Reg Std File

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

JUN 1 1992

MEMORANDUM

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Metalaxyl. Ciba-Geigy Response to Guidance Document (FRSTR) Dated 9/88. MRID # 418703-01 through -07. CBRS # 8043. DP Barcode: D164655.

FROM: Leung Cheng, Chemist
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division (H7509C)

THROUGH: Francis B. Suhre, Section Head
Chemistry Branch II - Reregistration Support
Health Effects Division (H7509C)

TO: Lois Rossi, Chief
Reregistration Branch
Special Review/Reregistration Division (H7508C)

Attached is a review of residue chemistry data submitted by Ciba-Geigy in response to the Metalaxyl Guidance Document dated 9/88. This information was reviewed by Acurex Corporation under the supervision of CBRS, HED. The data assessment has undergone secondary review in the branch and has been revised to reflect branch policies.

Please see our conclusions in the attached review regarding the adequacy of the information provided by Ciba-Geigy.

Revised chemical status sheet is also included. If you need additional input, please advise.

Attachment: Acurex review of Registrant's Response to Residue Chemistry Data Requirements

cc(without Attachment): Cheng
cc(with Attachment): Circu, RF, SF, Reg Std Update File, Susan Lewis/Ben Chambliss, PIB/FOD, SRRD, Acurex
RDI:FSuhre:5/29/92:EZager:6/1/92
H7509C:CBII-RS:LCheng:CM#2:RM810:5/26/92:02:METALAXYL\ACUREX1

METALAXYL
(Chemical Code No. 113501)
(CBRS No. 8043; DP Barcode D164655)

TASK 3

Registrant's Response to Residue Chemistry Data Requirements

October 24, 1991

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

Acurex Corporation
Environmental Systems Division
4915 Prospectus Drive
P.O. Box 13109
Research Triangle Park, NC 27709

METALAXYL
(Chemical Code No. 113501)
(CBRS No. 8043; DP Barcode D164655)

TASK 3

Registrant's Response to Residue Chemistry Data Requirements

October 24, 1991

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

Acurex Corporation
Environmental Systems Division
4915 Prospectus Drive
P.O. Box 13109
Research Triangle Park, NC 27709

METALAXYL

(Chemical Code 113501)

(CBRS No. 8043; DP Barcode D164655)

REGISTRANTS RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

Task-3

BACKGROUND

The Metalaxyl Guidance Document (FRSTR) dated 9/88 required residue chemistry data pertaining to animal metabolism, storage stability, residues in or on corn and peanut raw agricultural commodities, and processing studies on potatoes, sugar beets, corn, rice, sorghum, cottonseed, pineapples, and sunflower seeds.

In response to these requirements, CIBA-GEIGY Corp. submitted data on metabolism in hens and goats, storage stability of residues and residue sample storage intervals, and data from field trials on corn. These data were reviewed in the Metalaxyl Reregistration Standard Update dated 3/91.

Recently, CIBA-GEIGY Corp. submitted data pertaining to residues in or on corn (1991; MRID 41870301) and peanut (1991; 41870306), and processing studies on potatoes (1991; MRID 41870307), corn (1991; MRID 41870301), rice (1991; MRID 41870303), sorghum (1991; MRID 41870302), cottonseed (1991; MRID 41870305), and sunflower seed (1991; MRID 41870304). These data, assigned, CBRS No. 8043, are reviewed here for their adequacy in fulfilling outstanding residue chemistry data requirements. A rotational crop study (MRID 41870308) submitted with this package is being forwarded to EFED and is not reviewed here. The Conclusions and Recommendations stated herein pertain only to the magnitude of the residue in the subject crops and processed commodities.

The qualitative nature of the residue is adequately understood. The residues of concern are metalaxyl and its metabolites containing the 2,6-dimethylamine (DMA) moiety. Method I in PAM, Vol. II is adequate for tolerance enforcement.

Codex MRLs of 0.05 ppm have been proposed (Step 6) for residues of metalaxyl *per se* in or on potatoes, cottonseed, and sunflower seed. These MRLs differ from the U.S. tolerances with respect to residue level and the compound(s) regulated. Compatibility of these MRLs with the corresponding U.S. tolerances would not be possible without a major revision in the U.S tolerance definition. There are no Codex MRLs proposed or established for metalaxyl residues in or on cereal grains or peanuts.

