

111401

5-9-96



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

MAY - 9 1996

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Profenofos in Support of the Reregistration Eligibility Decision.

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

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

TO: Mike Metzger, Chief
Risk Characterization Analysis Branch
Health Effects Division (7509C)

Action Requested

Provide a dietary exposure analysis to estimate the chronic and acute dietary exposure and risk from profenofos for uses which are being supported through reregistration.

Discussion

The tolerance expression should be revised to reflect profenofos *per se* as the only regulated residue as per the HED Metabolism Committee decision (See memo, C. Eiden, 11/5/95). Changes in and revocation of existing tolerances, and the addition of a new tolerance, are based on a tolerance reassessment resulting from the changes in the tolerance expression.

Toxicological Endpoint:

The Reference Dose (RfD) used in the analysis is 0.00005 mg/kg bwt/day, based on a NOEL of 0.005 mg/kg bwt/day and uncertainty factor of 100. The NOEL is based on a six month dog feeding study which demonstrated the toxic effect of plasma and red blood cell cholinesterase inhibition (See IRIS). Profenofos is classified as a Group E, negative for carcinogenicity in both rats and mice.

1/11

The endpoint for acute dietary risk assessment is the plasma cholinesterase inhibition (males) and red blood cell cholinesterase inhibition (females) NOEL of 0.5 mg/kg/day. A margin of exposure (MOE) of 10 is considered adequate (See Tox Endpoint Selection Document, 1/26/96).

Residue Information

Tolerances for profenofos are published in 40 CFR §180.404 and 186.4975. Tolerances had been established in/on cottonseed (3.0 ppm), eggs and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep (0.05 ppm) and milk (0.01 ppm). The established tolerances on animal commodities are adequate but should be redefined in terms of profenofos *per se*.

CBRS recommends the revocation of tolerances for poultry commodities and a decrease in the existing tolerance for cottonseed. There are no other suggested revocations or reassessed tolerances (See memo, C. Eiden, 11/5/95). However, even with these crops included in the chronic risk analysis, and the tolerance for cottonseed remaining at the higher tolerance figure, the $\%RfD$ was not exceeded in any subgroup.

Anticipated residues were provided by CBRS (See memo, C. Olinger, 9/12/90) based on cottonseed processing and livestock feeding studies. Note that DRES evaluates all livestock commodities at 100% crop treated because the percent use on cotton (with an assumption of national distribution of food items) is factored into livestock anticipated residues.

As the annual use of profenofos on cotton varies from year to year, the percent crop treated figure used was 10 per cent. This may be an underestimation, but would be accurate for certain years (Personal communication, A. Grube, 4/29/96).

Results

A summary of the residue information included in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC), and anticipated residues to estimate the Anticipated Residue Contribution (ARC) for the general population and 22 subgroups. Summaries of the TMRCs and ARCs and their representations as percentages of the Reference Dose (RfD) are included as Tables 2 and 3. The results of the acute dietary analysis are included in Table 4.

Existing tolerances (See Table 2) result in a TMRC which represents 7.7% of the RfD for the U.S. general population, 21.0% for Non-Nursing Infants (< 1 year old) and 18.1% for children (1-6).

The chronic analysis for profenofos is not a worst case estimate of dietary exposure, and includes some residues at anticipated levels and 100 percent of the commodities assumed to be treated with profenofos. Based on the risk estimates calculated in this analysis, it appears that chronic dietary risk from the uses recommended through reregistration, is not of concern.

Acute Exposure:

The acute analysis (See Table 4) entailed all published uses of profenofos and includes those commodities which CBRS recommends to be revoked. Even with these commodities included in the acute analysis, it appears that acute dietary risk from the uses recommended through reregistration, is not of concern.

The DRES detailed acute analysis estimates the distribution of single-day exposures for the overall U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of sulprofos in the commodity supply.

The Margin of Exposure (MOE) is a measure of how close the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure ($NOEL/exposure = MOE$). Generally, acute dietary margins of exposure greater than 100 tend to cause no dietary concern when the data are compared to an endpoint from an animal study. The lowest MOE value of 250 (See Table 4) is above the acceptable level and demonstrates no acute dietary concern.

