mix in diet), 3.0, 7.5, 15.0, and 75.0 ppm to 70 Crl:CD (SD) BR rats/sex/group (20/sex/group as satellites for blood sampling and evaluation of toxicity). Chronic NOEL = 15 ppm (reduced bodyweight gain (8% to 18% less than controls) in both sexes at 75 ppm; increased number of enlarged kidneys in females at 75 ppm). **Adverse effect: increased incidence of aneurysms in blood vessels and an increased incidence in progressive glomerulo-nephrosis in males at 75 ppm**. Oncogenicity NOEL \geq 75 ppm. **Acceptable**. (H. Green & M. Silva, 3/8/90).

CHRONIC, RAT (see combined rat, above)

042 047297, Summary of 1959 study conducted at Hazleton. Rats were fed 0, 10, 30 or 100 ppm for 104 weeks. Kidney damage in males at 100 ppm is reported but the adverse effect cannot be assessed from the summary paragraph.

CHRONIC, DOG

****065 074850**, "Testing for Toxicity by Repeated Oral Administration (1-year feeding study) to Beagle Dogs", (Hoechst Aktiengesellschaft, Pharma Research, Toxicology and Pathology, 6230 Frankfurt (M) 80, West Germany, Report # 89.0188, 1/20/89). Endosulfan technical (96.5% pure) was fed in the diet for 1 year at 0, 3, 10, 30, and 30/45/60 ppm (54 days at 30 ppm, 52 days at 45 ppm, and 19-40 days at 60 ppm) to 6 Beagle dogs/sex/dose. All dogs at 30/45/60 ppm were sacrificed by treatment day 147 due to onset of nervous symptoms after dose was increased to 60 ppm. **No adverse effect**. NOEL = 10 ppm (After day 135, at intervals, 3 males and 2 females at 30 ppm experienced violent contractions of the upper abdomen and convulsive movement (males) beginning 2 1/2 to 6 hours post-administration). **Acceptable**. (H. Green & M. Silva, 3/5/90).

041 045581, "One Year Repeated Oral Administration of Thiodan Technical in Dogs; Final Report."

(5/12/59, Hazleton Labs, NCT 252-33) Endosulfan (technical, no purity stated, Lot # MR 3931), given orally in capsules at 0, 0.075, 0.25 and 0.75 mg/kg/day for 1 year, dosed 6 days a week (the 0.075 mg/kg/day group received 2.5 mg/kg/day for the first three days); no observed effects noted at any dose; only 2 dogs/sex/dose; lacks complete serum chemistry and histopathological analyses; incomplete, unacceptable, not upgradeable. No dose-related observable toxic effects. (G. Patterson, 9/12/86)
No EPA one-liner.

ONCOGENICITY, RAT (see combined rat, above)

012 008617 (1984, Hoechst Aktiengesellschaft) Correspondence - no data.

007 921663, "Bioassay of Endosulfan for Possible Carcinogenicity." (1978, Hazleton for NCI) Endosulfan, technical, 98.8%; fed in the diet to 20/sex for controls and 50/sex/test group, Osborne-Mendel rats; fed at 0, 408 or 952 ppm (time-weighted average, males) and 0, 223 or 445 ppm (time-weighted average, females) for 73 - 81 weeks; high mortality in treated males - cannot determine a NOEL; onco NOEL (females) > 445 ppm (TWA); systemic NOEL < 408 **Adverse effects** indicated: males for kidney chronic inflammation, toxic nephropathy and associated calcium deposition in kidneys and other tissues, parathyroid hyperplasia and testicular atrophy - seen in both test groups. **Unacceptable**, not upgradeable (high mortality in both test groups of males precluding any useful oncogenicity data, inadequate number of matched controls, no analysis of diet, dose selection with numerous changes in all groups, housing of animals in same room with other studies using toxic substances, no hematology, no individual data). (Gee, 11/14/86)

042 47299 Summary of 921663.

ONCOGENICITY, MICE

****064 075035**, "Carcinogenicity Study in Mice, 24 Month Feeding Study", (Pharma Research Toxicology and Pathology, Hoechst Aktiengesellschaft, F.R.G., 4/6/88). Endosulfan technical (\geq 97.1% pure) was fed in the diet for 24 months at 0 (sesame oil), 2, 6, and 18 ppm to 80 NMRI Hoe:NMRKf (SPF71) mice/sex/group (with interim sacrifices of 10/sex/group at 12 and 18 months). **No adverse effect**. Oncogenicity NOEL \geq 18 ppm (an oncogenic effect was not observed). Chronic NOEL = 6 ppm (reduced bodyweight gain (approximately 5% reduction) reported in main group males at 18 ppm; increased mortality reported in main group females at 18 ppm). **Acceptable**. (Green & Silva, 3/9/90).