CONCLUSIONS

1. Method AG-395 adequately recovered metalaxyl from fortified samples. However, apparent residues in or on untreated sunflower seed and control samples of all processed commodities were above the stated 0.05 ppm detection limit. Moreover, apparent residues were greater than the 0.1 ppm tolerance level in four of eight control seed samples reported and also in control seed meal. High apparent residues were observed in untreated peanut hulls, vines, and hay, also. The registrant needs to explain these findings.

2a. The peanut field trial data indicate that tolerance-exceeding residues can result in or on peanut nutmeats from at-pegging applications of a G formulation at 1 lb ai/A (the maximum rate for this registrant's 1% G MAI formulation). The registrant stated that these data were submitted in support of the 5% G label (EPA Reg No. 100-628), on which a maximum rate of 0.5 lb ai/A is specified at pegging.

2b. If the registrant does not intend to support the 1% G formulation (EPA Reg. No. 100-664), they should cancel this registration or amend this label to specify a maximum rate of 0.5 lb ai/13,000 linear feet at pegging. Otherwise they must propose a revised tolerance that is supported by adequate residue data. In addition, an explanation of the high apparent residues in control samples of hay (up to 4.5 ppm), hulls (0.63 ppm), and vines (2.4 ppm) is required, in order for these data to be found acceptable.

2c. Residue data are adequate to support reregistration of metalaxyl use on peanuts, provided the maximum use rate (at-pegging) for both the 1% and 5% G formulations is 0.5 lb ai/A or 0.5 lb ai/13,000 linear feet with 40 inch row spacing. Since the residue data were generated at PHI's of 65-92 days, the current PHI (45 days) must also be amended.

3a. The data in this submission support the 0.1 ppm tolerances for grain crops and forage grasses that currently cover metalaxyl residues in corn grain, forage, and fodder.

3b. The corn grain processing study is adequate. Residues did not concentrate during wet or dry milling of corn grain. These data satisfy the requirements of the Guidance Document. No food/feed additive tolerance is required.

4. The sorghum grain processing study is adequate. Residues did not concentrate in flour or starch. These data satisfy the requirements of the Guidance Document. No food/feed additive tolerance is required.

5a. The available data on rice are insufficient to determine the potential for concentration of residues during processing. The data indicate that residues concentrated in bran processed from grain with residues below the validated detection limit. The raw data needed to determine the actual residues in or on grain were not provided. Therefore, a concentration factor could not be calculated.

5b. In the submission on rice, the registrant estimated the exaggerated rates of the broadcast preemergence treatments by comparing those rates with the amount of active ingredient applied to seed for planting one acre and arrived at overestimated factors of 64 and 192x. The registrant must explain the calculations used to arrive at these estimates.

6. The sunflower seed processing study indicated that residues concentrated up to 1.5x in seed meal. The registrant must propose a feed additive tolerance for residues in sunflower seed meal. The data indicate that a level of 0.2 ppm would be appropriate. Residues did not concentrate in hulls, crude oil, refined oil, or soapstock. Data requirement for sunflower seeds is satisfied pending an explanation regarding the high metalaxyl values in control samples.

7. The cottonseed processing study is adequate. Residues did not concentrate in meal, hulls, crude oil, refined oil, or soapstock. These data satisfy the requirements of the Guidance Document. No food/feed additive tolerance is required.

8. The potato processing study fulfills the Guidance Document requirements for this crop. The data indicate that residues of metalaxyl concentrate up to 15.3x in dried peel, up to 2.4x in potato flakes, and up to 1.4x in potato chips. The registrant should amend the feed additive tolerance for dried processed potato waste to 10 ppm. The data support the established food additive tolerance.

RECOMMENDATIONS

The registrant must submit additional information from the test on rice described in MRID 41870303. Raw data and/or chromatograms are required from the analysis of the rice grain and processed bran samples from the test in which the higher exaggerated rate was applied. The registrant must account for the high apparent residues in control samples of sunflower seed and processed commodities (MRID 41870304).

The high apparent residues in control samples of peanut and sunflower seed commodities must be explained.

The registrant must amend the current food/feed additive tolerances for residues in dried processed potato waste to 10 ppm. In addition, a feed additive tolerance for residues in sunflower seed meal is required.