Attachments

cc: DRES; Caswell 453AA; CBRS II (C. Eiden), PM-52 K. Davis

TABLE 1

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 266AA

DATE: 04/29/96

PAGE: 1

CHEMICAL Profenofos (Curatron) Caswell #266AA CAS No. 41198-08-7 A.I. CODE: 111401 CFR No. 180.404	STUDY TYPE 6mo feeding- dog NOEL= 0.0050 mg/kg 0.20 ppm LEL= 0.0500 mg/kg 2.00 ppm ONCO: E (Rfd/PR Committee)	EFFECTS Plasma and RBC Che inhibition. Measurements of brain Che not adequate. No evidence of carcinogenicity in rats or mice.	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
			ADI UF -->100 OPP Rfd= 0.000050 EPA Rfd= 0.000000	No data gaps.	HED reviewed 03/03/87 WHO reviewed 1990 Rfd/PR reviewed 11/09/95

FOOD CODE	FOOD	FOOD FORM	PEI.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
270030A	COTTONSEED-OIL	18 PROCESSED OIL	8F2057	P 3.000000	0.025000	PROCESS STUDY	10.00	0.002500
270030A	COTTONSEED-OIL	18 PROCESSED OIL	8F2057	P 3.000000	1.600000	PROCESS STUDY	10.00	0.160000
500000B	MILK-NON-FAT SOL	10 RAW-FRESH OR NFS	8F2057	P 0.010000	0.000100	FEEDING STUDY	100.00	0.000100
500000B	MILK-NON-FAT SOL	21 COOKED-NFS	8F2057	P 0.010000	0.000100	FEEDING STUDY	100.00	0.000100
500000B	MILK-NON-FAT SOL	51 COOKED-CANNED	8F2057	P 0.010000	0.000100	FEEDING STUDY	100.00	0.000100
50000FA	MILK-FAT SOLIDS	10 RAW-FRESH OR NFS	8F2057	P 0.010000	0.000100	FEEDING STUDY	100.00	0.000100
50000FA	MILK-FAT SOLIDS	21 COOKED-NFS	8F2057	P 0.010000	0.000100	FEEDING STUDY	100.00	0.000100
50000FA	MILK-FAT SOLIDS	51 COOKED-CANNED	8F2057	P 0.010000	0.000100	FEEDING STUDY	100.00	0.000100
50000SA	MILK SUG (LACT)	21 COOKED-NFS	8F2057	P 0.010000	0.000100	FEEDING STUDY	100.00	0.000100
50000SA	MILK SUG (LACT)	51 COOKED-CANNED	8F2057	P 0.010000	0.000100	FEEDING STUDY	100.00	0.000100
530018A	BEEF-MEAT BYP	21 COOKED-NFS	8F2057	P 0.050000	0.002000	FEEDING STUDY	100.00	0.002000
530018A	BEEF-MEAT BYP	26 COOKED-FRESH-PICKLED,CORNEED,OR CURED	8F2057	P 0.050000	0.002000	FEEDING STUDY	100.00	0.002000
530018B	BEEF-OTH ORGAN	21 COOKED-NFS	8F2057	P 0.050000	0.002000	FEEDING STUDY	100.00	0.002000
530018B	BEEF-OTH ORGAN	51 COOKED-CANNED	8F2057	P 0.050000	0.002000	FEEDING STUDY	100.00	0.002000
53001DA	BEEF-DRIED	21 COOKED-NFS	8F2057	P 0.050000	0.000200	FEEDING STUDY	100.00	0.000200
53001FA	BEEF-FAT	10 RAW-FRESH OR NFS	8F2057	P 0.050000	0.000200	FEEDING STUDY	100.00	0.000200