007 035628, "Bioassay of Endosulfan for Possible Carcinogenicity." (Hazleton, 1978, for NCI) Endosulfan, technical, 98.8%; fed to 20/sex in controls and 50/sex/test group - B6C3F1 mice - at 0, 3.5 or 6.9 ppm (time-weighted average, males) and 0, 2.0 or 3.9 ppm (time-weighted average, females) for 73 weeks followed by 14 weeks on control diet; onco NOEL (females) > 3.9 ppm (TWA); cannot determine NOEL for males due to high mortality in test groups. Unacceptable (high mortality in males precluding useful data, inadequate number of matched controls, housing of mice in same room with those on other studies with toxic materials with a possibility of cross-contamination, no individual data, no analysis of diet, dose selection.) Gee, 11/14/86.

042 047300, Summary of 035628.

012 008617, (1984, Hoechst Aktiengesellschaft) Correspondence- no data.

REPRODUCTION, RAT

002 921665 -68, (1966, IBT) JPC, 3/28/85. Non-validated IBT study; no EPA one-liner.

012 008613, (1984, Hoechst Aktiengesellschaft) Correspondence - no data.

022 035789, "Effect of Endosulfan-Technical (Code: HOE 02671 0 I AT209) on Reproductive Function of Multiple Generations in the Rat." (1984, Huntingdon HST 204/83768). Endosulfan, 97%; two generation study at 0, 3, 15 and 75 ppm; **no adverse effects on reproduction; marginal decrease in litter weight at 75 ppm; organ weights of liver, kidney increased at 75 ppm without histopathology to confirm. **Acceptable**. A preliminary study in 023. No EPA one-liner. Parental NOEL = 15 ppm. (Gee, 10/25/85)

023 035790, (1982, Huntingdon) J. Gee, 10/25/85. Addendum to 022 035789.

024 035791, (1985, Huntingdon) J. Gee, 10/25/85. Addendum (histopath) to 022 035789.

037 036881, (no date given, FMC) Summary of 022 035789.

TERATOLOGY, RAT

026, 057 017686, 060606, "Teratology Study with FMC in Rats." (Raltech, 10/2/80, Study No. 79041) Endosulfan, 97.3%; dose levels were 0 (corn oil), 0.66, 2.0 or 6.0 mg/kg/day by oral gavage; 25/group, Sprague Dawley rats; maternal NOEL = 2 mg/kg/day (decreased body weight gain and increased clinical signs at 6 mg/kg/day. Developmental NOEL = 2 mg/kg/day (developmental toxicity, growth retardation is evident at 6 mg/kg/day). **No adverse effect. Initially reviewed as incomplete (JPC, 3/28/85 and JAP, 11/15/86) because of lack of analyses of dosing solutions and dose justification. Record 060606 is a retrospective study for content, homogeneity and stability in corn oil. Record 060605 (see below) is a range-finding study for dose selection. The collective data are upgraded to **acceptable** status with no adverse developmental effect. (Gee, 9/19/88)

EPA 1-liner: Minimum. Teratogenic NOEL = 6 mg/kg (the teratogenic effects noted were accompanied by frank maternal toxicity.) Maternal NOEL = 2 mg/kg (reduced body weight, hyperactivity, rough coat, flaccidity and brown exudate.) Fetotoxic NOEL = 2 mg/kg (skeletal, visceral and external anomalies; decrease in pup size and weight.)

037 036884, (1985, Hazleton [formerly Raltech]), This record contains historical control data for the rat teratology study found in 009, 026 017686. Note: The second review changes the earlier finding of adverse effect in 009 017686 to a finding of **no adverse effect**. (JAP, 5/6/86)

057 060605, "Range-finding Study with FMC 5462 in Pregnant Rats", (Raltech Scientific Services - now Hazleton, Study No. 79031, 10/8/80), Endosulfan, 97.3%, given by oral gavage at 0 (corn oil), 1.25, 2.5, 5, 10, 20 or 40 mg/kg, days 6 - 19 of gestation, CD Sprague Dawley rats, 6 per group except 1 only at 40 mg/kg; all died at 20 and 40 mg/kg, 4/6 at 10 mg/kg; clinical signs at all doses including salivation, piloerection, poor muscle tone, hyperactivity, tremors and convulsions. **Supplementary** data for CDFA # 017686. (Gee, 9/19/88)

003 921664, (1980, Raltech) One page summary of 026 017686.