DETAILED CONSIDERATIONS

Residue Analytical Methods

CIBA-GEIGY Corp. analytical Method AG-395 was used to determine residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline (DMA) moiety and N-[2-(hydroxymethyl)-6-methylphenyl]-N-(methoxyacetyl)alanine methyl ester in corn grain and processed commodities (1991; MRID 41870301), sorghum commodities (1991; MRID 41870302), rice commodities (1991; MRID 41870303), sunflower commodities (1991; MRID 41870304), cottonseed commodities (1991; MRID 41870305), peanut commodities (1991; MRID 41870306), and potato commodities (1991; MRID 41870307).

Method AG-395 is an improved version of Method AG-348, which is published as Method I in PAM, Vol. II. It has undergone a successful Agency validation trial and has been validated using ^{14}C-plant residues. The method was discussed in detail in the 1987 FRSTR Residue Chemistry Chapter. In method AG-395, residues are extracted in methanol:water and refluxed with methanesulfonic acid and then basified, converting the residues of concern to DMA. After cleanup, the DMA residues are analyzed using GLC with a nitrogen/phosphorus detector in the nitrogen mode. The stated detection limit is 0.05 ppm.

Concurrently with the residue samples analyzed in the current submissions, untreated samples were fortified with metalaxyl and analyzed using method AG-395. The recovery data are presented in Tables 1 through 3. Apparent residues in or on control samples of corn, sorghum, rice, and cottonseed commodities were <0.05 ppm (nondetectable). Apparent residues in controls of peanut vines, hay, and shells (Table 3) were above the 0.05 ppm detection limit, though well below the established tolerances. The apparent residues in or on most of the sunflower commodity controls, however, were greater than the established tolerances of 0.1 ppm (Table 2). The concentration of residues in the sunflower processing study can be evaluated in spite of this problem. However, the registrant should explain these high control values.

Table 1. Recoveries of metalaxyl from fortified control samples using method AG-395.

Substrate	MRID	Fortification (ppm)	Recovery (%)
Rice grain	41870303	0.1-0.5	78
processed commodities		0.05-0.2	82-98

7

Substrate	MRID	Fortification (ppm)	Recovery (%)
Corn grain	41870301	0.20	94
processed commodities		0.05-0.2	67-119
Sorghum forage, hay and fodder	41870302	1-5	80-88
Sorghum grain		0.05-0.1	84-104
processed commodities		0.05-0.5	71-94
Cotton fodder	41870305	0.1-2	89-102
Cottonseed		0.1-0.5	76-91
processed commodities		0.05-0.5	63-106
Potatoes	41870307	0.05-1	74-125
processed commodities		0.05-5	69-110

Table 2. Recoveries of metalaxyl from fortified controls of sunflower forage, seed, and processed fractions using method AG-395.

Substrate	Controls (ppm)	Fortification (ppm)	% Recovered
Forage	0.16-0.46	0.5-1	83-95
Seed	0.06-0.18	0.1-0.5	71-99
processed commodities	0.06-0.12	0.05-3	73-101

Table 3. Apparent residues in controls (eight samples of each matrix) and recoveries of metalaxyl from fortified controls of peanut vines, hay, nutmeats, and shells using AG-395 (1991; MRID 41870306).

Substrate	Controls (ppm)	Fortification (ppm)	% Recovered
Vines	<0.5-2.4	1-20	66-113
Hay	0.08-4.5	1-20	71-92
Nutmeats	<0.05	0.1-1	71-87
Hulls	<0.05-0.06	0.05-1	74-102

Magnitude of the Residue in Plants

Peanuts. Tolerances have been established for residues of metalaxyl and its metabolites containing the 2,6-dimethylamine (DMA) moiety and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester in or on peanut nutmeats, peanut hulls, and peanut forage and hay at 0.2, 2, and 20 ppm, respectively (40 CFR §180.408[a]).

The 1% G (MAI) formulation (EPA Reg. No. 100-664) is registered for soil application to peanuts at planting at 0.25 lb ai/A and at pegging at 1 lb ai/A (1 lb ai/ca. 13,000 linear feet, 40-inch rows); no PHI is specified. The label for a 5% G (EPA Reg. No. 100-628) states the same use pattern except that the maximum rate is 0.5 lb ai/A (0.5 lb ai/12,400 linear feet, 42-inch rows) and 45-day PHI is specified.

