

US EPA ARCHIVE DOCUMENT



ASM
06/OPP#
C

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

RECEIVED

September 10, 1998

FOR PUBLIC DOCKET

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

11PP

MEMORANDUM

SUBJECT: Parathion Reregistration. Anticipated Residue Estimates Based on Available Monitoring Data.

DP Barcode No.: D249346

Chemical No.: 057501

Reregistration Case No.: 0155

FROM: Bonnie Cropp-Kohlligian, Environmental Scientist
Reregistration Branch II
Health Effects Division [7509C]

Bonnie Cropp-Kohlligian

THRU: Alan P. Nielsen, Branch Senior Scientist
Reregistration Branch II
Health Effects Division [7509C]

Alan P. Nielsen 9/10/98

TO: Richard Griffin, Risk Assessor
Reregistration Branch II
Health Effects Division [7509C]

Parathion anticipated residue (AR) estimates were provided in the Residue Chemistry Chapter for the Parathion Reregistration Eligibility Decision (RED) document dated 5/27/98. Subsequent dietary risk analyses for parathion using these AR estimates indicated the need for further refinements to the parathion dietary exposure estimates. Table 1 below summarizes AR estimates for residues of parathion and paraoxon in/on commodities of soybeans, barley, corn, and wheat which are based on available monitoring data and incorporate percent crop treated data as well as available processing data.

1911

Table 1: Anticipated Residue (AR) estimates for the combined residues of parathion and paraoxon in/on soybeans, barley, corn, and wheat commodities. [NOTE: Percent crop treated data provided in the most recent parathion usage report (dated 6/3/98) issued by BEAD have been incorporated into the average AR estimates and should not be used in the DEEM analyses for chronic or acute dietary risk.]

Food Code	Food Name/Food Form	Anticipated Residues		Source
		Average Residue (ppm)	95th Percentile (ppm)	
Soybean				
270100A	Soybean-oil	0.00007	0.006	Based on FDA monitoring data from whole grain, soybean samples. Note: No soybean processing data are available; however, based on available cottonseed processing data which indicate that residues of parathion and paraoxon do not concentrate in refined cottonseed oil, the maximum theoretical concentration factor for soybean oil has not been applied to the AR estimates for soybean oil.
28023AA	Soybeans-unspecified	0.00007	0.006	
28023AB	Soybeans-mature, seeds dry	0.00007	0.006	
28023WA	Soybeans-flour, full fat	0.00007	0.006	
28023WB	Soybeans-flour, low fat	0.00007	0.006	
28023WC	Soybeans-flour, defatted	0.00007	0.006	
Corn				
15004AA	Corn-pop	0.00006	0.006	Based on FDA monitoring data from whole grain, corn and whole grain, popcorn samples.
24002EA	Corn, grain-endosperm	0.00006	0.006	
24002HA	Corn, grain-bran	0.00006	0.006	
24002SA	Corn sugar	0.00006	0.006	
270020A	Corn, grain-oil	0.0002	0.02	Based on the AR estimate for corn grain derived from FDA monitoring data multiplied by the concentration factor for refined corn oil (3x) determined from processing data.
Wheat				
24007AA	Wheat-rough	0.0003	0.02	Based on PDP monitoring data from whole grain, wheat samples.
24007GA	Wheat-germ	0.0003	0.02	
24007WA	Wheat-flour	0.0002	0.006	Based on FDA monitoring data from wheat flour.
24007HA	Wheat-bran	0.002	0.1	Based on the AR estimate for wheat grain derived from PDP monitoring data multiplied by the concentration factor for wheat bran (4.6x) determined from processing data.

29/11

Food Code	Food Name/Food Form	Anticipated Residues		Source
		Average Residue (ppm)	95th Percentile (ppm)	
Barley				
24001AA	Barley	0.0003	0.02	Translated from the wheat grain AR estimate which is based on PDP monitoring data. Note: The maximum use rates of parathion on wheat and barley are the same and the percent of wheat and barley crops treated with parathion are essentially the same.

BACKGROUND

Parathion [*O,O*-diethyl *O-p*-nitrophenyl thiophosphate] is an insecticide registered for use on alfalfa, barley, corn, cotton, canola, sorghum, soybean, sunflower, and wheat.