010 021600, (1980, Raltech) Nine page summary of 026 017686.

037 036882, (No date given, FMC) Half page summary of 026 017686.

037 036883, (1981, EPA) Evaluation of study in 026 017686.

041 045580, (1985, Hazleton) Exact duplicate of historical control data in 037 036884.

012 008616, (1984, Hoechst Akiengesellschaft) Correspondence - no data.

TERATOLOGY, RABBIT

037 036880, (No date given, FMC) Summary of 027 035798.

027, 057 035798, 060607, "Teratology Study with FMC 5462 in Rabbits." (Raltech, 7/27/81, Study No. 80070, FMC A79-370) Endosulfan, 97.3%; given by oral gavage to New Zealand White rabbits, days 6 - 28 of gestation; 0 (corn oil), 0.3, 0.7 or 1.8 mg/kg/day, 20 - 26 per group; minimal maternal toxicity at 1.8 mg/kg; NOEL = 0.7 mg/kg/day; no developmental toxicity at any level tested. **No adverse effect indicated. Initially reviewed as unacceptable but upgradable (missing analysis of dosing solutions and justification of dose selection), JAP, 11/15/85. CDFA Record # 060607 contains analyses of dosing solutions for content, stability in corn oil and homogeneity. CDFA Record # 060604 reports on a second range-finding study justifying dose selection. The collective data are upgraded to **acceptable** status. (Gee, 9/19/88)

041 045582, "Final Report: Range-Finding Study with FMC 5462 in Pregnant Rabbits." (12/30/81, Raltech Study No. 79032), Endosulfan (technical, 97.3%), teratogenicity range-finding study in rabbits, given by oral gavage at 0, 0.5, 1.0 and 2.0 mg/kg in corn oil and at 0, 0.625, 1.25, 2.5, 5.0, 10.0, 20.0, 40.0 and 80.0 mg/kg in corn oil; volume of corn oil had an effect on observed signs of toxicity; no survivors in 5.0 mg/kg and above groups, mortality 2/6 in 2.0 mg/kg and 0/6 in 1.0 mg/kg group with signs of maternal toxicity present. Submitted as justification for dose selection in the rabbit teratology study reviewed above (# 035798). The doses, however, do not match those stated on pg. 79, Amendment No. 4, of the submission which states Study No. 79032 was conducted with doses of 0, 1, 2, 4, 8 and 12 mg/kg. (Patterson, 9/19/86)

057 060604, "Range-Finding Study with FMC 5462 in Pregnant Rabbits (Supplier: Dutchland Laboratories, Inc.) Raltech Study No. 79032." (Raltech Scientific Services, WI, 12/30/81), Endosulfan, 97.3%, given by oral gavage to New Zealand White rabbits, days 6 - 28 of gestation, 3 - 10 per group, at 0 (corn oil), 1, 2, 4, 8 or 12 mg/kg/day; no survivors at 8 and 12 mg/kg/day, 4/8 at 4 mg/kg (2 may have been misinjection); clinical neurotoxic signs at 2 mg/kg and above; decreased weight gain at 4 mg/kg; dose justification for full study, CDFA # 035798; no report on fetal findings. **Supplemental** data. (Gee, 9/19/88)

MUTAGENICITY, GENE

Mammalian systems

025 035792, "Mutagenicity Evaluation of HOE 002671-Substance Technical in the Mouse Lymphoma Forward Mutation Assay - Final Report." (1984, LBI, Project 20989), Mouse lymphoma L5178Y TK+/- cells; endosulfan - 97.2%; 0, 6.25, 12.5, 18.8, 25.0, 37.5, 50, 75 or 100 ug/ml, four hours; with and without rat liver activation; **no increase in mutation frequency**; no repeat experiment to confirm. **Unacceptable** (no repeat trial). Gee, 10/24/85. No EPA one-liner.

