~~M. Nelson~~
F. Griffith
8F3617

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

JUL 5 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for the Proposed Use of Metalaxyl on Sugar Beet Tops and Roots, PP#8F3617/8H5554

FROM: Rita Briggs, Ph.D. RB
Dietary Risk Evaluation System (DRES) Staff
HED/SACB (H7509C)

THROUGH: James P. Kariya
Acting Section Head, DRES
Health Effects Division (H7509C)

TO: Susan Lewis, PM 21
Fungicide-Herbicide Branch
Registration Division (H7505C)

Action Requested

To provide an estimate of dietary exposure to metalaxyl from published tolerances, pending tolerances and the proposed tolerance on sugar beet. Note that DRES did not take any action with respect to the legume vegetables (dry and succulent) included in the present petition because DEB informed us that the registrant will be requesting deletion of all uses of metalaxyl on this crop group (F.D. Griffith, DEB memo and personal communication). The DRES analysis can be revised when the petitioner requests the specific change in legume vegetables.

Discussion

1. Toxicology Endpoint: The routine chronic DRES analysis used a reference dose (ADI) of 0.06 mg/kg body weight/day, based upon a NOEL of 6.25 mg/kg body weight/day for increased alkaline phosphatase activity and liver weights, and an uncertainty factor of 100 from a 6 month dog feeding study. This value has been approved by HED (05/23/86) and Agency (07/08/86) reference dose committees.

2. Residue Information: Food uses evaluated were published tolerances from 40 CFR 180.408, food additive tolerances from 185.4000, pending tolerances for the root and tuber vegetables group, strawberries, alfalfa and barley, as well as the proposed use on sugar beet tops and roots. DEB recommended for a tolerance of 10 ppm on sugar beet tops, 0.5 ppm on sugar beet roots (beet sugar) and for a feed additive tolerance of 5 ppm on sugar beet

molasses. The published secondary residues for meat and milk were reported to be adequate to support the secondary metalaxyl residues for this petition (Griffith memo, 4/30/90). DEB (personal communication with Joel Garbus and F.D. Griffith) also recommended for a food additive tolerance of 5 ppm on sugar beet molasses. DRES assumed for the purpose of this analysis that all molasses consumed came from sugar beets since there are no data to determine how much molasses consumed is made from either corn sugar or sugar beets. Also note that since published tolerances exist for beet tops and roots as well as for barley, the difference between the proposed and published tolerance was added to bring the total tolerances up to those recommended by DEB. A summary of the residue information used in the analysis is attached as Table 1.

3. Exposure Analysis: The DRES chronic exposure analysis uses tolerance level residues and 100 per cent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. Since anticipated residue and percent of crop treated data were unavailable, the estimates from the present analysis were derived from the TMRCs (Table 2). The following table summarizes the contribution from the published, pending, and the proposed tolerances to the total TMRCs for the overall U.S. population, non-nursing infants, and children aged 1-6 years.

TMRC Exposure Summaries

	Overall U.S. Population	Non-nursing Infants	Children Aged 1 - 6
Published Tolerances:	0.010347[a] 17.2[b]	0.019707 32.8	0.020356 33.9
Pending Tolerances:	0.000709 1.2	0.001238 2.1	0.001098 1.8
Proposed Tolerances:	0.000186 0.3	0.000190 0.3	0.000445 0.7
TOTAL:	0.011242 18.7	0.021133 35.2	0.021897 36.4

a Exposure in mg/kg body weight/day
b Exposure expressed as percent of the ADI

4. Dietary Risk Assessment: The proposed use of metalaxyl on sugar beets does not significantly increase exposure. As shown in Table 2 and the table above, exposure estimates range between about 14 and 36 percent of the reference dose for the various population

groups. The proposed use on sugar beets accounts for less than 1 percent of the ADI for the overall U.S. population, non-nursing infants and children aged 1-6. Therefore, based on the present DRES analysis, HED has no objection to this petition.

Attachments

cc: DRES (Kariya), DEB (Loranger), Caswell #375AA, TOX (Gardner).