CIBA-GEIGY Corp. submitted data (1991; MRID 41870306) from eight tests conducted in TX(1), OK(1), NC(1), GA(2), AL(2), and VA(1) depicting combined metalaxyl and associated metabolite residues in or on peanuts (nutmeat), hulls, hay, and vines harvested 65-92 days after in-furrow application of the 5% G formulation at planting at 0.25 lb ai/A, followed by banded application of the 5% G at 0.5 or 1 lb ai/A at pegging. The registrant stated that 0.5 lb ai/A is the 1x rate on the 5% G label, rather than the 1 lb ai/13,000 linear feet rate specified by the Guidance Document. However, the EPA Reference Files System lists the 1% G (EPA Reg. No. 100-664) as an active Ciba-Geigy registration. Thus the at-pegging rates used in this study actually represent 0.5 and 1x. Whole peanuts were separated into nutmeat and shells. After preparation, treated samples and untreated controls were shipped and stored frozen (approximately -20 °C) for 9-13 months prior to analysis.

The results of analysis of treated samples are presented in Table 4. Two samples of nutmeats from the 1x treatment bore tolerance exceeding residues of 0.22 and 0.23 ppm. The other two samples from the 1x treatment contained <0.05 and 0.17 ppm.

Apparent residues in or on control samples (Table 3) were <0.05 ppm in or on nutmeats, <0.05-0.06 ppm in or on hulls, 0.1-0.63 ppm in or on hay (seven samples) and 4.5 ppm in or on one additional hay sample, and <0.05-2.4 ppm in or on vines. The registrant needs to explain these high control values.

Table 4. Metalaxyl residues in peanut raw agricultural commodities collected 65-92 days after treatment.

Commodity	Rate: 0.5x	Rate: 1x
	ppm	
Nutmeat	<0.05-0.16 (16)[a]	<0.05-0.23 (4)
Hulls	<0.05-0.81 (16)	0.05-1.7 (4)
Hay	0.28-5.7[b] (16)	0.35-7.0 (4)
Vines	0.65-4.4[b] (16)	1.2-8.7 (4)

[a]Number of samples given in parentheses. [b]Maximum value confirmed by reanalysis using alternate column.

9

The samples were analyzed using method AG-395. The detection limit was reported as 0.05 ppm for each peanut commodity, although higher apparent residues in controls of hulls, hay, and vines were observed. Recoveries are summarized in Table 3 above.

Geographic representation is adequate. The test states of GA(46%), AL(14%), TX(12%), NC(9%), VA(6%), and OK(5%) accounted for approximately 92% of the 1989 U.S. peanut production (Agricultural Statistics, 1990, p 118). These data indicate that tolerance-exceeding residues can result from at-pegging applications of a G formulation at 1 lb ai/A. The registrant stated that these data were submitted in support of the 5% G label (EPA Reg No. 100-628), on which a maximum rate of 0.5 lb ai/A is specified. If the registrant does not intend to support the 1% G formulation (EPA Reg. No. 100-664), they should cancel this registration or amend this label to specify a maximum rate of 0.5 lb ai/13,000 linear feet. Otherwise they must propose a revised tolerance that is supported by adequate residue data. In addition, an explanation of the high apparent residues in control samples of hay and vines is required.

Since the RAC's were sampled at 65 days and beyond, the current PHI (45 days) must also be amended.

Corn. Tolerances of 0.1 ppm have been established for residues of metalaxyl and its metabolites containing the 2,6-dimethylamine (DMA) moiety and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester in or on grain crops and forage grasses (40 CFR §180.408[a]).

CIBA-GEIGY Corp. submitted data pertaining to metalaxyl and associated metabolites in the raw agricultural and processed commodities of corn (1991; MRID 41870301). Field corn seed for three tests conducted in IL was treated using the 25% WP formulation at 0.5 oz ai/100 lb of seed (1x the maximum registered rate) prior to planting. In two of the tests, an additional preemergence broadcast (non-incorporated) soil application was made using the 2 lb/gal EC formulation at 2 or 6 lb ai/A. The registrant stated that the seed-plus-preemergence applications represent 284 and 853x exaggerated rates. We note that seed treatment using the 25% WP or 3 lb/gal FlC formulation is the only registered use of metalaxyl on corn. Although the addition of a preemergence treatment represents an exaggerated exposure, we cannot assume that the rate used in the preemergence treatment would result in the equivalent exposures claimed by the registrant.