Parathion is a List A reregistration chemical and was the subject of a Registration Standard dated 4/8/85, its associated Guidance Document dated 12/86, and a Reregistration Standard Update dated 8/17/93. The Residue Chemistry Chapter for the Parathion Reregistration Eligibility Decision (RED) document was completed 5/27/98.

The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlligian dated 5/21/98) has tentatively concluded that parathion residues of concern in plant commodities include parathion, its metabolite paraoxon [*O,O*-diethyl-*O-p*-nitrophenyl phosphate], and *p*-nitrophenol. The tolerance expression for plant commodities may be based on parathion only. Parathion residues of concern to be included in the risk assessment for plant commodities will include parathion and paraoxon. Residues of *p*-nitrophenol resulting from the use of parathion do not have to be included in the tolerance expression or considered in the aggregate risk assessment for parathion, but should be considered in conjunction with the cumulative risk assessment for *p*-nitrophenol.

For reregistration and risk assessment purposes, adequate plant metabolism data are available. Adequate field trial data for parathion residues of concern are available for all registered commodities, with the following exceptions: alfalfa RACs (forage and hay), aspirated grain fractions, barley RACs (grain, hay, and straw), cotton gin byproducts, soybean forage, and wheat RACs (grain, forage, hay, and straw). Adequate processing data for parathion residues of concern are available for all processed commodities except for soybean processed commodities and sunflower seed oil. Wheat processing data will be translated to the processed products of barley.

DETAILED CONSIDERATIONS

A minimum of 100 samples for a given commodity are required to provide sufficient monitoring data from which to calculate AR estimates (see the Draft OPP Policy for the Use of Anticipated Residues of Pesticides in Foods for Use in Chronic Dietary Exposure Assessments). Sufficient FDA surveillance monitoring data (United States only) collected in 1992-1996 (see Appendix A for details) are available for residues of parathion *per se* in/on corn grain (144 samples of whole grain corn plus 53 samples of whole grain popcorn), soybeans (175 samples of whole grain soybeans), wheat grain (692 samples of whole grain wheat), and wheat flour (112 samples of a variety of wheat flours). The limit of detection (LOD) for residues of parathion *per se* in/on analyzed samples is not known; however, the stated limit of quantitation (LOQ) for residues of parathion *per se* in/on analyzed samples is 0.02 ppm and; therefore, the calculated LOD for residues of parathion *per se* in/on analyzed samples is 0.006 ppm (i.e., the LOQ multiplied by 0.3).

Some FDA monitoring data are available for residues of paraoxon *per se* in/on some commodities analyzed; however, the number of samples analyzed for residues of paraoxon *per se* is insufficient for AR estimates. It should be noted that no residues of paraoxon were detected in/on any commodity analyzed. The LOD for residues of paraoxon *per se* in/on analyzed samples is not known; however, the stated LOQ for residues of paraoxon *per se* in/on analyzed samples is the same as for residues of parathion, 0.02 ppm.

Only samples collected from the United States will be used in the AR estimates. It is assumed that most of the corn grain, wheat grain, soybeans, barley grain and wheat flour consumed in the United States is domestically produced. Furthermore, no detectable residues of parathion or paraoxon were found in/on any imported corn grain, wheat grain, soybean, barley grain, or wheat flour sample analyzed in the FDA surveillance monitoring program from 1992 to 1996 and the number of these import samples is not sufficient to calculate AR estimates.

Sufficient PDP monitoring data collected in 1995 and 1996 are available for residues of parathion *per se* in/on wheat grain (940 samples of wheat grain). The stated LOD for residues of parathion *per se* in/on wheat grain is 0.013 ppm. PDP monitoring data are not available for residues of paraoxon.

Sufficient monitoring data are not available to calculate AR estimates for residues of parathion in/on barley grain commodities. Since the maximum use rates of parathion on wheat and barley are the same and the percent of wheat and barley crops treated with parathion are essentially the same, AR estimates for parathion residues of concern in/on wheat grain will be translated to barley grain.