TABLE 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 375AA DATE: 06/26/90 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Metalaxyl Caswell #375AA CAS No. 57837-19-1 A.I. CODE: 113501 CFR No. 180.408	6mo feeding- dog NOEL= 6.2500 mg/kg 250.00 ppm LEL= 25.0000 mg/kg 1000.00 ppm ONCO: Class E (HED WOTE)	Increased alkaline phosphatase activity, incr relative liver weights. No evidence of oncogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.060000 EPA RfD= 0.060000	No data gaps, however MTD was not reached in rat or mouse onco studies. Requirements to be re-evaluated after mutagenicity data are submitted.	HED complete 05/23/86. EPA verified 07/08/86. WHO last reviewed 1982. On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED	
01006AA	RASPBERRIES	3F2848			0.5000	
01009AA	BLUEBERRIES	7F3470			2.0000	
01016AA	STRAWBERRIES	6F3337		10.0000		
02001AA	CITRUS CITRON	3F2786			1.0000	
02002AA	GRAPEFRUIT-UNSPECIFIED	3F2786			1.0000	
02002AB	GRAPEFRUIT-PULP	3F2786			1.0000	
02002JA	GRAPEFRUIT-JUICE	3F2786			1.0000	
02003AA	KUMQUATS	3F2786			1.0000	
02004AA	LEMONS-UNSPECIFIED	3F2786			1.0000	
02004AB	LEMONS-PULP	3F2786			1.0000	
02004HA	LEMONS-PEEL	3F2786			1.0000	
02004JA	LEMONS-JUICE	3F2786			1.0000	
02005AA	LIMES-UNSPECIFIED	3F2786			1.0000	
02005AB	LIMES-PULP	3F2786			1.0000	
02005HA	LIMES-PEEL	3F2786			1.0000	
02005JA	LIMES-JUICE	3F2786			1.0000	
02006AA	ORANGES-UNSPECIFIED	3F2786			1.0000	
02006AB	ORANGES-PULP	3F2786			1.0000	
02006HA	ORANGES-PEEL	3F2786			1.0000	
02006JA	ORANGES-JUICE	3F2786			1.0000	
02007AA	TANGELOS	3F2786			1.0000	
02008AA	TANGERINES	3F2786			1.0000	
02008JA	TANGERINE-JUICE	3F2786			1.0000	
03001AA	ALMONDS	7F3740			0.5000	
03009AA	WALNUTS	7F3470			0.5000	
04001AA	APPLES-FRESH	3F2847			0.2000	
04001DA	APPLES-DRIED	3F2847			0.2000	
04001JA	APPLES-JUICE	3F2847			0.2000	
05001AA	APRICOTS-FRESH	7F3470			1.0000	
05001DA	APRICOTS-DRIED	7F3470			4.0000	H
05002AA	CHERRIES-FRESH	7F3470			1.0000	
05002DA	CHERRIES-DRIED	7F3470			1.0000	
05002JA	CHERRIES-JUICE	7F3470			1.0000	
05003AA	NECTARINES	7F3470			1.0000	
05004AA	PEACHES-FRESH	7F3470			1.0000	
05004DA	PEACHES-DRIED	7F3470			1.0000	
05005AA	PLUMS(DAMSONS)-FRESH	7F3470			1.0000	
05005DA	PLUMS-PRUNES(DRIED)	7F3470			4.0000	H
05005JA	PLUMS,PRUNE-JUICE	7F3470			4.0000	H
06001AA	AVOCADOS	1F2531			4.0000	

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FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM) PENDING	PUBLISHED	
06010AA	PAPAYAS-UNSPECIFIED	8E3605			0.1000	
06010AB	PAPAYAS-PULP	8E3605			0.1000	
06010DA	PAPAYAS-DRIED	8E3605			0.1000	
06010JA	PAPAYAS-JUICE	8E3605			0.1000	
06013AA	PINEAPPLE-FRESH/PULP	2F2743			0.1000	
06013DA	PINEAPPLE-DRIED	2F2743			0.1000	
06013JA	PINEAPPLE-FRESH/JUICE	2F2743			0.1000	
07006AA	CHICORY	8F3698		0.5000		
08019AA	GINGER	8F3698		0.5000		
08020AA	HOPS	7H5532			20.0000	H
08022AA	HORSERADISH	8F3698		0.5000		
08043AA	TURMERIC	8F3698				
10002AA	CANTALOUPES-UNSPECIFIED	3F2827			1.0000	
10002AB	CANTALOUPES-PULP	3F2827			1.0000	
10003AA	CASABAS	3F2827			1.0000	
10004AA	CRENSHAWS	3F2827			1.0000	
10005AA	HONEYDEW MELONS	3F2827			1.0000	
10007AA	PERSION MELONS	3F2827			1.0000	
10008AA	WATERMELON	3F2827			1.0000	
10010AA	CUCUMBERS	3F2827			1.0000	
10011AA	PUMPKIN	3F2827			1.0000	
10013AA	SQUASH-SUMMER	3F2827			1.0000	
10014AA	SQUASH-WINTER	3F2827			1.0000	
10017AA	BITTER MELON	3F2827			1.0000	
10020AA	TOWELGOURD	3F2827			1.0000	
11001AA	EGGPLANT	6F3387			1.0000	
11003AA	PEPPERS(SWEET/GARDEN)	6F3387			1.0000	
11003AB	CHILI PEPPERS	6F3387			1.0000	
11003AD	PEPPERS-OTHER	6F3387			1.0000	
11004AA	PIMIENTOS	6F3387			1.0000	
11005AA	TOMATOES-WHOLE	6F3387			1.0000	
11005JA	TOMATOES-JUICE	1H5314			3.0000	H
11005RA	TOMATOES-PUREE	1H5314			3.0000	H
11005TA	TOMATOES-PASTE	1H5314			3.0000	H
11005UA	TOMATOES-CATSUP	1H5314			3.0000	H
13001AA	BEETS-TOPS(GREENS)	3F2827			0.1000	
13001AA	BEETS-TOPS(GREENS)	8F3698		14.9000		
13002AA	CELERY	3F2827			0.1000	
13003AA	CHICORY (FRENCH OR BELGIAN ENDIVE)	3F2827			0.1000	
13005AA	BROCCOLI	3F2955			2.0000	

