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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

July 7, 1999

MEMORANDUM

SUBJECT: **Pirimiphos-methyl** (List B Case No. 2535/Chemical ID No. 108102). Revised Tolerance Reassessment Summary and Anticipated Residues for Acute and Chronic Dietary Risk Assessment. No MRID #. DP Barcode No. D257369.

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Anticipated residues were generated in conjunction with the preparation of the pirimiphos-methyl residue chemistry chapter for the HED reregistration eligibility decision document (RED) [memo, C. Swartz, D240744, 6/1/98]. The anticipated residues in stored grains and certain livestock commodities were subsequently used in acute and chronic dietary exposure and risk analyses for pirimiphos-methyl [memo, C. Swartz, D245961, 7/21/98]. Agency guidance for conducting acute dietary risk assessments was updated 11/4/98 [Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs]. The new guidance permits further refinement of the acute anticipated residues for pirimiphos-methyl; details of the calculation of revised acute anticipated residues are presented below. Updated usage information generated by the Biological and Economic Analysis Division (BEAD/OPP) was incorporated into

the assessment. In examining corn processing data submitted in support of reregistration, HED has determined that a tolerance for pirimiphos-methyl residues in corn oil is not necessary. Additional monitoring data from the United States Department of Agriculture (USDA) Pesticide Data Program (PDP) and the Food and Drug Administration (FDA) Pesticide Monitoring Program were used in the current assessment, and permit significant refinements to the anticipated residues for pirimiphos-methyl.

Recommendation

The revised tolerance reassessment summary (Attachment 1) supersedes the 6/1/98 tolerance reassessment. A separate tolerance for pirimiphos-methyl residues in corn oil is not needed.

The following acute and chronic anticipated residues (ARs) should be used in the Dietary Exposure Evaluation Model (DEEM™) to estimate acute and chronic dietary exposure and risk associated with the supported uses of pirimiphos-methyl. The anticipated residues are highly refined, and were largely derived from FDA and PDP monitoring data for pirimiphos-methyl *per se*. Four different anticipated residues were derived for popcorn, using FDA popcorn monitoring data and field corn residue trial data. Additional information is necessary to refine the anticipated residue estimates for popcorn. HED has concerns regarding the 34% detection rate in FDA popcorn monitoring samples, since usage data suggest <1 % crop treated (%CT). [Detected residues in popcorn were significant, and were above tolerance in one case.]

Table 1. Summary of Pirimiphos-Methyl Anticipated Residues for Dietary Exposure Analysis.

Commodity/ Food Form[1]	Data Source[2]	Acute AR (ppm)[3]	Chronic AR (ppm)[4]	Adjustment for Residue Reduction[5]	Adjustment for %CT[6]
Corn/ Endosperm	FDA	RDF 9 detects 718 @ 0.005 (½ LOD)	0.0146	0.3X	1.0
Corn/ Bran	FDA	RDF 9 detects 718 @ 0.005 (½ LOD)	0.0146	1X	1.0
Corn/oil	FDA	RDF 9 detects 718 @ 0.005 (½ LOD)	0.0146	0.06X	1.0
Corn/Sugar/HFCS	PDP	0.0005	0.0005	1X	1.0
Corn/Sugar/Molasses	PDP	0.0005	0.0005	1X	1.0
Popcorn (Assessment 1)[7]	RT	2.51	2.51	1X	0.01

Table 1. Summary of Pirimiphos-Methyl Anticipated Residues for Dietary Exposure Analysis.

Commodity/ Food Form[1]	Data Source[2]	Acute AR (ppm)[3]	Chronic AR (ppm)[4]	Adjustment for Residue Reduction[5]	Adjustment for %CT[6]
Popcorn (Assessment 2)[7]	RT/FDA	2.51	2.51	1X	0.34 (acute) 0.34 (chronic)
Popcorn (Assessment 3)[7]	FDA	1.42	1.42	1X	1.0
Popcorn (Assessment 4)[7]	RT	2.51	2.51	1X	1.0
Sorghum	RT	3.9	3.9	1X	0.02 (acute) 0.01 (chronic)
Beef liver	FS/FDA	3.61×10^{-5}	1.40×10^{-5}	1X	1.0
Beef kidney	FS/FDA	4.05×10^{-5}	1.89×10^{-5}	1X	1.0
Beef fat	FS/FDA	6.83×10^{-5}	3.16×10^{-5}	1X	1.0
Poultry fat	FS/FDA	1.36×10^{-5}	1.36×10^{-5}	1X	1.0

[1] The corn grain food forms listed are those found in the Dietary Exposure Evaluation Model (DEEM™) for corn; HFCS is high fructose corn syrup. Beef anticipated residues should be translated to similar commodities (liver, kidney and fat) of hogs, goats, and sheep.