The most recent parathion usage information (dated 6/3/98) issued by BEAD indicates that parathion is used on very small percentages of barley (1%), corn (1%; excluding sweet corn

which is 8%), soybeans (1%), and wheat (2%) domestic acreage. Percent crop treated data will be incorporated into the average residue estimates. For the average residue estimates, a value of zero will be used for the number of samples equal to the percentage of crop not treated multiplied by the total number of samples analyzed.

Soybean AR estimates:

Monitoring Data Summary:

FDA Surveillance Data (United States only) from 1992 to 1996:

175 Samples of Whole Grain, Soybeans were analyzed for parathion

0 Samples had detectable residues of parathion

Average Residue Calculation:

Assumptions for calculating the average combined residue level of parathion and paraoxon:

- 1% of domestic soybeans are treated with parathion
- 173 of the 175 samples analyzed had nondetectable residue levels of parathion estimated at zero for residues of parathion
- 2 of the 175 samples analyzed had nondetectable residue levels of parathion estimated at ½LOD or 0.003 ppm
- Residue levels of paraoxon are assumed to equal the residue levels of parathion

Average parathion residue in/on soybeans:

$$(2 \text{ samples})(0.003 \text{ ppm}) / (175 \text{ samples}) = 0.0000342 \text{ ppm}$$

Average combined residues of parathion and paraoxon in/on soybeans.

$$(0.0000342 \text{ ppm})(2) = 0.00007 \text{ ppm}$$

95th Percentile Calculation:

Assumptions for calculating the 95th percentile residue level of parathion and paraoxon combined:

- Soybeans is a highly blended commodity
- Residue levels of paraoxon are assumed to equal the residue levels of parathion

The 95th percentile of soybean samples analyzed had nondetectable residues of parathion estimated at ½LOD or 0.003 ppm

The 95th percentile of combined residues of parathion and paraoxon in/on soybeans:

$$(0.003 \text{ ppm})(2) = 0.006 \text{ ppm}$$

Corn grain AR estimates:

Monitoring Data Summary:

FDA Surveillance Data (United States only) from 1992 to 1996:

144 Samples of Whole Grain, Corn were analyzed for parathion

53 Samples of Whole Grain, Popcorn (Not Popped) were analyzed for parathion

0 Samples had detectable residues of parathion

Average Residue Calculation:

Assumptions for calculating the average combined residue level of parathion and paraoxon:

- 1% of domestic corn (other than sweet corn) is treated with parathion
- 195 of the 197 samples analyzed had nondetectable residues of parathion estimated at zero for residues of parathion
- 2 of the 197 samples analyzed had nondetectable residues of parathion estimated at ½LOD or 0.003 ppm
- Residue levels of paraoxon are assumed to equal the residue levels of parathion

The average parathion residues in/on corn grain:

$$(2 \text{ samples})(0.003 \text{ ppm}) / (197 \text{ samples}) = 0.00003 \text{ ppm}$$

The average combined residues of parathion and paraoxon in/on corn grain:

$$(0.00003 \text{ ppm})(2) = 0.00006 \text{ ppm}$$

95th Percentile Calculation:

Assumptions for calculating the 95th percentile residue level of parathion and paraoxon combined:

- Corn grain is a highly blended commodity
- Residue levels of paraoxon are assumed to equal the residue levels of parathion

The 95th percentile of corn grain samples analyzed had nondetectable residues of parathion estimated at ½LOD or 0.003 ppm

The 95th percentile of combined residues of parathion and paraoxon in/on corn grain:

$$(0.003 \text{ ppm})(2) = 0.006 \text{ ppm}$$

6911

Wheat grain AR estimates:

Monitoring Data Summary:

PDP Monitoring Data from 1995 and 1996

940 Samples of Whole Grain, Wheat were analyzed for parathion

939 Samples had nondetectable residues of parathion

1 Sample had 0.022 ppm of parathion detected

Average Residue Calculation:

Assumptions for calculating the average combined residue level of parathion and paraoxon:

- 2% of domestic wheat is treated with parathion
- 921 of 940 samples analyzed had nondetectable residues of parathion estimated at zero for residues of parathion
- 18 of 940 samples analyzed had nondetectable residues of parathion estimated at $\frac{1}{2}$ LOD or 0.0065 ppm
- Residue levels of paraoxon are assumed to equal the residue levels of parathion