53001FA	BEEF-FAT	21 COOKED-NFS	8F2057	P 0.050000	0.000200	FEEDING STUDY	100.00	0.000200
53001FA	BEEF-FAT	22 COOKED-FRESH-BAKED	8F2057	P 0.050000	0.000200	FEEDING STUDY	100.00	0.000200
53001FA	BEEF-FAT	23 COOKED-FRESH-BOILED	8F2057	P 0.050000	0.000200	FEEDING STUDY	100.00	0.000200
53001FA	BEEF-FAT	24 COOKED-FRESH-BROILED	8F2057	P 0.050000	0.000200	FEEDING STUDY	100.00	0.000200
53001FA	BEEF-FAT	25 COOKED-FRESH-FRIED	8F2057	P 0.050000	0.000200	FEEDING STUDY	100.00	0.000200
53001KA	BEEF-KIDNEY	21 COOKED-NFS	8F2057	P 0.050000	0.002000	FEEDING STUDY	100.00	0.002000
53001LA	BEEF-LIVER	25 COOKED-FRESH-FRIED	8F2057	P 0.050000	0.002000	FEEDING STUDY	100.00	0.002000
53001LA	BEEF-LIVER	31 COOKED-FRESH OR CANNED	8F2057	P 0.050000	0.002000	FEEDING STUDY	100.00	0.002000
53001MA	BEEF-LEAN	10 RAW-FRESH OR NFS	8F2057	P 0.050000	0.000200	FEEDING STUDY	100.00	0.000200
53001MA	BEEF-LEAN	21 COOKED-NFS	8F2057	P 0.050000	0.000200	FEEDING STUDY	100.00	0.000200
53001MA	BEEF-LEAN	22 COOKED-FRESH-BAKED	8F2057	P 0.050000	0.000200	FEEDING STUDY	100.00	0.000200
53001MA	BEEF-LEAN	23 COOKED-FRESH-BOILED	8F2057	P 0.050000	0.000200	FEEDING STUDY	100.00	0.000200
53001MA	BEEF-LEAN	24 COOKED-FRESH-BROILED	8F2057	P 0.050000	0.000200	FEEDING STUDY	100.00	0.000200
53002BA	GOAT-MEAT BYP	00 NOT SPECIFIED (NO CONSUMPTION)	8F2057	P 0.050000	0.002000	FEEDING STUDY	100.00	0.002000
53002BB	GOAT-OTH ORGAN	00 NOT SPECIFIED (NO CONSUMPTION)	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
53002FA	GOAT-FAT	23 COOKED-FRESH-BOILED	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53002FA	GOAT-FAT	25 COOKED-FRESH-FRIED	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53002KA	GOAT-KIDNEY	00 NOT SPECIFIED (NO CONSUMPTION)	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
53002LA	GOAT-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
53002MA	GOAT-LEAN	23 COOKED-FRESH-BOILED	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53002MA	GOAT-LEAN	25 COOKED-FRESH-FRIED	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53003AA	HORSE	00 NOT SPECIFIED (NO CONSUMPTION)	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
53005BA	SHEEP-MEAT BYP	21 COOKED-NFS	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
53005BB	SHEEP-OTH ORGAN	21 COOKED-NFS	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 266AA