[2] FDA = FDA monitoring data; PDP = PDP monitoring data; RT = Residue Trials; FS/FDA = Feeding study/FDA monitoring data.

[3] Either a point estimate or a residue distribution file (RDF) from monitoring data is specified for acute dietary exposure assessment. Refer to Table 2 (below) for the details of the residues detected.

[4] A point estimate derived from residue trials or monitoring data is specified for chronic dietary exposure assessment.

[5] The reduction factors were derived from processing studies submitted in support of registration and reregistration; the reduction factor for corn oil is based on residues in bleached/deodorized refined oil.

[6] The % crop treated (%CT) is listed as a percentage, and should be used in the relevant dietary exposure analyses. Note that the adjustment for %CT is not necessary when monitoring data are the source of the AR.

[7] Four assessments should be completed:

1) Use average field corn RT value, with an adjustment for 1% CT (BEAD usage information);
2) Use average field corn RT value and an adjustment for 34% detects in FDA popcorn monitoring;
3) Use popcorn AR from FDA monitoring data (average of detects) with no adjustment for %CT;
4) Use average field corn RT value with no adjustment for %CT (worst case).

DETAILED CONSIDERATIONS

Background

The nature of the residue in stored grain and livestock is adequately understood. Although the tolerance expression [40 CFR §180.409] includes only parent pirimiphos-methyl, both the parent and the des-ethyl metabolite are to be included in the risk assessment (memo, J. Stokes, 5/15/98, D228695). Since the des-ethyl metabolite was not identified in stored grain in metabolism studies, and has not been found in residue trials, the anticipated residues and dietary exposure analysis for grain include residues of parent only.

Acceptable residue trials and processing studies conducted on stored grains were submitted and reviewed by the Agency [C. Swartz, DP Barcode Nos. D227552; D228760; D229663; D230598; and D231449, 10/10/97]. The results of the studies were used to generate anticipated residues in stored grains and livestock dietary burdens for tolerance reassessment and risk assessment.

Acceptable ruminant and poultry feeding studies were submitted and reviewed by the Agency [C. Swartz, D194803 and D228209, 5/1/98]. The results of these studies (and residue trials conducted on stored grains) indicated that residues in certain livestock commodities could be classified under category 3 of 40 CFR §180.6(a), i.e., there is no reasonable expectation of detectable residues. Therefore, HED recommended revocation of tolerances for residues in meat (of cattle, goats, hogs, horses, sheep and poultry), milk, and eggs.

Anticipated residues generated in the residue chemistry chapter were limited to corn (grain and oil), grain sorghum, aspirated grain fractions, meat by-products and fat, and poultry fat. In the corresponding dietary exposure/risk analysis, anticipated residues in corn grain were applied to corn food forms such as popcorn, high fructose corn syrup (HFCS) and corn flour.

Although usage data generated by BEAD/OPP for the 6/98 assessment indicated less than 1% crop treated (%CT) for corn and sorghum, HED used a value of 14 %CT for corn in the 7/98 exposure analysis (based on the assumption that only food corn was treated) to account for the high percentage of detectable residues in FDA monitoring data relative to usage estimates.

Revised Usage Data

A quantitative usage analysis generated 4/8/99 (memo, A. Halvorson, attachment 2) updated the usage summary provided in the HED residue chemistry chapter. The likely maximum %CT for corn grain is 0.3%, with a weighted average of 0.1 %CT; the likely maximum for sorghum grain is 1.5 %CT, with a weighted average of 0.7 %CT. HED typically uses a default value of 1 %CT for the purpose of risk assessment when BEAD estimates <1%CT.

In a subsequent communication (A. Halvorson, 6/16/99), BEAD estimated 30% of stored food corn is treated via bin disinfestation, while 1% of stored food corn is treated with the top-dressing application [pre-treatment of grain storage bins (bin disinfestation) is not currently a registered use for pirimiphos-methyl]. The source of the food corn usage information was a report on post-

harvest handling, diseases, and pesticide usage for grain crops generated by the KEVRIC Co. (12/97). The report states that it was assumed that 1% of stored food corn is treated via top-dressing based on discussions with experts in the field. In addition, it was assumed that pirimiphos-methyl is used in concentrations and percentiles similar to chlorpyriphos-methyl, which is registered for use on wheat but not corn. Because so much was assumed with respect to pirimiphos-methyl usage on stored food corn, HED has low confidence in these usage estimates. For the purpose of risk assessment, the default values of 1%CT for field corn (grain) should be used for both acute and chronic dietary exposure analyses, based on the usage estimates provided by BEAD.