The average parathion residues in/on wheat grain:

$$(18 \text{ samples})(0.0065 \text{ ppm})/940 + (1 \text{ sample})(0.022 \text{ ppm})/940 = 0.0001478 \text{ ppm}$$

The average combined residues of parathion and paraoxon in/on wheat grain:

$$(0.0001478 \text{ ppm})(2) = 0.0003 \text{ ppm}$$

95th Percentile Calculation:

Assumptions for calculating the 95th percentile residue level of parathion and paraoxon combined:

- Wheat grain is a highly blended commodity
- Residue levels of paraoxon are assumed to equal the residue levels of parathion

The 95th percentile of wheat grain samples analyzed had nondetectable residues of parathion estimated at $\frac{1}{2}$ LOD or 0.0065 ppm

The 95th percentile of combined residues of parathion and paraoxon in/on wheat grain:

$$(0.0065 \text{ ppm})(2) = 0.02 \text{ ppm}$$

7811

Wheat grain flour:

Monitoring Data Summary:

FDA Surveillance Data (United States only) from 1992 to 1996:

112 Samples of Wheat flour were analyzed for parathion

0 Samples had detectable residues of parathion detected

Average Residue Calculation:

Assumptions for calculating the average combined residue level of parathion and paraoxon:

- 2% of domestic wheat is treated with parathion
- 109 of 112 samples analyzed had nondetectable residues of parathion estimated at zero for residues of parathion
- 3 of 112 samples analyzed had nondetectable residues of parathion estimated at ½LOD or 0.003 ppm
- Residue levels of paraoxon are assumed to equal the residue levels of parathion

The average parathion residues in wheat flour:

$$(3 \text{ samples})(0.003 \text{ ppm})/112 = 0.00008 \text{ ppm}$$

The average combined residues of parathion and paraoxon in wheat:

$$(0.00008 \text{ ppm})(2) = 0.0002 \text{ ppm}$$

95th Percentile Calculation:

Assumptions for calculating the 95th percentile residue level of parathion and paraoxon combined:

- Wheat flour is a highly blended commodity
- Residue levels of paraoxon are assumed to equal the residue levels of parathion

The 95th percentile of wheat flour samples analyzed had nondetectable residues of parathion estimated at ½LOD or 0.003 ppm

The 95th percentile of combined residues of parathion and paraoxon in wheat flour:

$$(0.003 \text{ ppm})(2) = 0.006 \text{ ppm}$$

Soybean, Corn, and Wheat Processed Commodities

For soybeans, no processing data are available. Therefore, the AR estimates for soybeans will be translated to the processed commodities of soybeans. Note: Based on available cottonseed processing data which indicate that residues of parathion and paraoxon do not concentrate in meal, hulls, and refined cottonseed oil, maximum theoretical concentration factors will not be applied to the AR estimates for the processed commodities of soybeans.

For field corn grain, residues of parathion and paraoxon do not concentrate in corn meal, flour, grits, or starch, but concentrate on average by ~3x in refined corn oil. Therefore, the AR estimates for corn grain will be translated to corn grain-endosperm, corn grain-bran, and corn sugar. Corn oil will be estimated at 3 times the AR estimates calculated for corn grain.

8711

For wheat grain, residues of parathion and paraoxon do not concentrate in wheat flour, middlings, or shorts, but concentrate by 4.6x in wheat bran. Therefore, the AR estimates calculated for wheat grain will be translated to wheat-germ. Wheat bran will be estimated at 4.6 times the AR estimates for wheat grain.

cc: BLCKohlligian (RRB2), Parathion Reg. Std. File, Parathion SF, RF.

RDI: RRB2 ResChem Team: 8/20/98 HED ChemSAC: 9/9/98

7509C:RRB2:BLCKohlligian:CM#2:Rm 804E:703-305-7462: 8/17/98.

APPENDIX A

FDA Surveillance Data (United States only) 1992-1996
Parathion Residues Only

Pesticide Limit of Quantitation for parathion in fatty and nonfatty foods = 0.02 ppm
Pesticide Limit of Quantitation for paraoxon is not stated.

