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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Assessment for Parathion

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THRU: Charles L. Trichilo, Chief
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TO: Bruce Kapner, PM#70
Special Review Branch
Registration Division (TS-767)

Residue Chemistry Branch has been requested to prepare a dietary exposure assessment for parathion [O,O-diethyl-O-p-nitrophenyl thiophosphate], based on FDA Monitoring data and FDA Total Diet Study data. Parathion is currently the subject of a Registration Standard. Most of the parathion tolerances were established during the 1950 Spray Residue Hearings; consequently, few residue data are available in RCB files for registered uses of parathion. Tolerances have been established for residues of parathion, per se, on a wide variety of crops, ranging from 0.1(N) to 5.0 ppm (40 CFR 180.121).

Nature of the Residue-Plants

The nature of the residue in plants is not adequately understood. Additional metabolism studies in cottonseed and cotton forage, wheat grain and forage, and potatoes are being required as part of the registration standard. However, the following metabolites of parathion have been identified in cotton, spinach, and/or bean foliage: paraoxon [O,O-diethyl-O-p-nitrophenyl phosphate; aka parathion oxygen analog], S-ethyl parathion [O,S-diethyl-O-p-nitrophenyl phosphate], S-phenyl parathion [O,O-diethyl-S-p-nitrophenyl phosphate], p-nitrophenol, O,O-diethyl phosphate, amino parathion [O,O-diethyl-O-p-aminophenylphosphorothioate], and amino paraoxon [O,O-diethyl-O-p-aminophenyl phosphate].

Nature of the Residue-Animals

The nature of the residue in animals is not adequately understood. Additional metabolism data are being requested as part of the registration standard. No tolerances are currently established for residues of parathion in or on any animal commodities. Residues of parathion, per se, are found in animal feed items. Metabolism data and feeding studies are needed to determine if residues transfer to meat, milk, poultry, and eggs.

Note to PM: The 3(c)2(b) letter requesting metabolism and residue data must be issued ASAP to avoid missing an entire growing season.

Analytical Methods

Parathion and paraoxon can be detected by the GC multiresidue method for organophosphates in PAM I. The methods involve acetonitrile extraction and detection using a thermionic, flame photometric, or N/P detector. These methods were used for the FDA monitoring data and most of the petition data discussed in this memo. Residue data in the earlier petitions (PP#32, PP#289) were generated using a colorimetric method.

Residue Data

A limited amount of residue data is available in the following petitions:

PP#32	clover, corn forage, forage grasses, hops, oats, olives, pea forage, and wheat
PP#289	rice
PP#8E0718	sunflower seed
PP#9E0823	alfalfa
PP#0F0878	cottonseed, soybeans
PP#1F1091	almonds, almond hulls, beet greens, sugar beets, filberts, pecans, potatoes, safflower seed, sorghum, sorghum forage and fodder, sugarcane, sugarcane fodder, sweet potatoes, and walnuts
PP#3E1302	mustard seed and rape seed

Alfalfa (PP#32). Residues ranged from 0 to 0.49 ppm, two to eight days after treatment.

Alfalfa hay (PP#9E0823). Residues ranged up to 12.6 ppm with application rates of 0.625 lb ai/A and 0.5 lb ai/A, and PHI's of 20 days.

Peanut hay (PP#32). Residues of 0.2 ppm were reported in two analyses with PHI's of 9 and 14 days.

Timothy hay (PP#32). A residue of 0.75 ppm parathion was found after treatment with 1% parathion dust at the rate of 52 lb/A.

Corn (PP#32). Two samples of corn husks were reported to have "nil" residue 24 days after application of 2% parathion dust was applied at 35 lb/A.

Wheat (PP#32). Two samples were analyzed. Parathion was applied at slightly less than the recommended rate. Residues of 0.05 ppm were found at a 10 day PHI, and 0.06 ppm at a 26 day PHI.

Milk (PP#32). A published study was submitted. However, the study is inadequate to determine residues of parathion in milk.