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13006AA	BRUSSEL SPROUTS	3F2827			0.1000	
13007AA	CABBAGE-GREEN AND RED	3F2955			2.0000	
13008AA	CAULIFLOWER	3F2955			2.0000	
13009AA	COLLARDS	3F2827			0.1000	
13010AA	CABBAGE-CHINESE/CELERY (INC. BOK CHOY)	3F2955			2.0000	
13011AA	KALE	3F2827			0.1000	
13012AA	KOHLRABI	3F2827			0.1000	
13013AA	LETTUCE-LEAFY VARIETIES	3F2827			0.1000	
13014AA	DANDELION	3F2827			0.1000	
13015AA	ENDIVE/CURLEY AND ESCAROLE	3F2827			0.1000	
13017AA	CRESS (GARDEN/FIELD)	3F2827			0.1000	
13020AA	LETTUCE-UNSPECIFIED	3F2827			0.1000	
13021AA	MUSTARD GREENS	3F2827			0.1000	
13022AA	PARSLEY	3F2827			0.1000	
13023AA	RHUBARB	3F2827			0.1000	
13024AA	SPINACH	2F2762			10.0000	
13025AA	SWISS CHARD	3F2827			0.1000	
13026AA	TURNIPS-TOPS	8F3698		15.0000		
13034AA	TARO-GREENS	8F3698		15.0000		
13039AA	CRESS/UPLAND	3F2827			0.1000	
13045AA	LETTUCE-HEAD VARIETIES	2F2762			5.0000	
14001AA	BEETS-ROOTS	3F2827			0.1000	
14001AA	BEETS-ROOTS	8F3698		0.4000		
14003AA	CARROTS	8F3698		0.5000		
14004AA	CELERIAC	8F3698		0.5000		
14006AA	TARO-ROOT	8F3698		0.5000		
14007AA	GARLIC	1F2500			3.0000	
14009AA	ARTICHOKES-JERUSALEM	8F3698		0.5000		
14010AA	LEEKS	1F2500			10.0000	
14011AA	ONIONS-DRY-BULB (CIPOLLINI)	1F2500			3.0000	
14011DA	ONIONS-DEHYDRATED OR DRIED	1F2500			3.0000	
14013AA	POTATOES(WHITE)-WHOLE	1F2500			0.5000	
14013AB	POTATOES(WHITE)-UNSPECIFIED	1F2500			0.5000	
14013AC	POTATOES(WHITE)-PEELED	1F2500			0.5000	
14013DA	POTATOES(WHITE)-DRY				4.0000	H
14013HA	POTATOES(WHITE)-PEEL ONLY	1F2500			0.5000	
14014AA	RADISHES-ROOTS	8F3698		0.5000		
14014AB	RADISHES-TOPS	8F3698		15.0000		
14015AA	RUTABAGAS-ROOTS	8F3698		0.5000		
14015AB	RUTABAGAS-TOPS	8F3698		15.0000		

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14016AA	SALSIFY(OYSTER PLANT)	8F3698		0.5000	
14017AA	SHALLOTS	1F2500			10.0000
14018AA	SWEETPOTATOES (INCLUDING YAMS)	8F3698		0.5000	
14019AA	TURNIPS-ROOTS	8F3698		0.5000	
14021AA	PARSNIPS	8F3698		0.5000	
14024AA	YAMBEAN,TUBER	8F3698		0.5000	
14026AA	CASSAVA (YUCA BLANCA)	8F3698		0.5000	
14030AA	PARSLEY ROOTS	8F3698		0.5000	
15001AA	BEANS-DRY-GREAT NORTHERN	3F2918			0.2000
15001AB	BEANS-DRY-KIDNEY	3F2918			0.2000
15001AC	BEANS-DRY-LIMA	3F2918			0.2000
15001AD	BEANS-DRY-NAVY (PEA)	3F2918			0.2000
15001AE	BEANS-DRY-OTHER	3F2918			0.2000
15001AF	BEANS-DRY-PINTO	3F2918			0.2000
15002AA	BEANS-SUCCULENT-LIMA	3F2918			0.2000
15003AA	BEANS-SUCCULENT-GREEN	3F2918			0.2000
15003AB	BEANS-SUCCULENT-OTHER	3F2918			0.2000
15003AC	BEANS-SUCCULENT-YELLOW/WAX	3F2918			0.2000
15004AA	CORN/POP	2F2695			0.1000
15005AA	CORN/SWEET	2F2695			0.1000
15006AA	PEANUTS-WHOLE	3F2919			0.2000
15007AA	PEAS(GARDEN)-MATURE SEEDS/DRY	3F2918			0.2000
15009AA	PEAS(GARDEN)-GREEN IMMATURE	3F2918			0.2000
15011AA	LENTILES-WHOLE	3F2918			0.2000
15011AB	LENTILES-SPLIT	3F2918			0.2000
15013AA	MUNG BEANS (SPROUTS)	3F2918			0.2000
15018AA	SUNFLOWER-SEEDS	3F2827			0.1000
15021AA	ALFALFA SPROUTS	8F3695		6.0000	
15022AA	BEANS-DRY-BROADBEANS(MATURE SEED)	3F2918			0.2000
15022AB	BEANS-SUCCULENT-BROADBEANS(IMMATURE SEED	3F2918			0.2000
15023AA	BEANS-DRY-PIGEON BEANS	3F2918			0.2000
15027AA	BEANS-UNSPECIFIED	3F2918			0.2000
15029AA	SOYBEANS-SPROUTED SEEDS	3F2818			1.0000
15030AA	BEANS-DRY-HYACINTH(MATURE SEEDS)	3F2918			0.2000
15030AB	BEANS-SUCCULENT-HYACINTH(YOUNG PODS)	3F2918			0.2000
15031AA	BEANS-DRY-BLACKEYE PEAS(COWPEAS)	3F2918			0.2000
15032AA	BEANS-DRY-GARBANZO(CHICK PEA)	3F2918			0.2000
16002AA	ASPARAGUS	6F3330			7.0000
16004AA	ONIONS-GREEN	1F2500			10.0000
24001AA	BARLEY	2F2695			0.1000