DATE: 04/29/96

PAGE: 2

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Profenofos (Curacron) Caswell #266AA CAS No. 41198-08-7 A.I. CODE: 111401 CFR No. 180.404	6mo feeding- dog NOEL= 0.0050 mg/kg 0.20 ppm LEL= 0.0500 mg/kg 2.00 ppm ONCO: E (Rfd/PR Committee)	Plasma and RBC CHE inhibition. Measurements of brain CHE not adequate. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP Rfd= 0.000050 EPA Rfd= 0.000000	No data gaps.	HED reviewed 03/03/87 WHO reviewed 1990 Rfd/PR reviewed 11/09/95

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
53005FA	SHEEP-FAT	21 COOKED-NFS	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53005KA	SHEEP-KIDNEY	21 COOKED-NFS	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
53005LA	SHEEP-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
53005MA	SHEEP-LEAN	21 COOKED-NFS	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53005MA	SHEEP-LEAN	31 COOKED-FRESH OR CANNED	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53005BA	PORK-MEAT BYP	21 COOKED-NFS	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
53006BB	PORK-OTH ORGAN	21 COOKED-NFS	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
53006BB	PORK-OTH ORGAN	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
53006FA	PORK-FAT	10 RAW-FRESH OR NFS	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53006FA	PORK-FAT	21 COOKED-NFS	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53006FA	PORK-FAT	23 COOKED-FRESH-BOILED	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53006FA	PORK-FAT	25 COOKED-FRESH-FRIED	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53006FA	PORK-FAT	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53006KA	PORK-KIDNEY	21 COOKED-NFS	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
53006LA	PORK-LIVER	21 COOKED-NFS	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
53006LA	PORK-LIVER	25 COOKED-FRESH-FRIED	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
53006MA	PORK-LEAN	21 COOKED-NFS	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53006MA	PORK-LEAN	25 COOKED-FRESH-FRIED	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
53006MA	PORK-LEAN	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	8F2057	P 0.050000	0.000200	EXTRAPOLATED	100.00	0.000200
55008BA	TURKEY-BYP	21 COOKED-NFS	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
55008BA	TURKEY-BYP	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
55008LA	TURKEY ORGAN	21 COOKED-NFS	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
55008LA	TURKEY ORGAN	25 COOKED-FRESH-FRIED	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
55008MA	TURKEY W/O SKIN	21 COOKED-NFS	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
55008MA	TURKEY W/O SKIN	31 COOKED-FRESH OR CANNED	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
55008MA	TURKEY W/O SKIN	62 COOKED-FRESH OR FROZEN-BAKED	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
55008MB	TURKEY+SKIN	21 COOKED-NFS	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
55008MB	TURKEY+SKIN	25 COOKED-FRESH-FRIED	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
55008MC	TURKEY-UNSPEC	21 COOKED-NFS	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
55013BA	POULTRY, OTH-BYP	00 NOT SPECIFIED (NO CONSUMPTION)	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
55013LA	POULTRY, ORGAN	25 COOKED-FRESH-FRIED	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
55013MA	POULTRY, OTHER	21 COOKED-NFS	8F2057	P 0.050000	0.002000	EXTRAPOLATED	100.00	0.002000
55014AA	EGGS-WHOLE	10 RAW-FRESH OR NFS	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55014AA	EGGS-WHOLE	21 COOKED-NFS	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55014AA	EGGS-WHOLE	22 COOKED-FRESH-BAKED	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55014AA	EGGS-WHOLE	23 COOKED-FRESH-BOILED	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55014AA	EGGS-WHOLE	25 COOKED-FRESH-FRIED	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55014AB	EGGS-WHITE ONLY	10 RAW-FRESH OR NFS	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55014AB	EGGS-WHITE ONLY	21 COOKED-NFS	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55014AB	EGGS-WHITE ONLY	22 COOKED-FRESH-BAKED	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 266AA

PAGE: 3

DATE: 04/29/96

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Profenofos (Curactron) Caswell #266AA CAS No. 41198-08-7 A.I. CODE: 111401 CFR No. 180.404	6mo feeding- dog NOEL= 0.0050 mg/kg 0.20 ppm LEL= 0.0500 mg/kg 2.00 ppm ONCO: E (Rfd/PR Committee)	Plasma and RBC ChE inhibition. Measurements of brain ChE not adequate. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP Rfd= 0.000050 EPA Rfd= 0.0000000	No data gaps.	HED reviewed 03/03/87 WHO reviewed 1990 Rfd/PR reviewed 11/09/95

FOOD CODE	FOOD	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
55014AB	EGGS-WHITE ONLY	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55014AB	EGGS-WHITE ONLY	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55014AC	EGGS-YOLK ONLY	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55014AC	EGGS-YOLK ONLY	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55014AC	EGGS-YOLK ONLY	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55014AC	EGGS-YOLK ONLY	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55015BA	CHICKEN-BYP	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55015LA	CHICKEN-ORGAN	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55015LA	CHICKEN-ORGAN	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55015LA	CHICKEN-ORGAN	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55015MA	CHICKEN-W/O SKIN	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55015MA	CHICKEN-W/O SKIN	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55015MA	CHICKEN-W/O SKIN	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55015MA	CHICKEN-W/O SKIN	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55015MA	CHICKEN-W/O SKIN	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55015MB	CHICKEN+SKIN	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000
55015MB	CHICKEN+SKIN	8F2057	P 0.050000	0.002000	FEEDING	100.00	0.002000