042 047291 and 047294, (FMC, 6/26/86). Rebuttal to review of 035792. Objection of no repeat trial in mouse lymphoma assay stands. Record # 047294 presents hydrolysis data which are useful. (J. Gee, 11/12/86)

Microbial systems

025 035796, "Study of the Mutagenic Activity "in vitro" of the Compound Endosulfan - Technical (Code HOE 002671 01 0003) with *Schizosaccharomyces pombe*." (1984, RBM, Italy), *Schizosaccharomyces pombe* ade biosynthetic pathway; endosulfan, technical, 97.2%; 0, 62.5, 125, 250 or 500 ug/ml, four hours; **no effect in mutation frequency** is reported. **Unacceptable** (no repeat experiment, no justification of high concentration). (Gee, 10/24/85) No EPA one-liner.

042 047306, "Microbial Mutagenicity Testing on Endosulfan.", (Institute of Environmental Toxicology, Japan, 1978), *Salmonella* strains TA1535, TA1537, TA1538, TA98 and TA100 with and without rat liver activation at 0, 5, 10, 50, 100, 500, 1000 or 5000 ug/plate in duplicate, single trial; **no increase in reversion rate** reported; **Unacceptable** (single trial - otherwise, a good report). (Gee, 11/12/86)

SUMMARY: Although there is no single test report which meets guidelines, there are three different tests (2 in microbial systems and one in mammalian) showing no mutagenic effect. The major problem with the three tests is no repeat trial was performed to confirm the negative response. If taken together, the data gap may be considered filled based on use of the three test systems to confirm each other. (Gee, 11/14/86)

MUTAGENICITY, CHROMOSOME

025 035794, "Micronucleus Test in Male and Female NMRI Mice Following Oral Administration.", (10/1983, Hoechst), Endosulfan, 97.2%; Mouse bone marrow micronucleus test, two doses by oral gavage; sampling of 5 males and 5 females at six hours only, 0, 0.2, 1.0 or 5.0 mg/kg; **no increase in micronuclei or change in PCE/NCE** was noted. **Unacceptable** (one sampling only at six hours). (Gee, 10/24/85) No EPA one-liner.

042 047292, Rebuttal to review of 035794 and includes statement that Hoechst will conduct another micronucleus study following EPA guidelines - no date indicated for completion.

042 047313, "Mutagenicity Studies involving Aldrin, Endosulfan, Dimethoate, Phosphamidon, Carbaryl and Ceresan.", (Osmania Univ., Hyderabad, India, published in Bull. Environm. Contam. Toxicol. 25: 277-282 (1980). Mouse micronucleus test. Endosulfan, no purity stated; given orally (in diet) at 0 or 43.3 mg/kg to 4 male mice in two daily doses with sacrifice 6 hours after second dose. 2000 polychromatic erythrocytes and normochromatic erythrocytes were scored for each animal; **no adverse effect** is reported (% of control PCE's with micronuclei was 0.28 and 0.52 for test group). **Unacceptable**, not upgradeable (single sex, single dose with no justification and no clinical obs reported, no individual data, protocol with single sacrifice time). (Gee, 11/13/86)

042 047309, "Mutagenic Study with Thiodan in Albino Mice", (IBT, 1972, E1057B) EPA lists the report as "valid" but CI (core invalid) for data requirement and as "replaced". Endosulfan technical, 98%; given to 12 male mice per group by i.p. injection at 0, 5 or 10 mg/kg b. wt.; mated 1:3 for 6 weekly periods; no deaths in treated groups; **no dominant lethal effect** reported. **Unacceptable**, not upgradeable (no individual data, fewer than 30 pregnant females per group, dose selection - two doses only and questionable if reached m.t.d.) (Gee, 11/13/86)

042 048638, "Endosulfan, Substance Technical, Chromosome Aberration in Human Lymphocytes Cultured in vitro", (RBM - Inst. di Ricerche Biomediche, Torino, Italy, 1986), Endosulfan technical, 97.9%; human lymphocytes from a male volunteer were stimulated with phytohemagglutinin (PHA), exposed for 4 hours to 0, 1, 10, 100 or 200 ug/ml with and without rat liver activation and scored after 23 additional hours (the last three with colchicine) for chromosomal aberrations and mitotic indices; 200 ug/ml was toxic. **Acceptable with no positive findings. (Gee, 11/13/86)