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24001AA	BARLEY	8F3695		0.1000		
24002EA	CORN/GRAIN-ENDOSPERM	2F2695			0.1000	
24002HA	CORN/GRAIN-BRAN	2F2695			0.1000	
24002SA	CORN SUGAR	2F2695			0.1000	
24003AA	OATS	2F2695			0.1000	
24004AA	RICE-ROUGH	2F2695			0.1000	
24004AB	RICE-MILLED	2F2695			0.1000	
24005AA	RYE-ROUGH	2F2695			0.1000	
24005GA	RYE-GERM	2F2695			0.1000	
24005WA	RYE-FLOUR	2F2695			0.1000	
24006AA	SORGHUM (INCLUDING MILO)	2F2695			0.1000	
24007AA	WHEAT-ROUGH	2F2764			0.2000	
24007GA	WHEAT-GERM				1.0000	H
24007HA	WHEAT-BRAN				1.0000	H
24007WA	WHEAT-FLOUR				1.0000	H
24012AA	MILLET	2F2695			0.1000	
25002SA	BEET SUGAR	6F3387			0.1000	
25002SA	BEET SUGAR	8F3617	0.4000			
25003SB	SUGAR-MOLASSES	8F3617	5.0000			H
26001AA	BUCKWHEAT	2F2695			0.1000	
26011AA	GUAR BEANS				0.2000	
27002OA	CORN/GRAIN-OIL	2F2695			0.1000	
27003OA	COTTONSEED-OIL	1F2500			0.1000	
27003WA	COTTONSEED-MEAL	1F2500			0.1000	
27007OA	PEANUTS-OIL	3F2918			0.2000	
27010OA	SOYBEANS-OIL	3F2818			1.0000	
27011OA	SUNFLOWER-OIL	3F2827			0.1000	
28023AA	SOYBEANS-UNSPECIFIED	3F2818			1.0000	
28023AB	SOYBEANS-MATURE/SEEDS DRY	3F2818			1.0000	
28023WA	SOYBEANS-FLOUR/FULL FAT	3F2818			1.0000	
28023WB	SOYBEANS-FLOUR/LOW FAT	3F2818			1.0000	
28023WC	SOYBEANS-FLOUR/DEFATTED	3F2818			1.0000	
50000DB	MILK-NON-FAT SOLIDS	1F2500			0.0200	
50000FA	MILK-FAT SOLIDS	1F2500			0.0200	
50000SA	MILK SUGAR (LACTOSE)	1F2500			0.0200	
53001BA	BEEF-MEAT BYPRODUCTS	1F2500			0.0500	
53001BB	BEEF(ORGAN MEATS)-OTHER	1F2500			0.0500	
53001DA	BEEF-DRIED	1F2500			0.0500	
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	1F2500			0.4000	H
53001KA	BEEF(ORGAN MEATS)-KIDNEY	1F2500			0.4000	H

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53001LA	BEEF(ORGAN MEATS)-LIVER	1F2500			0.4000	H
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2500			0.0500	
53002BA	GOAT-MEAT BYPRODUCTS	1F2500			0.0500	
53002BB	GOAT(ORGAN MEATS)-OTHER	1F2500			0.0500	
53002FA	GOAT(BONELESS)-FAT	1F2500			0.4000	H
53002KA	GOAT(ORGAN MEATS)-KIDNEY	1F2500			0.4000	H
53002LA	GOAT(ORGAN MEATS)-LIVER	1F2500			0.4000	H
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2500			0.0500	
53003AA	HORSE	1F2500			0.4000	H
53005BA	SHEEP-MEAT BYPRODUCTS	1F2500			0.0500	
53005BB	SHEEP(ORGAN MEATS)-OTHER	1F2500			0.0500	
53005FA	SHEEP(BONELESS)-FAT	1F2500			0.4000	H
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	1F2500			0.4000	H
53005LA	SHEEP(ORGAN MEATS)-LIVER	1F2500			0.4000	H
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT	1F2500			0.0500	
53006BA	PORK-MEAT BYPRODUCTS	1F2500			0.0500	
53006BB	PORK(ORGAN MEATS)-OTHER	1F2500			0.0500	
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	1F2500			0.4000	H
53006KA	PORK(ORGAN MEATS)-KIDNEY	1F2500			0.4000	H
53006LA	PORK(ORGAN MEATS)-LIVER	1F2500			0.4000	H
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2500			0.0500	
55008BA	TURKEY-BYPRODUCTS	1F2500			0.0500	
55008LA	TURKEY-GIBLETS (LIVER)	1F2500			0.4000	H
55008MA	TURKEY-FLESH(W/O SKIN & W/O BONES)	1F2500			0.0500	
55008MB	TURKEY-FLESH(+SKIN & W/O BONES)	1F2500			0.4000	H
55008MC	TURKEY-UNSPECIFIED	1F2500			0.0500	
55013BA	POULTRY/OTHER-BYPRODUCTS	1F2500			0.0500	
55013LA	POULTRY/OTHER-GIBLETS(LIVER)	1F2500			0.4000	H
55013MA	POULTRY/OTHER-FLESH (+SKIN & W/O BONES)	1F2500			0.4000	H
55014AA	EGGS-WHOLE	1F2500			0.0500	
55014AB	EGGS-WHITE ONLY	1F2500			0.0500	
55014AC	EGGS-YOLK ONLY	1F2500			0.0500	
55015BA	CHICKEN-BYPRODUCTS	1F2500			0.0500	
55015LA	CHICKEN-GIBLETS(LIVER)	1F2500			0.4000	H
55015MA	CHICKEN-FLESH(W/O SKIN & W/O BONES)	1F2500			0.0500	
55015MB	CHICKEN-FLESH(+SKIN & W/O BONES)	1F2500			0.4000	H