6

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Profenofos (Curacron) Caswell #266AA CAS No. 41198-08-7 A.I. CODE: 111401 CFR No. 180.404	6mo feeding- dog NOEL= 0.0050 mg/kg 0.20 ppm LEL= 0.0500 mg/kg 2.00 ppm ONCO: E. (Rfd/PR Committee)	Plasma and RBC ChE inhibition. Measurements of brain ChE not adequate. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP Rfd= 0.000050 EPA Rfd= 0.000000	No data gaps.	HED reviewed 03/03/87 WHO reviewed 1990 Rfd/PR reviewed 11/09/95

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.000333	0.000333	665.714000	0.000000	0.000004	7.77000
U.S. POPULATION - SPRING SEASON	0.000326	0.000326	652.600000	0.000000	0.000004	7.65400
U.S. POPULATION - SUMMER SEASON	0.000332	0.000332	663.920000	0.000000	0.000004	7.69000
U.S. POPULATION - FALL SEASON	0.000340	0.000340	679.216000	0.000000	0.000004	7.90800
U.S. POPULATION - WINTER SEASON	0.000334	0.000334	667.146000	0.000000	0.000004	7.81800
NORTHEAST REGION	0.000334	0.000334	667.812000	0.000000	0.000004	7.77000
NORTH CENTRAL REGION	0.000335	0.000335	669.622000	0.000000	0.000004	7.32200
SOUTHERN REGION	0.000320	0.000320	639.810000	0.000000	0.000004	7.89000
WESTERN REGION	0.000351	0.000351	702.164000	0.000000	0.000004	8.18800
HISPANICS	0.000403	0.000403	806.174000	0.000000	0.000005	10.36200
NON-HISPANIC WHITES	0.000328	0.000328	655.280000	0.000000	0.000004	7.30800
NON-HISPANIC BLACKS	0.000330	0.000330	659.054000	0.000000	0.000005	9.27800
NON-HISPANIC OTHERS	0.000367	0.000367	733.238000	0.000000	0.000005	9.54400
NURSING INFANTS (< 1 YEAR OLD)	0.000242	0.000242	483.312000	0.000000	0.000003	6.87400
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000861	0.000861	1722.262000	0.000000	0.000011	21.02000
FEMALES (13+ YEARS, PREGNANT)	0.000236	0.000236	472.330000	0.000000	0.000003	5.29600
FEMALES 13+ YEARS, NURSING	0.000285	0.000285	569.606000	0.000000	0.000003	6.66200
CHILDREN (1-6 YEARS OLD)	0.000741	0.000741	1481.308000	0.000000	0.000009	18.10200
CHILDREN (7-12 YEARS OLD)	0.000506	0.000506	1011.548000	0.000000	0.000006	11.09200
MALES (13-19 YEARS OLD)	0.000360	0.000360	719.892000	0.000000	0.000004	7.88800
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000288	0.000288	576.774000	0.000000	0.000003	6.33200
MALES (20 YEARS AND OLDER)	0.000259	0.000259	518.862000	0.000000	0.000003	6.04600
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000222	0.000222	444.762000	0.000000	0.000003	5.33200

*Current TMRC does not include new or pending tolerances.

**New TMRC includes new, pending, and published tolerances.

TABLE 3

TOLERANCE ASSESSMENT SUMMARY FOR Profenofos (Curacron)
USING ANTICIPATED RESIDUES
CASWELL #266AA

DATE: 04/29/96

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

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)
RESULT IN AN ARC OF: 0.000004 MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO: 7.770 % OF THE ADI.

NO NEW ANTICIPATED RESIDUES ARE IN THE FILE.

NO OTHER PENDING ANTICIPATED RESIDUES ARE IN THE FILE

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)
RESULT IN AN ARC OF: 0.000011 MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO: 21.020 % OF THE ADI.

NO NEW ANTICIPATED RESIDUES ARE IN THE FILE.