042 047312, "Endosulfan: Lack of Cytogenetic Effects in Male Rats." (Industrial Toxicology Research Centre, India, 1978, published in Bull. Environm. Contam. Toxicol. 20: 826-833 (1978). Endosulfan, no purity stated; given to 8 male rats per group by oral gavage at 0, 11, 22, 36.6 or 55 mg/kg b. wt.; bone marrow and spermatogonial cells were analyzed for aberrations 4 hours after colchicine injection. **No adverse effects** indicated. **Unacceptable**, not upgradeable (single sex, no data). (Gee, 11/13/86)

MUTAGENICITY, DNA

025 035793, "Evaluation of HOE 002671-Substance Technical in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay - Final Report", (1984, LBI, project 20991), Primary rat hepatocytes, unscheduled DNA synthesis; endosulfan - technical grade (purity not stated); 0, 0.102, 0.255, 0.510, 1.02, 5.10, 10.2, 25.5 or 51.0 ug/ml; toxic at 51.0; triplicate cultures. **No detectable increase in grains/nucleus at any concentration. **Acceptable.** (Gee, 10/24/85)
No EPA one liner.

025 035795, "Study of the Mutagenic Activity of the Compound Endosulfan - Technical with *Saccharomyces cerevisiae*." (1984, RBM, Italy), Endosulfan, 97.4%; *Saccharomyces cerevisiae* D4 diploid strain, 0, 100, 500, 1000 or 5000 ug/ml, four hours, with and without activation, assayed ade and trp, **no increase in mutation was detected; DMSO as solvent; no repeat experiment; four plates per concentration. **Acceptable.** (Gee, 10/24/85)
No EPA one-liner.

012 008614, (1984, Hoechst Aktiengesellschaft) Correspondence - no data

042 047306, "Microbial Mutagenicity Testing on Endosulfan", (Inst. of Environmental Toxicology, Japan, 1978), *Bacillus subtilis*; endosulfan, 99%, strains H17 and M45, tested without activation at 0, 20, 100, 200, 500, 1000 or 2000 ug/disk in 20 ul, 1 plate per concentration, kanamycin and mitomycin C as controls; no difference in growth between strains and no cytotoxicity - therefore, a "no test". **No adverse effect** indicated. **Unacceptable** (no activation, no justification for concentrations used). Not upgradeable. (Gee, 11/13/86)

NEUROTOXICITY

028 035799, "Acute Delayed Neurotoxicity Study with Endosulfan Technical (Code: HOE 002671 0I Z097 0003) in the Domestic Hen." (1983, Huntingdon) Hens - domestic; endosulfan - 97.2%; 96 mg/kg with atropine - 2-PAM to protect at LD50; redosed in 21 days; histopathology on 9 of 17 survivors of initial 40 birds; **no compound related delayed neuropathology is reported. Acceptable. Rebuttal by FMC, 182-042, # 47293, contains statement that Huntingdon guaranteed adequate pen space to observe gait of hens and that FIFRA guidelines state a minimum of 6 hens must survive for histopathological examination. Reconsideration of the initial finding of the study as unacceptable based on 10 hens per pen and not all survivors examined (9/17), changes the report to

acceptable. (Gee, 10/24/85 and 11/12/86)

** 106 162457 "Neurotoxicological Screening in the Male and Female Wistar Rat; Acute Oral Toxicity," (Bury, D.; Hoechst Marion Roussel, Preclinical Development Germany, Drug Safety, FRG; Study #: 96.0373; Report #: 97.0149; 7/7/97). Endosulfan technical (98.6% pure) was administered by oral gavage (single dose) to fasted Wistar rats (10/sex/dose) at 0, 6.25, 12.5, 25, 50 and 100 mg/kg (males) and 0, 0.75, 1.5, 3, 6 and 12 mg/kg (females). The vehicle was 2% starch mucilage (potato starch in deionized water), the stability of endosulfan in the vehicle was for 4 hours and the duration of observation was 15 days. The neurotoxicological screening (Functional Observational Battery & motor activity) was performed 7 days prior to treatment initiation and 14 days post-dosing. Three weeks post-dosing, controls (10/sex) and 5/sex (all other doses except 4/sex at 100 mg/kg) were terminated for neuropathological examination. SYSTEMIC NOEL = 12.5 mg/kg (males) & 1.5 mg/kg (females) (There was an increase in clinical signs in males at ≥ 25 mg/kg and in females at ≥ 3 mg/kg, which lasted for 1 day.) Acceptable. No adverse effect. M. Silva, 2/18/99.