Data were presented on residues in each RAC matrix from the three tests. Treatment-to-sampling intervals were 61 days for forage, 96 days for silage, and 167 days for grain and fodder. The samples were stored at -20 °C for 8-13 months prior to analysis using GLC method AG-395. Residues were <0.05 ppm (nondetectable) in or on one sample of grain, forage, fodder, and silage from the seed-treatment test. Residues were <0.05 ppm (nondetectable) and 0.05 and 0.06 ppm in or on samples of grain from the tests in which soil application was made at 2 and 6 lb ai/A (two samples from each test).

Residues were <0.05-0.5 ppm in or on a total of 12 samples of forage, silage, and fodder from the two seed-plus-soil tests. Apparent residues in or on one control sample of each commodity were nondetectable (<0.05 ppm).

Grain samples from each test were processed into grits, meal, flour, crude oil, and refined oil (dry milling) and starch, crude oil, and refined oil (wet milling) fractions at the Food Protein and Research Development, Texas A & M University using a laboratory simulation of industrial practice. The dry- and wet-milled fractions were kept frozen at approximately -15 °C for 9-10 months prior to analysis. Residues were analyzed using method AG-395. Recovery data are presented in Table 1. Residues were <0.05 ppm (nondetectable) in one sample of each commodity processed from grain from each of the three tests.

These data support the 0.1 ppm tolerance for forage grasses that currently covers corn forage and fodder. In addition, data from this study indicate that residues did not concentrate in any wet or dry milled commodity processed from metalaxyl treated corn grain. No food/feed additive tolerance is required. These data fulfill the requirements of the Guidance Document.

Processed food/feed

Potatoes. A tolerance of 0.5 ppm has been established for residues of metalaxyl and its metabolites containing the 2,6-dimethylamine (DMA) moiety and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester in or on potatoes (40 CFR §180.408[a]). Food and feed additive tolerances of 4 ppm have been established for these same residues in processed potatoes, including potato chips (40 CFR §185.4000[a]) and dried processed potato waste (40 CFR §186.4000[a]).

CIBA-GEIGY Corp.(1991; MRID 41870307) submitted data pertaining to residues of metalaxyl and associated metabolites in or on potatoes and processed commodities. Potato plants were treated at 1x the maximum use rate, consisting of one broadcast non-incorporated application of the 2 lb/gal EC formulation at 2 lb ai/A at planting followed by four foliar applications of the 58% WP formulation at 1.16 lb ai/A administered at 14-day intervals beginning 6 weeks after planting. Exaggerated treatments using 3x and 5x the maximum rate were also applied. Samples were harvested 6 days after the last treatment, shipped frozen, and stored at ca. -20 °C for 423-431 days (up to 14 months) prior to analysis. Using a laboratory simulation of commercial processing, mature potato tubers were processed into potato chips, flakes, and waste fractions. A total of six samples of mature potato tubers, consisting of three combined pairs of A and B replicates from each of the three applied rates, along with one control sample were analyzed. For processed commodities, also, three pairs of replicate samples and one control sample were analyzed from each test. Analyses were conducted using GLC method AG-395. The limit of detection was 0.05 ppm for combined residues. Recovery data are presented in Table 1. Apparent residues in or on control samples were <0.05 ppm (nondetectable). The residue data are summarized in Table 5.

This study fulfills the requirements of the Guidance Document for a potato processing study. The data indicate that residues concentrate up to 15.3x in dried peel (1.22 ppm processed from potatoes bearing 0.08 ppm), up to 2.4x in potato flakes (0.19 ppm in flakes from potatoes bearing 0.08 ppm), and up to 1.4x in potato chips (0.07 ppm in chips from potatoes with residues of 0.05 ppm). The registrant should amend the feed additive tolerance for dried processed potato waste to 10 ppm.

Table 5. Residue levels in processed commodities of potatoes (1991; MRID 41870307).

Substrate	Residues (ppm) 1x	3x	5x
Mature tubers	<0.05-0.05	<0.05-0.05	0.07-0.09
Potato chip process:			
Potatoes before process	<0.05	<0.05	0.06
Potato chips	<0.05	0.07	0.06
Potato flake process:			
Potatoes before process	<0.05	0.07	0.08
Wet peel and trimmings	<0.05	<0.05	0.07
Dry peel and trimmings	0.25	0.53	1.22
Sliced and peeled potatoes	0.05	0.05	0.10
Potato flakes	0.05	0.11	0.19

Rice. A tolerance of 0.1 ppm has been established for residues of metalaxyl and its metabolites containing the 2,6-dimethylamine (DMA) moiety and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester in or on grain crops (40 CFR §180.408[a]).