TABLE 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 06/26/90 PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Metalaxyl Caswell #375AA CAS No. 57837-19-1 A.I. CODE: 113501 CFR No. 180.408	6mo feeding- dog NOEL= 6.2500 mg/kg 250.00 ppm LEL= 25.0000 mg/kg 1000.00 ppm ONCO: Class E (HED WOTE)	Increased alkaline phosphatase activity, incr relative liver weights. No evidence of oncogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.060000 EPA RfD= 0.060000	No data gaps, however MTD was not reached in rat or mouse onco studies. Requirements to be re-evaluated after mutagenicity data are submitted.	HED complete 05/23/86. EPA verified 07/08/86. WHO last reviewed 1982. On IRIS.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.010347	0.011241	18.735332	1.490402		
U.S. POPULATION - SPRING SEASON	0.010373	0.011691	19.485130	2.196248		
U.S. POPULATION - SUMMER SEASON	0.010583	0.011286	18.810695	1.172497		
U.S. POPULATION - FALL SEASON	0.010138	0.010942	18.237210	1.340077		
U.S. POPULATION - WINTER SEASON	0.010256	0.011003	18.338367	1.245222		
NORTHEAST REGION	0.011313	0.012015	20.025228	1.169593		
NORTH CENTRAL REGION	0.010176	0.011067	18.445620	1.485360		
SOUTHERN REGION	0.009194	0.010290	17.149493	1.826268		
WESTERN REGION	0.011242	0.012048	20.079645	1.343295		
HISPANICS	0.011913	0.012356	20.593537	0.737880		
NON-HISPANIC WHITES	0.010338	0.011168	18.613625	1.382838		
NON-HISPANIC BLACKS	0.009358	0.010846	18.076167	2.480050		
NON-HISPANIC OTHERS	0.012357	0.013535	22.558207	1.963090		
NURSING INFANTS (< 1 YEAR OLD)	0.007862	0.008559	14.265177	1.161458		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.019706	0.021133	35.221130	2.377635		
FEMALES (13+ YEARS, PREGNANT)	0.008078	0.008548	14.246373	0.782788		
FEMALES 13+ YEARS, NURSING	0.009621	0.010108	16.847488	0.812478		
CHILDREN (1-6 YEARS OLD)	0.020355	0.021897	36.494952	2.569763		
CHILDREN (7-12 YEARS OLD)	0.014336	0.015567	25.944212	2.050837		
MALES (13-19 YEARS OLD)	0.009614	0.010407	17.345075	1.322060		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.008591	0.009401	15.667970	1.350302		
MALES (20 YEARS AND OLDER)	0.008189	0.008921	14.869017	1.221077		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.008432	0.009212	15.353095	1.299645		

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

END OF DOCUMENT

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

APR 30 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8F3617/8H5554 - Metalaxyl on Sugar Beet Tops and Roots, Legume Vegetables (Dry and Succulent) Crop Group; Legume Vegetables Foliage Crop Group; Grass Forage, Fodder, and Hay Crop Group; and Non-grass Animal Feeds Crop Group.
Evaluation of the September 21, 1989 Amendment.
(MRID Nos. 412501-01 and 410552-03) [DEB Nos. 5934, 5935, and 6545) [HED Nos. 0-0044 and 1010]

FROM: Francis D. Griffith, Jr., Chemist
Dietary Exposure Branch
Health Effects Division (H7509C)

TO: Susan Lewis, PM 21
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Toxicology Branch - Herbicide, Fungicide and Antimicrobial Support
Health Effects Division (H7509C)

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division (H7509C)

Ciba-Geigy Corporation, Agricultural Division, has submitted this amendment consisting of a cover letter dated September 21, 1989, a revised Section B (amended labels for three Ridomil® formulations), revised Section F (new tolerance proposals), and a supplementary Section D (multiresidue method validation data and additional enforcement method validation data) in response to several deficiencies outlined and summarized in our review of November 28, 1988 by F.D. Griffith, Jr. (which see). These deficiencies are repeated and listed in the body of this review in the order they appeared in that review followed by the petitioner's response, then DEB comments. Our conclusions and recommendation follow.

SUMMARY OF DEFICIENCIES REMAINING TO BE RESOLVED

None

CONCLUSIONS

1. DEB Conclusion on **Directions for Use**

The petitioner has proposed new directions for use of Ridomil® by deleting all proposed uses of metalaxyl on the legume vegetables (succulent and dried) and foliage crop groups, the grass forage, fodder, and hay crop group, and the non-grass animal feeds crop group. The deficiency on plant back restrictions to have both Ridomil® labels in agreement becomes moot, and thus is resolved. The petitioner now has proposed an adequate set of directions for use of Ridomil® (metalaxyl) on sugar beets.

2. DEB Conclusion on **Nature of the Residue - Livestock**

Upon further consideration, DEB will not delay this petition while the petitioner completes the FRSTR livestock metabolism studies. This action is consistent with current Branch policy applied to other metalaxyl petitions involving major livestock feed items. Thus, the deficiency is resolved. The metalaxyl residues of concern in livestock are now as they were previously; i.e., metalaxyl *per se*, and metabolites containing the 2,6-dimethylaniline moiety and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester.

3. DEB Conclusion on **Residue Analytical Methods**

The petitioner has submitted multiresidue method recovery data following protocols I through IV for metabolites CGA-94689 and CGA-100255. The data have been forwarded to FDA. This part of the deficiency is resolved.

Since the petitioner has withdrawn proposed directions for use and tolerances for metalaxyl on non-grass animal feeds crop group, the grass forage, fodder, and hay crop group, the legume vegetables (succulent and dried) crop group, and the legume vegetables foliage crop group, the residue analytical method deficiencies relating to these crop groups becomes moot, and thus these parts of the method deficiency are resolved.

The petitioner has provided additional metalaxyl method validation data for levels from 2 to 15 ppm along with supporting chromatographic data. The method AG-395 is suitable to gather metalaxyl residue data on sugar beet tops and roots, and it is suitable to enforce the proposed metalaxyl tolerances. This part of the method deficiency is resolved.

The petitioner has supplied the additional supporting chromatographic data. We are now able to perform independent verification of the residue results. While numerous unidentified analytical responses (UARs) are present, the method in the hands

of a skilled residue analyst will not present a problem. This part of the deficiency is resolved.