** 182-0122; 228573; "A Developmental Neurotoxicity Study with Technical Grade Endosulfan in Wistar Rats"; (R.G. Gilmore, L.P. Sheets, H.E. Hoss; Bayer CropScience LP, Toxicology, Stilwell, KS; Report No. 201563; 9/26/06); Thirty mated female Wistar rats/group received 0, 50, 150 or 400 ppm of Endosulfan Technical (batch no. EGPC400349; purity: 99.1%) in the diet from day 6 of gestation through day 21 of lactation (0, 3.74, 10.8, and 29.8 mg/kg/day) (note: the concentration of the test material in the dietary preparations was adjusted to the expected food consumption during the lactation period in order to maintain a reasonably constant level of test material consumption during this period). Offspring from 23 litters in the control, 50 and 150 ppm groups and pups from 21 litters in the 400 ppm groups were assessed neurologically up to 75 days post-natal in the functional observational battery (FOB), measurement of motor activity, auditory startle response, passive avoidance learning and memory and water maze learning and memory assessments. The motility, numbers and morphology of the sperm of the male pups were evaluated. The neuropathologic examination and morphometric analysis of selected neurological tissues from the pups were performed. The mean body weight of the dams was decreased in a dose-related manner during the gestation ($p < 0.05$ or 0.01). This effect persisted through the lactation period with the mean body weights of the dams in the 150 and 400 ppm significantly less than that of the controls through day 7 of lactation ($p < 0.05$ or 0.01). The mean food consumption was likewise affected for all of the treatment groups during gestation (NS, $p < 0.05$ or 0.01). The treatment did not affect the gestation of the fetuses. The mean body weights of the pups in all of the treatment groups during the lactation period were less than those of the control (NS, $p < 0.05$ or 0.01). There was no treatment-related effect on the live birth, viability or lactation indices. For the developmental landmarks, the preputial separation was delayed for the male pups in the 150 and 400 ppm groups (0: 44.9 days vs. 150: 47.1 and 400: 46.8 days, $p < 0.05$). The time to vaginal opening for the females pups was not affected in a dose-related manner. The sperm motility, count and morphology of the male pups were not affected by the treatment. No treatment-related effects were noted in the FOB for either the dams or the pups. The motor activity assessment of the pups did not reveal any treatment-related effects. The auditory startle response, passive avoidance learning and memory and water maze learning and memory assessments did not indicate any treatment-related effects on the pups. No neuropathological lesions were noted in either the 21-day old pups or the 70-day old adults. Morphometric analysis of the brain of these animals did not demonstrate any treatment-related effects. **No adverse effect indicated. Maternal NOEL:** < 3.74 mg/kg/day (based upon lower mean body weights and lower food consumption demonstrated by the 50 ppm dams); **Developmental NOEL:** < 3.74 mg/kg/day (based upon the lower mean body weights of the offspring in the 50 ppm group); **Developmental Neurotoxicity NOEL:** 29.8 mg/kg/day (based upon the lack of a neurologically-related effect noted in the offspring at the highest dose tested); **Study acceptable.** (Moore, 11/22/06)

104 162455 "Acrylamide: Neurotoxicological Screening in Rats--Positive Control Study," (Bury; Hoechst AG, Frankfurt, FRG; 4/11/95). This volume contains a positive control recommended for acute neurotoxicity studies performed in rat. No worksheet. M. Silva, 3/3/99.

103 162456 "Carbaryl: Neurotoxicological Screening in Rats--Positive Control Study," (Bury; Hoechst AG, Frankfurt, FRG; 3/27/95). This volume contains a positive control recommended for acute neurotoxicity studies performed in rat. No worksheet. M. Silva, 3/3/99.

082 126557 "Endosulfan - Active Ingredient Technical: Testing for Subchronic Dermal Toxicity (21 applications over 30 days) in Wistar Rats," (Ebert, Leist and Kramer; Hoechst, AG, FRG; 2/22/85, Study #: 83.0508). Endosulfan technical (97.2% pure) was administered dermally 21 times over 30 days (Mon - Fri) to Wistar rats (6/sex/dose) at 0 (sesame oil), 1, 3, 9, 27 and 81 (males only) mg/kg to the shaved nape skin. Exposure was for 6 hours under an occlusive bandage. Systemic NOEL = 1 mg/kg (Pathological effects were observed in livers of both sexes at ≥ 3 mg/kg. Mortality was observed in males at 9 & 81 mg/kg and in females at 27 mg/kg. Clinical signs in animals that died were increased salivation, blood-encrusted nose, passivity, dyspnea, tono-clonic convulsions and increased respiratory rate.) ChE NOEL < 1 mg/kg (There was a significant decrease in serum ChE in males at ≥ 9 mg/kg, however this decrease was also observed in females at the same dose. Brain ChE was decreased in both sexes at all doses (significant in females at all doses, in males at ≥ 3 mg/kg). No adverse dermal effect. These data are supplemental. M. Silva, 2/24/99.