Revision of the Tolerance Reassessment Summary

Corn processing studies submitted by the registrant under MRID No. 41804701 were reviewed and deemed unacceptable (memo, C. Swartz, DP Barcode No. D162371, 4/24/91). More recent (acceptable) processing studies in which residues concentrated in refined corn oil were used to derive the concentration factor and concomitant tolerance required for residues in corn oil; these studies did not include bleaching/deodorizing steps. However, upon examination of the older processing data, HED noted that residues in refined oil were reduced by an average of 0.06X following bleaching and deodorizing. HED guidance issued 10/24/88 (memo, C. Trichilo) stipulates that tolerances for residues in oil should be established in food grade oil, which has been refined, bleached and deodorized. Therefore, HED now concludes a separate tolerance for pirimiphos-methyl residues in corn oil is not required. The revised tolerance reassessment summary is attached (Attachment 1).

A reduction factor of 0.3X should be applied for corn endosperm in the dietary exposure/risk analysis; the average reduction factor was determined for corn meal and flour in the submitted processing studies.

Monitoring Data

The USDA Pesticide Data Program (PDP) tested 249 milk samples for pirimiphos-methyl and 134 milk samples for the des-ethyl metabolite in 1997; no parent or metabolite residues were found in any of the monitored milk samples. However, these data are not relevant for this assessment since HED has recommended revocation of the tolerance for residues in milk. In addition, PDP analyzed 298 samples of high fructose corn syrup for pirimiphos-methyl during 1998, with no detections at the LOD of 0.001 ppm. Therefore, in the dietary risk analysis, a value of ½ LOD, or 0.0005 ppm should be used for high fructose corn syrup (no concentration factor is needed).

FDA monitoring data were generated during 1992-1998 on numerous commodities; residues of pirimiphos-methyl *per se* were analyzed in whole grain corn, popcorn (un-popped), popcorn (snack food), corn meal/milled products, corn oil, and hominy and breakfast foods. In corn milled products, 2 of 41 samples had detectable residues, at <0.01 ppm and 0.01 ppm. Other commodities such as breakfast foods and hominy (11 samples) and corn oil (6 samples) contained

no detectable pirimiphos-methyl residues. The remaining corn monitoring data are summarized below.

HED has recommended for revocation of the import tolerances on wheat flour and kiwi. A tolerance for residues in wheat flour is not needed; additional data are needed to support uses on both wheat and kiwi. However, FDA monitoring data from 1992-1998 showed no detectable (LOD = 0.01 ppm) residues of pirimiphos-methyl *per se* in kiwi (128 samples) and wheat flour/milled products (211 samples). Residues were detected in 2 of 1,024 surveillance samples of wheat grain, at 0.018 and 0.079 ppm.

Tables 2 and 3 summarize FDA monitoring data for corn and popcorn. Residues reported as trace detects in the surveillance data are listed as <0.01 ppm; the value of 0.005 ppm (½ LOD) was used in calculating the average residue in corn grain.

Table 2. FDA Surveillance Monitoring Data for Pirimiphos-methyl *per se* in Corn Grain (Listed as Corn, Whole Grain and Bean/Pea/Corn, Corn).

Year	# Sampled	# Detects	Residues (ppm)
1992	16	0	--
1993	164	0	--
1994	203	0	--
1995	82	0	--
1996	113	3	0.02, 0.04, 0.16
1997	17	2	4.4, 0.14
1998	132	4	1.1, 0.6, 0.539, <0.01
Total	727	9	Average(including non-detects @ ½ LOD = 0.0146 ppm

Table 3. FDA Surveillance Monitoring Data for Pirimiphos-methyl *per se* Residues in Popcorn (Un-popped).[1]

Year	# Sampled	# Detects	Residues (ppm)
1992	10	1	0.08
1993	10	2	0.53; 1.81

Table 3. FDA Surveillance Monitoring Data for Pirimiphos-methyl *per se* Residues in Popcorn (Un-popped).[1]

Year	# Sampled	# Detects	Residues (ppm)
1994	13	4	1.22, 0.03, 0.23, 1.93
1995	10	3	2.04, 1.95, 1.4
1996	10	4	0.13, 2.02, 3.5, 10.75* (10.71, confirmatory)
1997	11	8	0.1, 1.03, 0.887, 0.54, 2.6, <0.01, 0.01, <0.01
1998	6	2	1.025, 0.253
Total	70	24	Average of detects = 1.42 ppm

[1] One sample of popcorn, snack food had detectable residues of 0.156 ppm in 1993.

* Residue is above tolerance for corn grain.

HED has concerns regarding the frequency of detections (34% of samples analyzed) in popcorn. Although the number of samples is insufficient for quantitative use in risk assessment, the data suggest that use of corn grain residues for popcorn in the acute and chronic dietary exposure assessments may underestimate dietary exposure/risk. The BEAD report indicates the states with the highest usage of pirimiphos-methyl on stored grain are IA and TX. Residues were detected in popcorn from MO, KS, NE, and IA, while the major producer of popcorn is NE, with additional production in IN, IL and IA. Although HED considers popcorn to be a blended commodity, the challenge of achieving homogeneous sampling in the field, along with the top-dressing use pattern for pirimiphos-methyl, may explain the wide range of residues and tolerance-exceeding values encountered in monitoring [personal communication regarding sampling, C. Olinger (HED/RRB1) with Pauline Wohlgemuth, (FDA/Dallas District), 6/23/99].