Parathion in fatty foods: Extraction Reference 304 E1-E5; Cleanup Reference 304 C1/C2; Determination Reference 302 DG2
Parathion in nonfatty foods: Extraction Reference 303 E1-E5; Cleanup Reference 303 C1/C2; Determination Reference 302 DG

YEAR	PROD CODE	PRODNAME	SAMP COVR	PCT COVR	RES FND	PCT FND	RES TRAC	MEAN	MAX
1996	02A01	WHOLE GRAIN, CORN	18	100	0	0	0	0.000000	0.
1995	02A01	WHOLE GRAIN, CORN	23	100	0	0	0	0.000000	0.
1994	02A01	WHOLE GRAIN, CORN	56	90	0	0	0	0.000000	0.
1993	02A01	WHOLE GRAIN, CORN	31	62	0	0	0	0.000000	0.
1992	02A01	WHOLE GRAIN, CORN	16	53	0	0	0	0.000000	0.
144 Total									
1996	02A02	WHOLE GRAIN, BARLEY	6	86	1	17	1	0.000000	T
1995	02A02	WHOLE GRAIN, BARLEY	9	100	1	11	1	0.000000	T
1994	02A02	WHOLE GRAIN, BARLEY	9	100	0	0	0	0.000000	0.
1993	02A02	WHOLE GRAIN, BARLEY	15	100	0	0	0	0.000000	0.
1992	02A02	WHOLE GRAIN, BARLEY	1	100	0	0	0	0.000000	0.
1992	02A02	WHOLE GRAIN, BARLEY	11	100	0	0	0	0.000000	0.
1992	02A02	WHOLE GRAIN, BARLEY	2	100	0	0	0	0.000000	0.
53 Total									
1996	02A04	WHOLE GRAIN, POPCORN (NOT POPPED)	10	100	0	0	0	0.000000	0.
1995	02A04	WHOLE GRAIN, POPCORN (NOT POPPED)	9	90	0	0	0	0.000000	0.
1994	02A04	WHOLE GRAIN, POPCORN (NOT POPPED)	13	100	0	0	0	0.000000	0.
1993	02A04	WHOLE GRAIN, POPCORN (NOT POPPED)	10	100	0	0	0	0.000000	0.
1992	02A04	WHOLE GRAIN, POPCORN (NOT POPPED)	10	100	0	0	0	0.000000	0.
1992	02A04	WHOLE GRAIN, POPCORN (NOT POPPED)	1	100	0	0	0	0.000000	0.
53 Total									
1996	02A09	WHOLE GRAIN, WHEAT	151	99	0	0	0	0.000000	0.
1995	02A09	WHOLE GRAIN, WHEAT	144	99	0	0	0	0.000000	0.
1994	02A09	WHOLE GRAIN, WHEAT	178	83	0	0	0	0.000000	0.
1993	02A09	WHOLE GRAIN, WHEAT	117	80	1	8	0	0.000145	0.017
1992	02A09	WHOLE GRAIN, WHEAT	98	76	0	0	0	0.000000	0.
1992	02A09	WHOLE GRAIN, WHEAT	4	100	0	0	0	0.000000	0.
692 Total									
1996	02A10	WHOLE GRAIN, SOYBEANS	25	96	0	0	0	0.000000	0.
1995	02A10	WHOLE GRAIN, SOYBEANS	18	47	0	0	0	0.000000	0.
1994	02A10	WHOLE GRAIN, SOYBEANS	33	58	0	0	0	0.000000	0.
1993	02A10	WHOLE GRAIN, SOYBEANS	60	100	0	0	0	0.000000	0.