083 126558 "Endosulfan - Active Ingredient Technical: Testing for Subchronic Dermal Toxicity (21 applications over 30 days) in SPF Wistar Rats," (Ebert, Weigand and Kramer; Hoechst, AG, FRG; 3/11/85, Study #: 83.0118). Endosulfan technical (97.2% pure) was administered dermally 21 times over 30 days (Mon - Fri) to SPF Wistar rats (6/sex/dose--Main group & 5/sex/dose--recovery group) at 0 (sesame oil), 12, 48, 96 and 192 mg/kg (males) or 3, 6, 12 and 48 mg/kg (females) to the shaved nape skin. Exposure was for 6 hours under an occlusive bandage. The recovery group was observed for 14 days after the final dermal treatment. Systemic NOEL = Males = 48 mg/kg; Female = 6 mg/kg (Females at ≥ 12 mg/kg showed pilo-erection, increased salivation and lacrimation. At 48 mg/kg, females also showed blood-encrusted nares and dacryohemorrhage and 4/6 females died between days 2 & 22 following tono-clonic convulsions. Males at 192 mg/kg died (1/6-day 6 & 1/6-day 9). Liver and kidney pathology was observed in males at 192 mg/kg (high dose) and in females at 48 mg/kg (high dose).) ChE NOEL = 48 mg/kg (Serum at 192 mg/kg and brain ChE at 96 mg/kg were significantly decreased in males immediately after treatment. No differences were observed after the recovery period.) No adverse dermal effect. These data are supplemental. M. Silva, 2/26/99.

084 126577 "Endosulfan - Active Ingredient Technical: Testing for Subchronic Inhalation Toxicity (21 exposures in 29 days) in SPF Wistar Rats," (Hollander, Weigand and Kramer; Hoechst, AG, FRG; 8/15/84, Study #: 84.0103). Endosulfan technical (97.2% pure) was administered by inhalation (aerosol, nose only) 21 times over 29 days (Mon - Fri, 6 hours/day) to Wistar rats (15/sex/dose) at 0 (air only), 0 (ethanol - polyethylene 400 (1:1)), 0.5, 1.0 and 2.0 ug/L air. Following the 29 day treatment period, 10/sex/dose were terminated and the remaining 5/sex/dose were observed over a 29 day recovery period. NOEL = 1.0 ug/L (One/10 males at 2.0 ug/L showed poor condition from day 12 until termination. Signs were emaciation, pale skin, squatting position and high-legged position. Bodyweight gains were decreased in males at 2.0 ug/L from day 20 of treatment (not significant). On day 20 of treatment, males showed a significant decrease in food consumption at 2.0 ug/L. Relative water consumption was slightly increased from days 9 to 24 in males at \geq vehicle control (including 0.5, 1.0 & 2.0 ug/L), when compared to air only control. Clinical chemistry for females showed significant (but reversible) effects in chloride, calcium, creatinine and SGOT at 2.0

ug/L.) No adverse inhalation effect was observed. These data are supplemental. M. Silva, 3/2/99.

ADDITIONAL STUDIES AND SUPPLEMENTAL LITERATURE

Volume 182-008 contains the 1982 EPA registration standard.