For the purpose of this assessment, four analyses should be completed to reflect four sets of popcorn anticipated residue calculations. First, the average residue from field corn trials should be used with the BEAD estimate of 1% CT; second, the average residue in field corn from residue trials should be used along with an adjustment of 34% “CT” to account for the detection rate in FDA popcorn monitoring samples. Third, the average detected residue from FDA popcorn monitoring should be used, with no adjustment for %CT, and finally the average residue trial value should be used with no adjustment for %CT. The first analysis may underestimate risk, while the subsequent analyses are expected to be more conservative. Additional information regarding the popcorn monitoring samples and/or usage on popcorn should be obtained to refine the anticipated residue in popcorn.

The FDA surveillance monitoring for pirimiphos-methyl residues encompassed a wide range of commodities including root/tuber, cole crops, edible seeds, leafy vegetables, and a variety of fruits. None of the samples had detectable pirimiphos-methyl residues, indicating that dietary exposure to pirimiphos-methyl from imported commodities is not likely to be significant, even though there are terrestrial food uses in other countries.

Chronic Anticipated Residues

The approach used to generate pirimiphos-methyl chronic anticipated residues for the residue chemistry chapter involved calculating average residues in grains from residue trials and adjusting the residues for percent crop treated (%CT). The resulting values were used for human consumption in the dietary exposure analysis and to calculate anticipated dietary burdens for livestock. The anticipated burdens and average tissue/feed ratios determined in feeding studies were used to calculate anticipated residues in livestock commodities.

In the current assessment, changes have been made to reflect the new usage and monitoring data, as well as to incorporate the revised tolerance for residues in corn oil. The corn grain average (anticipated) residue was calculated from monitoring data (with no adjustment for %CT) assuming residues of ½ LOD for non-detects. The corn grain AR was translated to corn oil; the reduction factor of 0.06X from processing studies should be applied in the dietary exposure analysis.

Since the Dietary Exposure Evaluation Model (DEEM™) software does not contain whole grain corn as a food form, the anticipated residue in corn grain should be used for corn endosperm and bran in the dietary exposure analysis; the 0.3X reduction factor determined for meal and flour from processing studies should be applied to endosperm. The PDP monitoring data for HFCS were also incorporated; the average residue of 0.0005 ppm was calculated from ½ the LOD of 0.001 ppm (no adjustment for %CT, since the monitored commodity is considered to be blended). The HFCS anticipated residue should be translated to corn sugar/molasses in the dietary exposure analysis.

The sorghum average (anticipated) residue was calculated from residue trials; the adjustment for weighted average of % CT (<1%) should be applied in the dietary exposure analysis.

In order to calculate residues in fat and meat by-products, anticipated dietary burdens were determined using the anticipated residues in grains, and the results of the feeding studies were used to estimate residues in livestock commodities via use of average tissue/feed ratios. The FDA surveillance monitoring program analyzes only food corn; in the current assessment, residues in feed corn were assumed to be the same as those in food corn.

Revised chronic anticipated residues are summarized in Table 4, and chronic anticipated residues in livestock commodities are derived in Tables 5-8.

Acute Anticipated Residues

Previously determined acute anticipated residues in grains (for human dietary consumption) consisted of average residues from residue trials; the adjustment for %CT was not included. When sufficient monitoring data are available in blended commodities, residue distribution files (RDFs) may be incorporated into the acute assessment. For the current assessment, a corn (grain) RDF prepared from FDA monitoring data incorporates 9 detected residues, and incorporates 718 values of ½ LOD for non-detectable residues. The corn grain RDF should be translated to corn oil; the 0.06X reduction factor for corn oil should be applied in the dietary exposure analysis. The corn grain RDF should be used for endosperm and bran in the dietary exposure analysis, with the 0.3X reduction factor for endosperm.

The point estimate of ½ LOD (0.0005 ppm) for HFCS was used, based on 298 PDP monitoring samples with non-detectable residues. This residue value should be translated to corn sugar/molasses in the dietary exposure analysis. Since current HED policy is to use average field trial residues for blended commodities, the acute anticipated residue for grain sorghum is the same as the chronic anticipated residue for grain sorghum. However, in the acute analysis, the adjustment for likely maximum %CT should be applied (2%).