NO OTHER PENDING ANTICIPATED RESIDUES ARE IN THE FILE

TABLE 4

DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 09:15 Tuesday, April 30, 1996 22

 *NAME: PROFENOFOS
 CASWELL NO: 266AA CFR NO: CFR180.404 A 00000.0005 000000.200 000100 Chronic Dog EFF. LEV. CORE GRADE DOC. NO.
 *CAS NO: 41198-08-7 SHAUGHNESSY NO: 111401 B 00000.0300 000000.300 000100 Chronic Rat Enzymatic Minimum *
 STATUS CODES: RPA C 00000.2000 000001.000 000100 Reprductn Rat Enzymatic Minimum 0000000821
 RDV INFO: The LD value used in this analysis is 0.0001 MG/KG of BODY WEIGHT/DAY Rat Enzymatic Minimum 0000000822
 FILE INFO: No Tolerance Data Are Used--Without User Modifications. AR DATA: No User Modifications

 -U.S. POP.--48 STATES *****

ESTIMATED % OF POTENTIAL MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
0.00	0.000000	0.00
99.67	0.000336	335.54

ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

X	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:	100	100	99	98	95	92	89	84	79	74	68	43	26	17	3	0	0

INFANTS(<1 YEAR)

ESTIMATED % OF POTENTIAL MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
0.00	0.000000	0.00
89.32	0.000823	822.97

ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

X	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:	100	99	98	98	97	96	96	95	94	94	93	88	82	73	31	8	3

CHILDREN(1-6 YRS)

ESTIMATED % OF POTENTIAL MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
0.00	0.000000	0.00
99.90	0.000761	760.99

ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

X	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:	100	100	100	100	100	100	99	99	99	98	98	94	85	74	19	3	1

1 DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 09:15 Tuesday, April 30, 1996 23

 *NAME: PROFENOFOS
 CASHELL NO: 266AA CFR NO: CFR180.404 A 00000.0005 000000.200 000100 Chronic Dog EFF. LEV. CORE GRADE DOC. NO.
 *CAS NO: 4198-08-7 SHAUGHNESSY NO: 111401 B 00000.0300 000000.300 000100 Chronic Rat Enzymatic Minimum
 STATUS CODES: RPA C 00000.2000 000001.000 000100 Reproductn Rat Enzymatic Minimum 0000000821
 *RDV INFO: The LD value used in this analysis is 0.0001 MG/KG of BODY WEIGHT/DAY
 FILE INFO: No Tolerance Data are Used--Without User Modifications. AR DATA: No User Modifications

 - FEMALES(13+ YRS)

ESTIMATED % OF POTENTIAL

PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
0	0.00	0.00
99	99.75	234.48

ANTICIPATED RESIDUES:

ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=	1	2	3	4	5	10	15	20								
0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20

TOLERANCES:

MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
100	0	0
99	0	0
98	0	0
96	0	0
93	0	0
88	0	0
82	0	0
76	0	0
69	0	0
62	0	0
55	0	0
25	0	0
10	0	0
4	0	0
0	0	0

MALES(13+ YRS)

ESTIMATED % OF POTENTIAL

PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
0	0.00	0.00
99	99.87	280.39

ANTICIPATED RESIDUES:

ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=	1	2	3	4	5	10	15	20								
0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20

TOLERANCES:

MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
100	0	0
100	0	0
99	0	0
98	0	0
96	0	0
94	0	0
91	0	0
86	0	0
81	0	0
75	0	0
68	0	0
37	0	0
17	0	0
8	0	0
0	0	0

General U.S. Population
 Exposure = RDV x X
 = 0.0001 x 15
 High End Exposure = 0.0015
 MOE = Noel + Exposure
 = 0.5 mg/kg/day + 0.0015 mg/kg/day
 MOE = 333

Infants (< 1 year)

Exposure = RDV x X
= 0.0001 x 20
High End Exposure = 0.002

MOE = Noel + Exposure
= 0.5 mg/kg/day + 0.002 mg/kg/day
MOE = 250

Children (1-6 years)

Exposure = RDV x X
= 0.0001 x 20
High End Exposure = 0.002

MOE = Noel + Exposure
= 0.5 mg/kg/day + 0.002 mg/kg/day
MOE = 250

Females (13+ Years):

Exposure = RDV x X
= 0.0001 x 10
High End Exposure = 0.001

MOE = Noel + Exposure
= 0.5 mg/kg/day + 0.001 mg/kg/day
MOE = 500

Males (13+ Years):

Exposure = RDV x X
= 0.0001 x 10
High End Exposure = 0.001

MOE = Noel + Exposure
= 0.5 mg/kg/day + 0.001 mg/kg/day
MOE = 500