10911

YEAR	PROD CODE	PRODNAME	SAMP COVR	PCT COVR	RES FND	PCT FND	RES TRAC	MEAN	MAX
1992	02A10	WHOLE GRAIN, SOYBEANS	39	100	0	0	0	0.000000	0.
175 Total									
1995	02E01	WHEAT FLOUR, WHEAT FLOUR, BROMATED	1	100	0	0	0	0.000000	0.
1996	02E02	WHEAT FLOUR, WHEAT FLOUR, ENRICHED, BROM	1	100	0	0	0	0.000000	0.
1995	02E02	WHEAT FLOUR, WHEAT FLOUR, ENRICHED, BROM	3	100	0	0	0	0.000000	0.
1994	02E02	WHEAT FLOUR, WHEAT FLOUR, ENRICHED, BROM	3	100	0	0	0	0.000000	0.
1996	02E04	WHEAT FLOUR, WHEAT FLOUR, DURAM	2	100	0	0	0	0.000000	0.
1995	02E04	WHEAT FLOUR, WHEAT FLOUR, DURAM	1	100	0	0	0	0.000000	0.
1994	02E04	WHEAT FLOUR, WHEAT FLOUR, DURAM	3	100	0	0	0	0.000000	0.
1992	02E04	WHEAT FLOUR, WHEAT FLOUR, DURAM	1	100	0	0	0	0.000000	0.
1996	02E05	WHEAT FLOUR, WHEAT FLOUR, ENRICHED	11	100	0	0	0	0.000000	0.
1995	02E05	WHEAT FLOUR, WHEAT FLOUR, ENRICHED	9	100	0	0	0	0.000000	0.
1994	02E05	WHEAT FLOUR, WHEAT FLOUR, ENRICHED	7	100	0	0	0	0.000000	0.
1993	02E05	WHEAT FLOUR, WHEAT FLOUR, ENRICHED	1	100	0	0	0	0.000000	0.
1992	02E05	WHEAT FLOUR, WHEAT FLOUR, ENRICHED	1	100	0	0	0	0.000000	0.
1992	02E05	WHEAT FLOUR, WHEAT FLOUR, ENRICHED	5	83	0	0	0	0.000000	0.
1994	02E09	WHEAT FLOUR, WHEAT FLOUR, PHOSPHATED	3	100	0	0	0	0.000000	0.
1992	02E05	WHEAT FLOUR, WHEAT FLOUR, PHOSPHATED	2	100	0	0	0	0.000000	0.
1995	02E10	WHEAT FLOUR, WHEAT FLOUR, SELF-RISING, E	1	100	0	0	0	0.000000	0.
1993	02E10	WHEAT FLOUR, WHEAT FLOUR, SELF-RISING, E	1	100	0	0	0	0.000000	0.
1992	02E10	WHEAT FLOUR, WHEAT FLOUR, SELF-RISING, E	2	100	0	0	0	0.000000	0.
1996	02E13	WHEAT FLOUR, WHEAT FLOUR, WHOLE	6	100	0	0	0	0.000000	0.
1995	02E13	WHEAT FLOUR, WHEAT FLOUR, WHOLE	6	100	0	0	0	0.000000	0.
1994	02E13	WHEAT FLOUR, WHEAT FLOUR, WHOLE	7	100	0	0	0	0.000000	0.
1993	02E13	WHEAT FLOUR, WHEAT FLOUR, WHOLE	2	100	0	0	0	0.000000	0.
1992	02E13	WHEAT FLOUR, WHEAT FLOUR, WHOLE	1	100	0	0	0	0.000000	0.
1992	02E13	WHEAT FLOUR, WHEAT FLOUR, WHOLE	1	100	0	0	0	0.000000	0.
1992	02E13	WHEAT FLOUR, WHEAT FLOUR, WHOLE	1	100	0	0	0	0.000000	0.
1996	02E99	WHEAT FLOUR, WHEAT FLOUR N.E.C.	6	100	0	0	0	0.000000	0.
1995	02E99	WHEAT FLOUR, WHEAT FLOUR N.E.C.	7	100	0	0	0	0.000000	0.
1994	02E99	WHEAT FLOUR, WHEAT FLOUR N.E.C.	10	100	0	0	0	0.000000	0.
1993	02E99	WHEAT FLOUR, WHEAT FLOUR N.E.C.	4	100	0	0	0	0.000000	0.
1992	02E99	WHEAT FLOUR, WHEAT FLOUR N.E.C.	2	100	0	0	0	0.000000	0.
1992	02E99	WHEAT FLOUR, WHEAT FLOUR N.E.C.	1	100	0	0	0	0.000000	0.
112 Total									

11/2/11