The petitioner presented an explanation for the variably positive control samples. This is satisfactory. The petitioner pointed out the positive controls are low in relation to the proposed tolerance and the method's overall sensitivity. This part of the deficiency is resolved.

4. DEB Conclusion on **Storage Stability**

There are adequate storage stability data for metalaxyl to support the crop field trial residue data for metalaxyl in sugar beet tops and roots.

5. DEB Conclusion on **Magnitude Residue - Crop Field Trials**

Since directions for use and tolerances for metalaxyl have been withdrawn, deficiencies relating to the need for additional geographically representative crop field trial data on representative commodities of the legume vegetables foliage crop group, legume vegetables (succulent and dried) crop group, non-grass animal feeds crop group, grass forage, fodder, and hay crop group, and details of the legume vegetable processing study become moot and, thus, these parts of the deficiency are resolved.

Since analytical method concerns are resolved on sugar beets, DEB does not expect residues of metalaxyl to exceed the proposed tolerances of 10 ppm on sugar beet tops and 0.5 ppm on sugar beet roots when Ridomil® is used as directed. This part of the deficiency is resolved.

The petitioner has proposed the suggested food additive tolerance (FAT) on sugar beet molasses at 5 ppm metalaxyl. This part of the deficiency is resolved.

6. DEB Conclusion in **Magnitude of the Residue - Meat/Milk/Poultry/Eggs**

Since questions relating to animal metabolism, analytical methods, and additional crop field trial data have been resolved above, this deficiency is now resolved. Previously submitted and reviewed metalaxyl feeding studies are adequate to support the secondary metalaxyl tolerances for this petition only.

DEB points out that questions raised by the FRSTR relating to the nature of the residue in livestock may engender the need for additional livestock metalaxyl feeding studies.

7. DEB Conclusions on **Harmonization of Tolerances**

An updated International Residue Limit (IRL) Status Sheet is attached to this review that shows there is no problem with harmonizing the proposed U.S. metalaxyl tolerance on sugar beets with Canadian or Mexican tolerances. The proposed U.S. metalaxyl on sugar beets tolerance cannot be harmonized with Codex at this time as Codex tolerances are set for the parent only, metalaxyl.

RECOMMENDATION

There being no further residue chemistry deficiencies associated with the revised petition, DEB makes the following recommendations, Tox Br considerations permitting.

Since residues are not expected to exceed the proposed tolerances under the proposed Ridomil® conditions of use, DEB recommends for the 10 ppm metalaxyl tolerance on sugar beet tops, 0.5 ppm metalaxyl tolerance on sugar beet roots, and for the feed additive tolerance of 5.0 ppm in sugar beet molasses.

DETAILED CONSIDERATIONS

DIRECTIONS FOR USE

Deficiency

The petitioner needs to revise the Ridomil® 5G label to make it in agreement with the Ridomil® 2E label for rotational uses and plant back restrictions relating to grass forages crop group and non-grass animal feeds crop group; i.e., a 60-day rotational interval.

Petitioner's Response

The petitioner has submitted amended labels for Ridomil® 5G (EPA Registration No. 100-628) containing 5% ai metalaxyl, Ridomil® 2E (EPA Registration No. 100-607) containing metalaxyl at 2 lbs ai/gallon or 25.1% ai, and Ridomil® MZ58 (EPA Registration No. 100-629) containing 10% ai metalaxyl.

DEB Comments

On the Ridomil® 5G and Ridomil® 2E labels, the petitioner has amended these labels by deleting all proposed metalaxyl uses on the legume vegetables (succulent and dried) and legume forages crop groups; the grass forage, fodder, and hay crop group; and the non-grass animals feeds crop group. Thus, the petitioner is now only proposing uses of metalaxyl on sugar beets. The deficiency on plant back restrictions relating to grass forages crop group and non-grass animal feeds crop group to have the two

labels in agreement becomes moot and is thus resolved. The plant back or planting time from last Ridomil® application for sugar beets is 0 days on both labels.

These labels have been previously reviewed for use of Ridomil® on sugar beets as a systemic fungicide to control fungi caused diseases such as damping off and downy mildew. Metalaxyl is proposed for soil application, preplant incorporation, or surface application at planting at a rate of 1 to 2 lbs ai/acre. Ridomil® 2E can also be applied by irrigation sprinkler, ground application in water at a 20 gallons/acre maximum application, or by air at 5 gallons/acre water minimum application.

Metalaxyl may also be used as a foliar spray at a rate of 0.15 to 0.2 lb ai/metalaxyl mixed with mancozeb. The repeat foliar application interval is 14 days for a maximum of four applications per sugar beet growing season and a preharvest interval of 7 days.

The petitioner has now proposed an adequate set of directions for use of metalaxyl on sugar beets.

NATURE OF THE RESIDUE - LIVESTOCK

Deficiency

Metabolism studies are needed utilizing ruminants and poultry in which animals should be dosed for a minimum of 3 days with ^{14}C-metalaxyl at a level sufficient to make residue identification and quantification possible. Milk and eggs should be collected twice daily during the dosing period. Animals should be sacrificed within 24 hours of the final dose. The distribution and characterization of residues should be determined in milk, eggs, liver, kidney, muscle, and in skin and gizzard for poultry. If the metabolism of metalaxyl in ruminants or poultry is different than that in rats or with each other, then a porcine metabolism study would be required.

Petitioner's Response

The petitioner did not submit the requested studies. Instead, in letters dated April 14 and September 21, 1989 signed by Karen S. Stumpf of Ciba-Geigy, the petitioner requests DEB reconsider the need for these animal metabolism studies in the interim period to comply with the FRSTR requests.