081 126555 "Progress Report for: Acute Oral Administration (rats); Acute Dermal Application (rabbits) & Acute Eye Application (rabbits)," (Elsea, J.R., Hazleton Laboratories, Falls Church, VA; 1/11/57). This volume contained summarized protocols and data for acute oral, dermal and eye application studies performed with endosulfan technical in rats and rabbits. Acute Oral: Male albino rats (5/dose) were gavaged with 10.0, 21.5, 46.4, 100, 215 and 464 mg/kg endosulfan. Rats were observed for 7 days after dosing (Time = 0, 1, 2, 4, 24 hours & 2, 3, 4, 5, 6 & 7 days). The NOEL = 10.0 mg/kg, LD₅₀ = 110 mg/kg and clinical signs ranged from slight depression, preening, salivation, excessive masticatory movements, lacrimation, exophthalmia and rapid, labored respiration to bloody nasal discharge, ataxia, sprawling of the limbs, tremors, depressed or absent righting, placement and pain reflexes and Straub-like tails. Death was immediately preceded by phonation, tonic and clonic convulsions, gasping and coma. Autopsies for animals which died on study showed hyperemic or hemorrhagic lungs, irritation of the small intestine and congested kidneys and adrenals. Acute Dermal: Albino rabbits (4/dose) were treated dermally, under occlusion, with technical endosulfan (cotton-seed oil) at 0, 46.4, 100, 215, 464 and 1000 mg/kg for 24 hours. Rabbits were observed for 7 days post-dosing (Time = 0, 1, 2, 4, 24 hours & 2, 3, 4, 5, 6 & 7 days). NOEL = 46.4 mg/kg, LD₅₀ = 359 mg/kg and clinical signs showed diarrhea, lacrimation rapid and labored respiration, slight spreading of the limbs, depression, excessive ambulatory movements, tremors, depressed or absent righting and placement reflexes, inability to hold the head erect, running movements of the limbs, phonation and tonic & clonic convulsions. There was slight irritation or erythema at each dose which subsided in surviving animals at 1-4 days. At higher doses, slight atonia and/or slight desquamation during the final 3-4 days was observed. Autopsies for animals which died on study showed congested lungs containing hemorrhagic areas, granular-appearing livers, irritation of the large intestine and congested kidneys. Acute Eye: A group of 3 albino rabbits was treated at 3.0 mg/kg in the conjunctival sac of the left eye of each rabbit. Treated eyes were held closed for 30 seconds following application after which an immediate reading was made. Observations were performed at 1, 4 & 24 hours and daily for the next 6 days. Very mild eye irritation was noted (slight erythema, vascularization of sclera and nictitating membrane & lacrimation) which subsided at 24 hours. No adverse effects on these studies. No worksheets. These data are supplemental. M. Silva, 3/4/99.

081 126556 "Testing of the therapeutic effect of diazepam (Valium®) and phenobarbital (Luminal®) in the event of acute poisoning with endosulfan - active ingredient technical (Code: Hoe 002671 OI ZD97 0003) in Wistar rats," (Ebert & Weigand; Hoechst AG, Frankfurt, FRG; Study #: 83.0114; 5/2/84). Female Wistar rats were treated orally with a single lethal dose (80 mg/kg; 97.2% pure) of endosulfan (vehicle = 2% starch solution). Approximately 10-20 minutes after endosulfan treatment, animals were treated as follows:

Endosulfan mg/kg	Therapeutic Agent	Initial Dose (mg/kg)	Subsequent Dose (mg/kg)	Route of Administration	# Rats
80	--	--	--	--	20

80	Diazepam	2	--	i.p.	5
80	Diazepam	2	2	i.p.	5
80	Diazepam	20	20	i.p.	5
80	Diazepam	60	--	i.p.	10
80	Phenobarbital	50	10	i.p.	10
80	Phenobarbital	70	20	i.p.	10
80	Phenobarbital	70	10	i.p.	10

Subsequent doses were administered before occurrence or after subsidence of the convulsive phase, by the following scheme:

Endosulfan (mg/kg)	Therapeutic Agent/Antidote	Initial 10-20 min	Subsequent 1-6 hr 1-6 d		Lethality After						# Rats
					2 h d	4 h	6 h	1 d	7 d	14	
80	0 (endosulfan)	--	--	--	12	19	19	20			20
80	Diazepam	2	--	--	0	2	4	5			5
80	Diazepam	2	2	--	0	3	4	5			5
80	Diazepam	20	20	--	0	2	3	4	4	4	5
80	Diazepam	60	--	--	0	3	4	10			10
80	Phenobarbital	50	10	--	0	3	5	5	7	7	10
80	Phenobarbital	70	20	--	2	3	3	3	6	6	10
80	Phenobarbital	70	10	10*	1	3	5	5	5	5	10

* = Daily

Although diazepam has anticonvulsive properties it provided only a delay in the lethality of endosulfan, rather than a therapeutic effect. Phenobarbital (anti-epileptic) proved to be an effective therapeutic agent for reducing clinical signs of endosulfan intoxication and lethality rate. These data are supplemental. M. Silva, 3/5/99.