Rice (PP#289). A single aerial application of 0.1 lb ai/A was made. Residues of parathion were <0.1 ppm at a 7 day PHI.

Pasture Grass (PP#289). Two aerial applications of 0.1 lb ai/A were made. Residues of 0.7 ppm parathion were reported after 7 days.

Sunflower seed (PP#8G0718). Fields were sprayed three and four times at the rate of 1 lb ai/A. Residues averaged 0.04 ppm parathion with PHI's of 14 to 48 days. No data were submitted on the processed fractions of sunflower seed, or sunflower forage.

Soybeans (PP#0F0878). One or two 1x or 2x applications were made. Residues of parathion and paraoxon were non-detectable (<0.02 ppm) in all samples. PHI's ranged from 16 to 37 days.

Almonds (PP#1F1091). No residues (<0.05 ppm) of parathion or paraoxon were found on almonds treated at 3 lb ai/A and a PHI of 30 days. From extrapolation of the data, it was determined that almond hulls would have residues of slightly less than 3.0 ppm (J. Wolff, 9/26/72).

Pecans (PP#1F1091). No residues of parathion or paraoxon were detected (<0.05 ppm) in pecans treated at 5.4 and 10.8 lb ai/A (1x and 2x), with PHIs of 55 days.

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Walnuts (PP#1F1091). One sample treated once at 8 lb ai/A (0.8x) showed no residue or parathion or paraoxon at 111 days.

Potatoes (PP#1F1091). Foliar applications at 1 and 2 lb ai/A (1x and 2X) resulted in no detectable residue (<0.05 ppm) of parathion or paraoxon at 29 days.

Safflower (PP#1F1091). One study using a single application of parathion at 1 lb ai/A (2x) showed no detectable residues in the whole seed (<0.05 ppm) and no detectable residues in the meal or oil (<0.2 ppm).

Sugarcane (PP#1F1091). Four studies at 6 lb ai./A (1x) showed no detectable residue (<0.05 ppm) of parathion or paraoxon.

Mustard seed (PP#3E1302). Ten samples treated at 1x or 2x were analyzed. The maximum residue found was 0.06 ppm parathion at PHI's of 20-30 days. No paraoxon was detected. No data were submitted on mustard greens.

Rape seed (PP#3E1302). No residues were detected (<0.01 ppm) in four samples treated once or twice. PHI's were 28-38 days. No data were submitted on rapeseed foliage.

The data summarized above, while they may be inadequate for the reevaluation of the tolerances, are sufficient to estimate residues for the purposes of the special review. Non-detectable residues of parathion and paraoxon are expected in nut crops, oil seeds, soybeans, and potatoes. No detectable residues of parathion, per se, are expected in rice. Residues of parathion in alfalfa are consistent with those found by FDA in their monitoring program.

FDA Monitoring Data

Surveillance Monitoring data (objective sampling) were received from FDA. These samples were collected in FY 84 and FY 85. The tolerance for each of the commodities sampled, along with the total number of samples, the average residue, the maximum residue, and the 95% confidence limit of an individual value (assuming a log-normal distribution) are presented below.

Commodity	Tolerance (ppm)	#samples	average residue	maximum residue	95% Confidence limit
Alfalfa meal	1.25	66	0.01	0.18	0.01
Apples	1	540	0.01	0.08	0.01
Artichokes	1	46	0.03	1.00	0.02
Barley	1	42	0.01	0.18	0.02
Beans, Green	1		ND	ND	-
Beets	1	58	ND	T	-
Black beans	1	10	ND	T	-
Blackberries	1	>16	ND	ND	-