CIBA-GEIGY Corp. (1989; MRID 41870303) submitted data pertaining to metalaxyl and associated metabolite residues in or on rice grain and processed commodities. Rice seed for three tests was treated using the 25% WP formulation at 0.5 oz ai/100 lb of seed (1x the maximum registered rate) and planted at approximately 100 lb of seed per acre. In two of the tests, an additional preemergence broadcast (non-incorporated) soil application was made using the 2 lb/gal EC formulation at 2 or 6 lb ai/A. The authors stated that the seed-plus-preemergence applications represent 64 and 192x exaggerated rates. We note that seed treatment using the 25% WP or 3 lb/gal FlC formulation is the only registered use of metalaxyl on rice. Although the addition of a preemergence treatment does represent an exaggerated exposure, we cannot assume that the rate used in the preemergence treatment would result in the equivalent exposures claimed by the registrant.

One sample of rice grain from each treatment was harvested 130 days posttreatment, stored at -20 °C for 6-7 months prior to processing. Grain and processed samples were shipped frozen to the analysis laboratory where they were stored for up to 6 months prior to analysis. Grain bearing no detectable residue (<0.05 ppm) was processed into hulls, unpolished grain, bran, and polished rice using a laboratory simulation of commercial processing. Residues were <0.05 ppm (nondetectable) in a total of three samples of each commodity, with the exception of one sample of bran containing detectable residues of 0.05 ppm. Chromatograms from the analysis of this bran sample and the grain from which it was processed were not provided. Apparent residues in or on one untreated sample of each commodity were <0.05 ppm (nondetectable).

Residues were analyzed using the adequate GLC method AG-395. The stated detection limit was 0.05 ppm for all commodities. However, this was validated only for rice grain. Recoveries from each commodity are summarized in Table 1.

These data are insufficient to determine the need for food or feed additive tolerances. The registrant estimated the exaggerated rates of those tests in which broadcast preemergence treatments were applied based on comparison with the amount of active ingredient applied to treated seed, and arrived at overestimated factors of 64 and 192x. The registrant must explain how they arrived at these concentration factors.

The data reported by the registrant indicate that residues concentrated in bran; however, a concentration factor could not be determined because chromatograms were not provided for those samples. In cases such as this, when RAC samples with no detectable residues yield processed samples with detectable residue, the Agency may estimate residue levels from chromatograms where the response is below the validated limit of detection but indicative of a measurable residue. Additional data are required.

Sorghum. A tolerance of 0.1 ppm has been established for residues of metalaxyl and its metabolites containing the 2,6-dimethylamine (DMA) moiety and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester in or on grain crops (40 CFR §180.408[a]).

CIBA-GEIGY Corp. submitted data (1991; MRID 41870302) pertaining to metalaxyl and associated metabolite residues in the processed commodities of sorghum grain. Grain sorghum was treated using the 25% WP formulation at 1 oz ai/100 lb of seed (two applications at 0.5 oz ai/100 lb seed; 12-day interval between the two applications) prior to planting. In two of the tests, an additional preemergence broadcast (non-incorporated) soil application was made using the 2 lb/gal EC formulation at 2 or 6 lb ai/A. The registrant stated that the seed-plus-preemergence applications represented 920 and 2,759x exaggerated rates. However, we note that seed treatment using the 25% WP or 3 lb/gal FlC formulation is the only registered use of metalaxyl on sorghum. Although the addition of a preemergence treatment represents an exaggerated exposure, we cannot assume that the rates used in the broadcast preemergence treatment would result in the equivalent exposures claimed by the registrant.

Samples of each RAC matrix were collected from each test. Treatment-to-sampling intervals were 61 days for forage and hay, 85 days for silage, and 138 days for fodder and grain. The samples were stored at -20 °C for 14-20 months. The residue data are presented in Table 6. Apparent residues in one control sample of each commodity were nondetectable (<0.05 ppm).

Table 6. Residues (ppm) found in the raw agricultural commodities of sorghum (1991; MRID 41870302).