In the previous assessment, acute anticipated residues in livestock commodities were 0.04 ppm, the maximum combined residues of pirimiphos-methyl and the des-ethyl metabolite. As stated in the 11/98 guidance, refined acute dietary burdens to livestock can be calculated by using average residues in blended feed items. The acute anticipated residues in beef cattle and poultry are then determined using the maximum tissue/feed ratios calculated from feeding studies. Although current Agency policy allows for a probabilistic analysis for livestock commodities, refined point estimates were determined for pirimiphos-methyl because all relevant livestock feed items are considered to be blended. Anticipated residues in feed items were used with maximum tissue/feed ratios to determine acute anticipated residues in livestock commodities.

Revised acute anticipated residues are summarized in Table 4, and acute anticipated residues in livestock commodities are summarized in Tables 5-8.

Table 4. Summary of Tolerances, Residue Trials, and Anticipated Residues in Grains.[1]

Commodity/ Food Form	Reassessed Tolerance (ppm)[2]	Average FT Residue (ppm)	% Crop Treated[3]		Acute Anticipated Residue (ppm)[4]	Chronic Anticipated Residue (ppm)[5]
			Wtd. Ave.	Est. Max.		
Corn[6]			0.1 (<1)	0.3 (<1)		
Grain	8	2.51			RDF (FDA data) 9 detects (Table 2) 718 @ ½ LOD	0.0146 (Average of FDA monitoring data)
Oil	n/a	n/a			RDF (FDA data) 9 detects (Table 2) 718 @ ½ LOD (0.06X reduction factor)	0.0146 (0.06X reduction factor)
HFCS	n/a	n/a			0.0005	0.0005
Sorghum			0.7 (<1)	1.5 (2)		
Grain	8	3.9			3.9	3.9
Aspirated grain fractions	20	9.5			9.5	9.5

1 Refer to the 6/1/98 Residue Chemistry Chapter for pirimiphos-methyl, which summarized average residues in grains.

2 The revised reassessed tolerances are attached; HED now concludes a tolerance for residues in oil is not needed.

3 Updated usage information was provided by BEAD/OPP (A. Halvorson, 4/8/99). HED typically assumes a default value of <1 %CT when BEAD estimates are <1. The weighted average (1989-1997 data) and likely maximum %CT were reported.

4 The estimated maximum of %CT should be applied to the sorghum residue in the acute analysis; the 0.06X reduction factor should be applied for corn oil.

5 The weighted average %CT should be applied to the sorghum residue in the chronic analysis; the 0.06X reduction factor should be applied for corn oil.

6 Since the DEEM™ software does not include consumption of whole grain corn, the anticipated residues in corn grain should be used for corn bran and endosperm in the dietary exposure analysis, with a reduction factor of 0.3X. [Anticipated residues in popcorn are described in more detail with the FDA monitoring data].

Using these data and the livestock feeding studies, acute and chronic anticipated residues in livestock commodities have been calculated as described below (Tables 5-8).

Table 5. Pirimiphos-methyl Dietary Burden Calculation: Beef Cattle.[1]

Feed Item	Reassessed Tolerance (ppm)[2]	Acute/Chronic Anticipated Residue (ppm)[3]	% in Diet[4]	% Dry Matter[5]	Dietary Burden (ppm)[6]		
					Maximum (Tol.)	**For Acute AR**	**For Chronic AR**
Corn, Grain	8	0.0146/0.0146	60	85	5.65	0.0103	0.0103
Aspirated Grain Fractions	20	0.1425/0.095	20	85	4.71	0.0335	0.0223
Total Dietary Burden (ppm)					**10.36**	**0.0438**	**0.0326**

1 Total Dietary burden = [Residue in feed (1) x % in diet(1)/%DM(1)] + [residue in feed(2) x % in diet(2)/%DM(2)]. No calculations were included for dairy cattle, since HED has recommended for revocation of the tolerance for residues in milk.

2 The revised reassessed tolerances are listed in Attachment 1.

3 The acute and chronic anticipated residues in corn grain are the same, calculated as the average of FDA monitoring data; the acute anticipated residue in sorghum aspirated grain fractions was derived from the anticipated residue value of 9.5 ppm and an adjustment for the likely maximum of 1.5%CT, while the chronic AR includes the adjustment for the weighted average %CT (<1%).

4 The maximum % of the feed in the diet (on a dry weight basis) was taken from Table 1 of the OPPTS Series 860 Residue Chemistry Test Guidelines.

5 Residues in beef cattle feed items are adjusted for the % dry matter (refer to the OPPTS Series 860 Residue Chemistry Test Guidelines).

6 The maximum theoretical dietary burden is calculated assuming reassessed tolerances in feed items, and is used for the purpose of tolerance setting (the revised reassessed tolerances have not changed for livestock commodities); the acute and chronic dietary burdens are calculated assuming acute/chronic anticipated residues, respectively.

Table 6. Calculation of Pirimiphos-methyl Acute and Chronic Residues in Beef Cattle Meat By-Products and Fat.