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Commodity	Tolerance (ppm)	#samples	average residue	maximum residue	95% Confidence limit
Boysenberries	1	17	0.01	0.10	0.02
Broccoli	1	279	0.01	0.03	0.01
Cabbage	1	462	0.01	0.23	0.01
Cantaloupe	none	410	T	0.01	-
Carrots	1	298	0.01	0.08	0.01
Carrot byp.	1	10	0.01	0.05	0.01
Celery	1	167	0.01	0.05	0.01
Cherries	1	125	0.02	0.63	0.04
Chick peas	1	6	ND	ND	-
Chinese cabbage	none	60	0.01	0.25	0.01
Coriander	none	71	T	0.05	-
Corn	1		ND	ND	
Cranberries	1	62	0.05	0.72	0.15
Dill	none	2	ND	ND	-
Endive	1	114	0.01	0.09	0.01
Grapes	1	320	0.01	0.03	0.01
Hops	1	2	0.03	0.06	-
Kale	1	37	0.01	0.10	0.01
Lemons	1	58	0.01	0.15	0.01
Lettuce	1	1322	0.01	0.46	0.01
Limes	1	38	ND	ND	-
Melons	1		ND	ND	
Mung Beans	1	45	0.01	0.06	0.01
Mustard Greens	1	85	T	0.01	-
Mushrooms	none	46	T	T	-
Nectarines	1	126	T	0.01	-
Oats	1	152	0.01	0.12	0.01
Oilseed Byp.	0.1	77	ND	ND	-
Okra	1	189	0.01	0.04	0.01
Onions	1	196	0.01	0.05	0.01
Oranges	1	306	0.01	0.36	0.01
Parsley	none	60	0.09	4.10	0.04
Parsnips	1	35	0.01	0.25	0.01
Peaches	1	241	0.02	0.40	0.03
Peanuts	1	47	ND	ND	-
Pears	1	>70	ND	ND	-
Peas	1	499	0.01	0.14	0.01
Peppers	1	1205	0.01	0.83	0.01
Pineapple	1		ND	ND	
Plums	1	>86	ND	ND	-
Radishes	1	141	0.08	4.60	0.03
Raspberries	1	153	0.01	0.12	0.01
Rice	1		ND	ND	
Rice Bran	1	10	T	0.02	-
Rutabagas	1	31	T	T	-
Sesame Seed	none	14	ND	ND	-
Sorghum	0.1(N)	66	T	T	-
Soybeans	0.1(N)	>37	ND	ND	-
Spinach	1	179	0.01	0.44	0.01
Squash	1	747	0.01	0.06	0.01

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Commodity	Tolerance (ppm)	#samples	average residue	maximum residue	95% Confidence limit
Strawberries	1	515	0.01	0.06	0.01
Sweet potatoes	1	77	0.01	0.05	0.01
Tangerines	1	199	ND	ND	-
Tomatoes	1	1424	T	0.02	0.01
Wheat	1	87	0.01	0.02	0.01

Paraoxon was detected in some of the FDA monitoring samples. Paraoxon was detected in one tomato sample (0.06 ppm), 10 cherry samples (T-0.15 ppm), 12 cranberry samples (T), and one endive sample (0.02 ppm).

FDA has summarized earlier monitoring data in a published report (Duggan, 1983). The report includes FDA Surveillance Monitoring data and data from the USDA National Residue Program from FY 69 - FY 76. Samples are grouped into commodity groups similar to those used previously for the FDA Total Diet Studies. Data on domestic and import samples are reported separately. The percentage of positive samples, the average residue, and the maximum residue are reported. These data are tabulated below.

Parathion Residues in Domestic Samples

	% Positive Samples	Average Residue (ppm)	Maximum Residue (ppm)
Dairy Products	0	ND	ND
Meat & Poultry	0	ND	ND
Eggs & Egg Products	1.4	-	-
Fish & Shellfish	0	ND	ND
Large Fruits	14.0	0.014	8.05
Small Fruits	11.0	0.006	1.00
Leaf & Stem Vegetables	21.8	0.046	13.65
Vine & Ear Vegetables	2.1	0.001	0.5
Beans	4.7	0.003	0.5
Root Vegetables	3.8	0.003	1.0
Grains	1.9	0.001	0.5
Grains-Animal Feed	1.1	0.0004	0.1
Processed Vegetable Products	6.7	0.051	13.90
Processed Fruit Products	9.1	0.004	0.5
Miscellaneous Processed Foods	1.1	0.002	2.0
Infant & Junior Foods	1.5	0.0008	0.5
Nuts	<1.0	-	-
Corn & Corn Products	0.4	0.0001	0.03
Cottonseed & Products	0	ND	ND
Peanuts & Products	0.7	0.0001	0.03