Commodity	Treatment		
	seed	seed/soil(2)[a]	seed/soil(6)[a]
Grain	<0.05, <0.05	0.09, 0.08	0.38, 0.19
Forage	0.07, 0.15	0.24, 0.20	0.59, 0.19
Hay	0.08, 0.07	0.29, 0.26	1.00, 0.64
Silage	<0.05, <0.05	0.15, 0.25	0.52, 0.74
Fodder	<0.05, <0.05	0.31, 0.23	0.38, 0.19

[a]Numbers in parentheses are lb ai/A rates for broadcast soil treatments.

Grain samples from each test were processed into flour and starch at the Research Development Center, Texas A & M University, using a laboratory simulation of industrial practice. The grain and processed fractions were kept frozen at approximately -15 °C for 13-16 months prior to analysis. One sample each of starch and flour from each of three treatments was analyzed. Residues were nondetectable (<0.05 ppm) in all of the starch samples. Residues were nondetectable (<0.05 ppm), 0.08 and 0.17 ppm in one sample of flour from the seed treatment and the low and high exaggerated treatments, respectively.

All samples were analyzed using adequate GLC method AG-395. The limit of detection was 0.05 ppm for each commodity. Recovery data are reported above in Table 1.

These data fulfill the requirements of the Guidance Document. Residue concentration did not occur in starch or flour processed from sorghum grain. No food/feed additive tolerance is required.

<u>Cottonseed</u>. A tolerance of 0.1 ppm has been established for residues of metalaxyl and its metabolites containing the 2,6-dimethylamine (DMA) moiety and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester in or on cottonseed (40 CFR §180.408[a]).

CIBA-GEIGY Corp. (1991; MRID 41870305) submitted data pertaining to residues of metalaxyl and associated metabolites in or on cottonseed and processed commodities. Cottonseed was treated using the 25% WP formulation at 0.5 oz. ai/100 lb of seed and planted at approximately 100 lb of seed per acre. In one test, one in-furrow application of the 5% G formulation at 0.01 lb ai/1,000 linear ft. of row (1x the maximum registered rate) was made at planting. In two additional tests, in-furrow treatments were made at 0.03 or 0.05 lb ai/1,000 linear ft of row (3 and 5x, respectively).

Measurable residues of 0.05 and 0.06 ppm, respectively, were detected in or on one sample (of two) analyzed from the 3x and 5x treated samples. All other samples bore nondetectable residues (<0.05 ppm), including two seed samples from the 1x test and a total of three samples of each processed commodity (hulls, meal, crude oil, refined oil, and soapstock). Residues were <0.05 ppm (nondetectable) in or on untreated samples of all commodities.

Samples were shipped frozen and stored at approximately -20 °C for 12-13 months prior to analysis. Residue analyses were conducted using GLC method AG-395. The detection limit was 0.05 ppm for total residues. Recovery data are summarized in Table 1.

This study satisfies the requirements of the Guidance Document for a processing study on cottonseed. Residues did not concentrate in any commodity. No food/feed additive tolerance is required.

<u>Sunflower seed</u>. A tolerance of 0.1 ppm has been established for residues of metalaxyl and its metabolites containing the 2,6-dimethylamine (DMA) moiety and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester in or on sunflowers (40 CFR §180.408[a]).

CIBA-GEIGY Corp. submitted data from a study conducted in KS to determine residues of metalaxyl and its metabolites in sunflower forage, seed, and processed fractions of the seed (1991; MRID 41870304). Seed for three tests were treated using the 25% WP formulation at 0.5 oz ai/100 lb of seed (1x the maximum registered rate) and planted at approximately 7 lb of seed per acre. In two of the tests, an additional preemergence broadcast (non-incorporated) soil application was made using the 2 lb/gal EC formulation at 2 or 6 lb ai/A. The authors stated that the seed-plus-preemergence applications represented 455x and 1,364x exaggerated rates. We note that seed treatment using the 25% WP or 3 lb/gal FlC formulation is the only registered use of metalaxyl on sunflowers. Whereas the addition of a preemergence treatment does represent an exaggerated exposure, we cannot assume that the rate used in the preemergence treatment would result in the equivalent exposures claimed by the registrant.