Beef Cattle Matrix	Total Pirimiphos-methyl Residues (ppm) (Feeding Level, ppm)[1]			Tissue/Feed Ratio (Feeding Level, ppm)[2]			Maximum Tissue/Feed Ratio	Acute AR (ppm)[3]	Average Tissue/Feed Ratio[4]	Chronic AR (ppm)[5]
	40	120	400	40	120	400				
Liver	0.033	0.049	0.02	8.25×10^{-4}	4.08×10^{-4}	5.0×10^{-5}	8.25×10^{-4}	3.61×10^{-5}	4.28×10^{-4}	1.40×10^{-5}
Kidney	0.037	0.082	0.055	9.25×10^{-4}	6.83×10^{-4}	1.38×10^{-4}	9.25×10^{-4}	4.05×10^{-5}	5.82×10^{-4}	1.89×10^{-5}
Fat	0.032	0.187	0.218	8.0×10^{-4}	1.56×10^{-3}	5.45×10^{-4}	1.56×10^{-3}	6.83×10^{-5}	9.68×10^{-4}	3.16×10^{-5}

1 Tissue residues at the three feeding levels were summarized in the 5/1/98 C. Swartz memo.

2 Tissue/feed ratios are determined by dividing the tissue residue level by the amount fed in ppm.

3 The acute AR is determined by multiplying the maximum tissue/feed ratio by the acute anticipated dietary burden (see Table 5, above).

4 The average tissue/feed ratio is calculated from the tissue/feed ratios at all three feeding levels.

5 The chronic AR is determined by multiplying the average tissue/feed ratio by the chronic anticipated dietary burden (see Table 5, above).

Table 7. Pirimiphos-methyl Dietary Burden Calculation: Poultry.[1]

Feed Item	Reassessed Tolerance (ppm)[2]	Acute/Chronic Anticipated Residue (ppm)[3]	% in Diet[4]	**Maximum** Dietary Burden (ppm)	**Acute/Chronic Anticipated** Dietary Burden (ppm)
Corn, Grain	8	0.0146	80	6.4	0.0117

1 Dietary burden = Residue in Feed Item (Tolerance or Anticipated Residue) x % in diet. Maximum dietary burden corresponds to tolerance-level residues; the acute/chronic anticipated residue in corn corresponds to the acute/chronic anticipated dietary burden.

[2] See Attachment 1.

[3] The acute and chronic anticipated residues in corn grain were calculated from FDA surveillance monitoring data.

[4] The maximum % of the feed in the diet (on an as-fed basis) was taken from Table 1 of the OPPTS Series 860 Residue Chemistry Test Guidelines.

Table 8. Calculation of Pirimiphos Acute and Chronic Residues in Poultry.

Poultry Matrix	Total Pirimiphos-methyl Residues (ppm) (Feeding Level, ppm)[1]		Tissue/Feed Ratio (Feeding Level, ppm)[2]		Max. Tissue/Feed Ratio	Acute AR (ppm)[3]	Ave. Tissue/Feed Ratio[4]	Chronic AR (ppm)[5]
	47	141	47	141				
Fat	0.054	0.164	1.15×10^{-3}	1.16×10^{-3}	1.16×10^{-3}	1.36×10^{-5}	1.16×10^{-3}	1.36×10^{-5}

[1] Tissue residues at the two feeding levels were summarized in the 5/1/98 C. Swartz memo.

[2] Tissue/feed ratios are determined by dividing the tissue residue level by the amount fed in ppm.

[3] The acute AR is determined by multiplying the maximum tissue/feed ratio by the acute anticipated dietary burden (Table 7).

[4] The average tissue/feed ratio is calculated from the tissue/feed ratios at both feeding levels.

[5] The chronic AR is determined by multiplying the average tissue/feed ratio by the chronic anticipated dietary burden (Table 7).

cc Reviewer (Cswartz); List B Rereg. File; SF
7509C:CSwartz:RRB1:CM2:Rm722H:703 305 5877:06/29/99
ExpoTeam Review: C. Olinger:6/30/99 ChemSAC Review:6/30/99