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	% Positive Samples	Average Residue (ppm)	Maximum Residue (ppm)
Soybeans & Products	0	ND	ND
Miscellaneous Animal Feeds	1.1	0.0009	0.5
Hay	6.3	0.010	1.0
Dehydrated Hay	14.3	0.038	2.68
Animal Byproducts	0	ND	ND
Fish Byproducts	0	ND	ND
Oilseed Byproducts	2.6	0.060	7.60
Grain Grain	1.2	0.0004	0.10
Cereal Byproducts	5.5	0.001	0.1
Vegetable Byproducts	2.9	0.006	1.0
Silage	<1	-	-

Parathion Residues in Import Samples

	% Positive Samples	Average Residue (ppm)	Maximum Residue (ppm)
Large Fruits	1.0	0.004	0.5
Small Fruits	1.1	0.003	2.0
Leaf & Stem Vegetables	8.5	0.016	1.0
Vine & Ear Vegetables	5.8	0.004	1.0
Beans	6.5	0.005	1.0
Root Vegetables	6.7	0.007	0.5
Grains	1.2	0.0008	0.1
Grain-Animal Feed	2.6	0.0004	0.03
Processed Vegetable Products	2.5	0.003	1.0
Processed Fruit Products	2.1	0.001	0.5
Miscellaneous Processed Foods	2.1	0.002	0.5

Residues of parathion, per se, are generally not found in meat, milk, poultry, and eggs. Residues in other commodities are generally much lower than the established tolerances. We recommend that a range of risks be calculated, ranging from the average residue found to the maximum residue found.

Residues of Parathion in Foods as determined by FDA Total Diet Studies

Analyses for parathion in foods are included in the FDA Total Diet Studies (Market Basket Surveys). FDA Market Basket Survey data FY 65 through FY 81/82 have been published (see list of references). Market basket survey data collected from 1982 to 1985 have not yet been published by FDA, but

have been made available to EPA for review. Paraoxon is also detected in the market basket surveys from 1982 to 1985.

Up until April, 1982, FDA Market Basket Surveys represented a two to four week food supply for the diet of a 16 to 19 year old male. Up through 1974, 30 market basket samples were taken each year. From 1974 to 1981/82, 20 market basket samples were taken each year. Each market basket consisted of 117 food items. The food items were prepared as ready to eat foods and composited into 12 classes of commodities: dairy products; meat, fish and poultry; grain and cereal products; potatoes; leafy vegetables; legume vegetables; root vegetables; garden fruits; fruits; oils, fats, and shortening; sugars and adjuncts; and beverages. These 12 composites were then analyzed for pesticide and other residues. In some years, the dairy product items, and the meat, fish, and poultry items were also analyzed separately. It is important to note that trace levels (levels greater than the limit of detection, but less than the level of quantitation) were averaged as zero. In FY 74, results were also reported with trace levels averaged as approximately one half the limit of quantitation.

Since FY 75, the FDA has also conducted Total Diet Studies for infant and toddler diets. Ten market baskets per year were collected from FY 75 to April, 1982, representing a basic 14 day diet for 6 month old infants and 2 year old toddlers. The foods were prepared as they would be at home and composited into eleven commodity classes. These classes are drinking water; whole milk, fresh; other dairy and substitutions; meat, fish, and poultry; potatoes; vegetables; fruit and fruit juices; oils and fats; sugars and adjuncts; and beverages.

Since April, 1982, only four market baskets per year have been taken. The revision of the FDA Total Diet Studies was described by Pennington (1983). Diets for 8 age-sex groups are now available (infants, young children, male and female teenagers, male and female adults, and male and female older persons). Each market basket consists of 234 individual food items prepared as ready to eat foods. Individual foods are no longer composited into the 12 classes of commodities, but are analyzed separately. These data have not yet been published by FDA, but have been made available to EPA for review. Paraoxon (parathion oxygen analog) is also detected in these analyses.