Sunflower forage and seed samples collected 162 days posttreatment were stored in a freezer at approximately -20 °C. Sunflower seed samples were processed into hulls, kernels, presscake (meal), crude oil, soapstock, refined oil, refined bleached oil, refined bleached hydrogenated oil, and refined bleached hydrogenated deodorized oil. Processing took place on a small scale in the laboratory by procedures that simulated industrial practice. After processing, fractions were stored in a freezer at approximately -20 °C. Total storage time between seed harvest and analysis of residues in seed and processed fractions was 12-13 months.

Residues were analyzed using GLC method AG-395. Recovery data and residues in or on control samples are presented above in Table 2. The detection limit was 0.05 ppm for total residues in each commodity. Apparent residues in control samples were greater than the limit of detection in or on all seed (0.09-0.18 ppm), hull (0.06 ppm), kernel (0.08 ppm), and seed meal (presscake; 0.12 ppm) samples.

Residues were <0.05 ppm in or on two samples of sunflower seed from the seed-treatment-only test. Residues in sunflower seed and processed fractions from the exaggerated-rate tests are presented in Table 7. Residues concentrated up to 1.34x in a sample of seed meal containing 0.75 ppm processed from seed bearing residues of 0.56 ppm. If the residue values from treated samples are corrected for the detectable control residues, the results indicate that residues concentrated 1.5x in meal. A feed additive tolerance is needed for this commodity. Residues did not concentrate in hulls, crude oil, refined oil, or soapstock.

Data requirement for sunflower seed is satisfied pending an explanation from the registrant regarding the high control values observed.

Table 7. Residues of metalaxyl in sunflower seed and processed commodities (1991; MRID 41870304).

Commodity	Controls (ppm)	Metalaxyl Residue (ppm) Seed/soil(2 lb ai/A)	Seed/soil(6 lb ai/A)
Seed	0.09-0.18	0.75	1.5
Seed Before Processing	0.08	0.56 (0.41)[a]	1.5
Cleaned Seed	0.06	0.43	1.1
Hulls	0.06	0.43	0.87
Kernels	0.08	0.65	1.3
Seed meal	0.12	0.75 (0.63)[a]	1.9
Crude Oil	<0.05	<0.05	0.05
Refined Oil	<0.05	<0.05	<0.05
Soapstock	<0.05	0.11	0.30

[a] Values in parentheses were corrected by subtracting apparent residues in controls of seed (average of 0.15 ppm) and meal (0.12 ppm).

References:

Citations for the MRID documents and Agency correspondence referred to in this review are presented below. Submissions reviewed in this document are indicated in shaded type.

41870301 Ross, J.A. (1991) Amendment 1 to ABR-90075: Metalaxyl Magnitude of the Residues in Field Corn Forage, Silage-Stage Forage, Fodder, And Grain Following Treatment With Apron 25W. Unpublished study prepared by CIBA-GEIGY Corp. 222 p.

41870302 Eudy, L.W. (1991) Metalaxyl Magnitude of the Residue in Processed Food/Feed Commodities of Grain Sorghum Following Seed Treatment With Apron 25W. Unpublished study prepared by CIBA-GEIGY Corp. 147 p.

41870303 Smith, J. (1991) Metalaxyl: Magnitude of the Residue in Processed food/feed commodities of rice following seed treatment with Apron 25W plus preemergence application of Ridomil 2E: Lab Project Number: AMR-90102. Unpublished study prepared by Ciba-Geigy Corp. 135 p.

41870304 Smith, J.W. (1991) Metalaxyl Magnitude of the Residues in Processed Food/Feed Commodities of Sunflowers Following Seed Treatment With Apron 25W. Unpublished study prepared by CIBA-GEIGY Corp. 138 p.

41870305 Smith, J.W. (1991) Metalaxyl Magnitude of the Residues in Processed Food/Feed Commodities of Cottonseed Following Seed Treatment With Apron 25W Plus In-Furrow Application of Ridomil 5G. Unpublished study prepared by CIBA-GEIGY Corp. 120 p.

41870306 Eudy, L. (1991) Metalaxyl: Magnitude of the residue in Peanut vines, hay, nutmeats and shells following in-furrow plus banded applications of Ridomil 5G: Lab Project Number: ABR-90107. Unpublished study prepared by Ciba-Geigy Corp. 172 p.

41870307 Eudy, L.W. (1991) Magnitude of the Residues in Processed Food/Feed Commodities of Potatoes Following Application of Ridomil 2E Plus Ridomil MZ58. Unpublished study prepared by CIBA-GEIGY Corp. 119 p.