Attachment 1. Revised Tolerance Reassessment Summary for Pirimiphos-Methyl

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.409:			
Corn	8.0	8.0	*corn, field, grain; corn, pop, grain*
Cattle, fat	0.2	0.02	The tolerance can be reduced based on an adequate cattle feeding study.
Cattle, kidney and liver	2.0	Revoke	Separate tolerances for residues in liver and kidney can be revoked, since they are covered under the tolerance for residues in mbyp.
Cattle, mbyp	0.2	0.02	The tolerance can be reduced based on an adequate cattle feeding study.
Cattle, meat	0.2	Revoke	Residues may be classified under Category 3 of 40 CFR §180.6(a), i.e. there is no reasonable expectation of detectable residues.
Eggs	0.5	Revoke	
Goats, fat	0.2	0.02	See comment under "cattle, fat."
Goats, kidney and liver	2.0	Revoke	See comment under "cattle, kidney and liver."
Goats, mbyp	0.2	0.02	See comment under "cattle, mbyp."
Goats, meat	0.2	Revoke	See comment under "cattle, meat."
Hogs, fat	0.2	0.02	See comment under "cattle, fat."
Hogs, kidney and liver	2.0	Revoke	See comment under "cattle, kidney and liver."
Hogs, mbyp	0.2	0.02	See comment under "cattle, mbyp."
Hogs, meat	0.2	Revoke	See comment under "cattle, meat."
Horses, fat	0.2	0.02	See comment under "cattle, fat."
Horses, kidney and liver	2.0	Revoke	See comment under "cattle, kidney and liver."
Horses, mbyp	0.2	0.02	See comment under "cattle, mbyp."
Horses, meat	0.2	Revoke	See comment under "cattle, meat."
Kiwi fruit	5.0	Revoke	Available metabolism and magnitude of the residue data do not support this tolerance without a US registration.
Milk, fat	3.0 (0.1 ppm (N) in whole milk)	Revoke	Residues may be classified under Category 3 of 40 CFR §180.6(a), i.e. there is no reasonable expectation of detectable residues
Poultry, fat	0.2	0.02	The tolerance can be reduced based on an adequate hen feeding study.
Poultry, mbyp	2.0	Revoke	Residues may be classified under Category 3 of 40 CFR §180.6(a), i.e. there is no reasonable expectation of detectable residues.

Attachment 1. Revised Tolerance Reassessment Summary for Pirimiphos-Methyl

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Poultry, meat	2.0	Revoke	
Sheep, fat	0.2	0.02	See comment under "cattle, fat."
Sheep, kidney and liver	2.0	Revoke	See comment under "cattle, kidney and liver."
Sheep, mbyp	0.2	0.02	See comment under "cattle, mbyp."
Sheep, meat	0.2	Revoke	See comment under "cattle, meat."
Sorghum, grain	8.0	8.0	*sorghum, grain, grain*
Tolerances listed under 40 CFR §185.4950:			
Corn milling fractions (except flour)	40	Revoke	Residues do not concentrate in milling fractions
Corn oil	88	Revoke	Residues do not concentrate in refined oil (bleached/deodorized).
Sorghum milling fractions (except flour)	40	Revoke	Residues in sorghum milling fractions are no longer included in Table 1 of OPPTS 860.1000, and are not considered in Agency dietary risk assessments.
Wheat flour	8.0	Revoke	Available data do not support use on wheat; however, since residues do not concentrate in wheat flour; the tolerance should be revoked even if the registrant eventually supports use on wheat grain. [Label directions to treat wheat "for export only" are considered to be impractical.]
Tolerances listed under 40 CFR §186.4950:			
Corn milling fractions (except flour)	40	Revoke	Residues do not concentrate in corn milling fractions.
Sorghum milling fractions (except flour)	40	Revoke	Residues in sorghum milling fractions are no longer included in Table 1 of OPPTS 860.1000, and are not considered in Agency dietary risk assessments.
Tolerances needed under 40 CFR §180.409:			
Aspirated grain fractions	none	20	A tolerance is required, based on residue and processing data which demonstrated concentration in aspirated grain fractions.
Rice grain	none	TBD[a]	Residue data and tolerances are required if the registered use is to be retained.
Wheat grain	none	TBD[a]	

[a] TBD = to be determined; additional residue data are needed to determine an appropriate tolerance level.

Attachment 2. Revised Quantitative Usage Analysis (BEAD/OPP, 4/99).

File located in f:\user\share\usage\report\REDS\pir-met9.wpd

Quantitative Usage Analysis for Pirimiphos-Methyl

Case Number: 2535 PC Code: 108102
Date: 4-8-99 Analyst: Alan Halvorson

Based on available pesticide usage information primarily for 1989 - 1997, total annual domestic usage of pirimiphos-methyl is approximately 12,000 pounds active ingredient (a.i.). In terms of pounds a.i., total pirimiphos-methyl usage is allocated mainly to stored corn grain (39%), ear tags for cattle/calves (36%), stored sorghum grain (15%), corn seed (5%) and sorghum seed (5%). On average, about half of sorghum seeds, 6% of corn seeds, less than 2% of cattle and less than 1% each of stored corn grain and stored sorghum grain are treated annually, Regions with significant usage on cattle include the Gulf Coast, Midwest and West, and states with significant usage on stored corn grain include Iowa and Texas.

Attachment 2. Revised Quantitative Usage Analysis (BEAD/OPP, 4/99).