DEB Comments

Ciba-Geigy has committed to run the requested metalaxyl livestock metabolism studies. These studies are due to the Agency in April 1990. Subsequent to our November 1988 review of this petition DEB concluded in PP# 8F3698 (metalaxyl in leaves of root and tuber vegetables crop group and root and tuber vegetables crop group), and in PP# 8F3695 (alfalfa forage and

hay, and barley grain forage, fodder, and straw) that we should continue regulating metalaxyl and its metabolite residues in meat, milk, poultry, and eggs while the petitioner completes the FRSTR livestock metabolism requirement. Upon further consideration, DEB will apply this principle to this petition. The livestock metalaxyl metabolism is now resolved. For this petition only, the metalaxyl residues of concern in meat, milk, poultry, and eggs are as previously defined; i.e., the metalaxyl parent and metabolites containing the 2,6-dimethylaniline (DMA) moiety and N-[2-hydroxymethyl-6-methylphenyl]-N-(methoxy-acetyl)alanine methyl ester.

DEB points out that petitions for use of metalaxyl on feed items submitted after April 1990 will not be considered further until the metalaxyl livestock metabolism concerns are resolved.

ANALYTICAL METHOD

Deficiency

For the analytical method used to gather metalaxyl residue data on sugar beets, the petitioner needs to provide validation data at the 2 to 15 ppm range where residues are reported. Additional supporting chromatographic data, especially control and spike samples are needed. The petitioner needs to provide reasons for variably positive controls.

For the non-grass animal feeds crop group and the grass forage crop group, the petitioner needs to supply additional supporting chromatographic data, an explanation for the variable positive control values, and additional method validation data (either repeat the original work or provide new data).

For legume vegetable (succulent or dried) crop group and legume vegetable foliage crop, the petitioner needs to provide additional recovery data for all pea (pisum) commodities and an explanation for variable positive control values.

Multiresidue method data are still needed for the metabolite CGA-94689.

Petitioner's Response (See MRID Nos. 412501-01 and 410552-03)

In response to the multiresidue method data deficiency for metabolite CGA-94689 the petitioner presented a study titled "Determination of the Metalaxyl Metabolites CGA-100255 and CGA-94689 (A & B Isomers) By U.S Food and Drug Administration Multiresidue Procedures" by H. Lee Hubbard dated February 24, 1989. The 78-page study is assigned Laboratory Project ID No. ABR-88156 and EPA MRID No. 410552-03.

In response to the deficiencies on the analytical method used to gather metalaxyl residue data on sugar beets, the

petitioner submitted a study titled "Metalaxyl: Response to EPA Review of Metalaxyl on Sugar Beets" by M.W. Cheung, dated September 18, 1989. The 97-page study is assigned Laboratory Project ID No. ABR-89075 and EPA MRID No. 412501-01.

DEB Comments

The petitioner has presented MRM recovery data for metalaxyl metabolites CGA-94689 and CGA-100255 through FDA protocols I through IV, not A through E. Much of these data can be translated from the Roman numeral protocols to the alphabet designation protocols. The petitioner has presented GC determination data using the various columns designated in protocols I, II, and III for EC and N/P but not FPD-S detector. There is no S in the molecules, thus, no need to try for recovery data for that system as the metabolites could not be recovered for that system. The metabolites could not be recovered through Florisil using either elution system. Adequate detection could not be obtained for these metabolites using post-column OPA derivatization fluorescence detection. The metabolites can be recovered using the Luke Method, but not necessarily at low sensitivity levels.

These data have been forwarded to FDA (see letter from F.D. Griffith, Jr., EPA/DEB to L. Sawyer, FDA/DCC dated April 24, 1990. This part of the deficiency is resolved.

The petitioner has withdrawn metalaxyl tolerances and deleted directions for use on the non-grass animal feeds crop group, the grass forage, fodder, and hay crop group, the legume vegetable (succulent and dried) crop group, and the legume vegetable foliage crop group. The residue analytical method deficiencies relating to these crop groups becomes moot, thus all are resolved.

For the deficiencies relating to the method for metalaxyl residues on sugar beets, the petitioner has presented additional supporting data. Control sugar beet tops were spiked with metalaxyl at 5.0, 10.0, and 15.0 ppm. Recoveries ranged from 68 percent (at 5 ppm) to 93 percent (at 10 ppm or the proposed tolerance) with an average recovery of 78 percent ($X = 78\% \pm 13.2\%$, $n = 3$). The petitioner also supplied adequate additional supporting chromatographic data to help validate these recovery data. The method has now been validated to gather the metalaxyl on sugar beet tops residue data. This part of the deficiency is resolved.

The petitioner provided four possible reasons for the large number of positive controls. The petitioner maintains the nature or exact reason for the positive values is not clearly understood, but potential sources are spray drift during application, volatility due to weather and/or soil conditions, cross contamination during the trial or sampling, and the possibility of a naturally occurring compound in sugar beets.

These explanations are acceptable to DEB. The deficiency is resolved.

The petitioner presented chromatographic support to show that the metalaxyl is in the control samples, in the reagents. Reagent blanks were non-detected for metalaxyl.

The petitioner points out the blank or positive control values are low (maximum 0.3 ppm) in relation to the proposed tolerance (10 ppm) and the method's overall sensitivity is low (0.05 ppm) in relation to the control values and the proposed tolerance. DEB agrees. We note that 7 out of the 14 control sugar beet tops have metalaxyl or its equivalent above 0.1 ppm. When compared to the actual metalaxyl residues reported from the proposed use application rate the control value ranges from < 1 to 16 percent of the value in the treated crops with one value about 10 percent and only three trials with values of > 6 percent. DEB agrees that a majority of the positive control values in sugar beet tops are low and can now be considered insignificant. The petitioner points out that when various control values were subtracted in recovery experiments, method AG-395 had recoveries ranging from 61 to 108 percent ($X = 83.7 \pm 12.6\%$, $n = 17$) from the low level spikes of 0.1 to 2 ppm.