The FDA Total Market Basket Survey Data are presented here for consideration in assessing dietary exposure, although the following deficiencies in these data are noted.

1. From FY 65 to April, 1982, the samples were composited. It is, therefore, impossible to determine the range of the individual components

of the samples. These data, then, do not represent worst case estimates of dietary exposure. Additionally, compositing could lead to dilution of a residue to below the limit of detection.

2. The number of samples is limited (20-30 samples of each of 12 food groups through FY 81/82, and four samples per year of each of 234 individual food items since 1982). The samples are not likely to be representative.
3. Minor crops are not covered.
4. The treatment history of the samples is unknown. It is highly unlikely that 100% of the samples have been treated at the maximum rate and minimum PHI.

The FDA Market Basket Survey data from FY 65 to FY 81/82 are presented in the tables below.

Parathion residues found in Composite Samples by Food Group

Adult Total Diet Studies

Food Group	Maximum Residue	
	FY79-82	FY65-82
Dairy Products	ND	ND
Meat, Fish, Poultry	ND	ND
Grain, Cereal	0.001	0.006
Potatoes	T	0.003
Leafy Vegetables	0.010	0.090
Legumes	0.001	0.035
Root Vegetables	0.010	0.010
Garden Fruits	0.001	0.093
Fruits	0.005	0.005
Oils and Fats	0.001	0.001
Sugars and Adjuncts	NE	ND
Beverages	ND	ND

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Maximum Parathion Residues from
Infant and Toddler Total Diet Studies FY76-FY81/82

Food Group	Infant	Toddler
water	ND	ND
milk	ND	ND
other dairy	ND	ND
meat, fish, poultry	ND	ND
grain, cereal	0.001	T
potato	ND	ND
vegetables	T	0.001
fruit & juice	0.001	0.003
oil & fat	T	0.003
sugar & adjuvants	ND	ND
beverages	ND	ND

Since April, 1982, eleven market baskets have been analyzed. Parathion residues were found in the individual food items tabulated below. Paraoxon was not found in any of the foods.

	# Positive Samples	Maximum Residue (ppm)
Peaches	9	0.042
Applesauce	5	0.009
Peaches (infant)	5	0.006
Peas	3	0.005
Spinach	1	0.007
Green Pepper	1	0.008
Radish	1	0.015
Ice Cream Sandwich	1	0.010
All Others	≤3	0.005

As part of the Total Diet Studies, the FDA also calculates the average daily intake of parathion for a 69.1 kg male teenager, and for infants and toddlers. The average daily intake of parathion for adults, infants, and toddlers were reported as follows.

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Average Daily Intake of Parathion (ug/kg/day)

	<u>Adult</u>	<u>Infant</u>	<u>Toddler</u>
FY65	ND		
FY66	0.01		
FY67	0.01		
FY68	0.01		
FY69	0.01		
FY70	0.003		
FY73	0.0029		
FY74	0.0019		
FY75	0.0010	T	T
FY76	0.0009	0.0008	T
FY77	0.0016	0.0112	0.0005
FY78	0.0036	0.0046	0.0027
FY79	0.0027	0.002	0.002
FY80	0.0010	0.003	ND
FY81/82	0.0027	0.003	0.002

CONCLUSIONS AND RECOMMENDATIONS

Residues of parathion, per se, are generally not found in meat, milk, poultry, and eggs. Residues in other commodities are generally much lower than the established tolerances. Non-detectable residues of parathion and paraoxon are expected in nut crops, oil seeds, soybeans, and potatoes. Non-detectable residues of parathion, per se, are expected in rice.

We recommend that a range of risks be calculated, ranging from the average residue found to the maximum residue found.

Note to PM: The 3(c)2(b) letter requesting metabolism and residue data must be issued ASAP to avoid missing an entire growing season.

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