File is located in f:\user\share\usage\report\REDS\pir-met9.wpd

Pirimiphos-Methyl Case #: 2535 AI #: 100102 EPA's QUANTITATIVE USAGE ANALYSIS Analyst: Alan Halvorson Date: Apr. 8, 1999

Site	Head Grown (000)	Head Treated (000) Likely Average	Head Treated (000) Likely Max	% of Head Treated Likely Average	% of Head Treated Likely Max	Lb AI Appld (000) Likely Average	Lb AI Appld (000) Likely Max	Avg Application Rates lb ai/ hd/year	Avg Application Rates appl/ year	Avg Application Rates lb ai/ hd/appl	Regions of Most Usage (Lb AI) and Their Combined % of U.S. Usage
U.S. Cattle/Calves --	96,136	1,211	2,421	1.3%	2.5%	4.1	8.3	0.003	1.00	0.003	-
- Beef Cow Herd	62,128	895	1,791	1.4%	2.9%	3.1	6.1	0.003	1.00	0.003	Gulf West Mdwest: >69%
SD beef cattle	1,950	245	327	13%	17%	0.8	1.1	0.003	1.00	0.003	-
- Milk Cow Herd	19,857	137	274	0.7%	1.4%	0.5	0.9	0.003	1.00	0.003	MN WI: 76%

Site	Pounds Produced (000,000)	Lbs Trtd (000,000) Likely Average	Lbs Trtd (000,000) Likely Max	% of Lbs Treated Likely Average	% of Lbs Treated Likely Max	Lb AI Appld (000) Likely Average	Lb AI Appld (000) Likely Max	Avg Application Rates lb ai/ ton/yr	Avg Application Rates appl/ year	Avg Application Rates lb ai/ ton/appl	States of Most Usage (Lb AI) and Their Combined % of U.S. Usage
Corn Seed	1,110	69	104	6%	9%	0.6	0.8	0.02	1.0	0.02	-
Sorghum Seed	86	44	66	52%	76%	0.5	0.8	0.02	1.0	0.02	-

Site	Bushels Produced (000,000)	Bu Trtd (000,000) Likely Average	Bu Trtd (000,000) Likely Max	% of Bu Treated Likely Average	% of Bu Treated Likely Max	Lb AI Appld (000) Likely Average	Lb AI Appld (000) Likely Max	Avg Application Rates lb ai/ 1000 bu/yr	Avg Application Rates appl/ year	Avg Application Rates lb ai/ 1000 bu/appl	States of Most Usage (Lb AI) and Their Combined % of U.S. Usage
Corn Grain	9,200	12	23	0.1%	0.3%	4	9	0.4	1.0	0.4	IA TX: 94%
Sorghum Grain	681	5	10	0.7%	1.5%	2	4	0.4	1.0	0.4	-
Wheat Grain	4,402	-	-	-	-	-	-	-	-	-	MO: -

Site	Bulbs Produced (000)	Bulbs Trtd (000) Likely Average	Bulbs Trtd (000) Likely Max	% of Bulbs Trtd Likely Average	% of Bulbs Trtd Likely Max	Lb AI Appld (000) Likely Average	Lb AI Appld (000) Likely Max	Avg Application Rates lb ai/ 1000 bulbs/yr	Avg Application Rates appl/ year	Avg Application Rates lb ai/ 1000 bulbs/appl	States of Most Usage (Lb AI) and Their Combined % of U.S. Usage
Iris Bulbs	-	20,000	40,000	-	-	0.1	0.3	0.006	3.0	0.002	WA: 100%
TOTAL						12	17				

Notes --
- Usage estimates are primarily based on 1989-1997 data.
- Average application rates for all cattle (ear tags) are assumed to be the same as those for SD beef cattle (ear tags).
- Data in the table may not appear to exactly multiply across or add down because of rounding.

Attachment 2. Revised Quantitative Usage Analysis (BEAD/OPP, 4/99).

- A dash (-) indicates that information on this site is NOT available in EPA sources or is insufficient.
- Beef cow herd includes cows/heifers that have calved (which are mostly beef cows); heifers and heifer calves; and steers, steer calves, bulls and bull calves.
- Milk cow herd includes cows/heifers that have calved (which are mostly milk cows); heifers and heifer calves; and steers, steer calves, bulls and bull calves.
- Corn and sorghum seeds produced were estimated using seeding rates of 14 pounds seed per acre for corn and 7.2 pounds seed per acre for sorghum.

Sources --
- Agricultural Marketing Research Services, The Market for Cattle Insecticides, 1993-1994 data
- EPA proprietary data, 1989-1993
- SD Dept. of Agric., South Dakota Agriculture: 1996-1997
- SD State Univ., 1995 South Dakota Beef Cattle Pesticide Use Survey
- The Kevric Co., Market Analysis of Postharvest Pesticide Use, Dec. 1997
- US Dept. of Commerce, 1992 Census of Agriculture: US
- USDA/NASS, Agricultural Chemical Usage, Postharvest Applications - Corn and Wheat, 1997 data