The petitioner points out the positive control problem is mainly in sugar beet tops, not roots, as only 2 out of 13 sugar beet root controls have positive low values. DEB agrees with the petitioner that positive controls are not a significant problem in the sugar beet roots metalaxyl analysis.

The petitioner has presented extensive additional supporting chromatographic data. Copies of chromatograms for all controls and all spikes were presented as well as all chromatograms for 6 out of 13 field trials. The petitioner took care to present these chromatograms in their sequence of analysis. DEB found this to be extremely helpful as we were able to perform an independent verification of the metalaxyl results in sugar beet tops and roots. These sets of chromatograms included the standards and the standard curves, controls, recoveries, and treated samples. The curves show numerous UARs but in the hands of a skilled residue analyst these UARs are not a problem. We also agree the positive controls do not present an enforcement problem for false positives as long as analysis of sugar beet tops and roots using method AG-395 is in the hands of a skilled residue analyst. This part of the deficiency is resolved.

DEB concludes the petitioner has used a validated method AG-395, to gather the metalaxyl residue data on sugar beet tops and roots. Since this method has completed a successful PMV it is suitable with the petitioner's additional recovery data to enforce the proposed tolerances. There are no remaining analytical method deficiencies for metalaxyl on sugar beets.

MAGNITUDE OF THE RESIDUE - STORAGE STABILITY

Deficiency

Adequate metalaxyl storage stability exist for 18 months. Metalaxyl storage stability data are needed for up to 3 years for non-grass animal feeds crop group and the grass forage, fodder, and hay crop group.

Petitioner's Response

The petitioner did not respond in this amendment.

DEB Comments

Since the petitioner withdrew the proposed tolerances and directions for use of metalaxyl on the non-grass animal feeds group and the grass forage, fodder, and hay crop group, the storage stability deficiency becomes moot; thus, is resolved. There are adequate storage stability data to support the metalaxyl on sugar beets residue data.

MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALS

Deficiencies

DEB defers judgment on the proposed metalaxyl tolerances for sugar beet roots at 0.5 ppm and sugar beet tops at 10 ppm until the petitioner resolves analytical method concerns noted above. No additional metalaxyl sugar beet field trial data are required. It appears that residues will not exceed the proposed tolerance under the conditions of the proposed use.

For the FAT on sugar beet molasses, the petitioner needs to submit a revised Section F proposing total metalaxyl tolerances of 5 ppm (10X concentration factor x proposed metalaxyl sugar beet root tolerance). DEB reiterates FATS are not required for sugar, dried beet pulp, or the cossettes.

DEB defers judgment on the proposed metalaxyl tolerance on legume vegetable (succulent or dried) crop group and foliage of legume vegetables crop group until the petitioner resolves analytical method concerns relating to this crop group and provides additional geographically representative data for the representative commodities dry and succulent beans (phaseolus) and dry and succulent peas (pisum).

The petitioner needs to provide complete details of the legume vegetables processing study that generated the proposed 11 ppm metalaxyl tolerance on cannery waste.

DEB defers judgment on the proposed metalaxyl tolerance on the legume vegetable foliage crop group until the petitioner has resolved our analytical method concerns relating to this crop

group and has provided satisfactory additional geographically representative crop field trial data on all representative commodities of the group.

DEB defers judgment on both the proposed rotational crop tolerances for the grass forage, fodder, and hay crop group until the petitioner has resolved analytical method concerns for the crop group, provided adequate storage stability data for up to 3 years of sample storage, and provides satisfactory additional geographically representative crop field trial residue data for each representative commodity in this group.

DEB defers judgment on the proposed rotational crop tolerances for the non-grass animals feeds group until the petitioner has resolved our analytical method concerns, and provides adequate storage stability data for up to 3 years of sample storage.

Petitioner's Response

The petitioner has proposed the following revised metalaxyl tolerances in a new Section F:

"Tolerances for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)-alanine methyl ester, expressed as metalaxyl equivalents, in or on the following raw agricultural commodities:

Sugar beet (tops)	10.0 ppm
Sugar beet (roots)	0.5 ppm,

"A food additive tolerance for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl equivalents, in or on the following food additive:

Molasses	5.0 ppm"

DEB Comments

Since the petitioner has withdrawn the tolerance and directions for use of metalaxyl on legume vegetables (succulent and dried) crop group and legume vegetables foliage crop group, the deficiencies relating to the need for additional geographically representative crop field trial residue data on the representative commodities dry and succulent beans (phaseolus) and dry and succulent peas (pisum), complete details of the legume vegetables processing study, and additional geographically representative crop field trial residue data on representative commodities of the legume vegetable foliage crop group becomes moot; thus, all of these parts of the deficiency are resolved.

Likewise, since tolerances and directions for use of metalaxyl on the grass forage, fodder, and hay crop group; and non-grass animal feeds crop group have been withdrawn the deficiencies relating to additional geographically representative crop field trial residue data for each representative commodity becomes moot; thus, this part of the deficiency is resolved.

As noted above, the analytical method deficiency on sugar beets has been resolved. DEB now concludes the petitioner has presented adequate field trial crop residue data for metalaxyl on sugar beets. Residues of metalaxyl on sugar beet tops are not expected to exceed the proposed 10 ppm tolerance and the proposed 5 ppm tolerance on sugar beet roots under the conditions of the proposed Ridomil® use. This part of the deficiency is resolved.

The petitioner is proposing a FAT on sugar beet molasses as DEB had suggested. This part of the deficiency is resolved.

MAGNITUDE OF THE RESIDUE - MEAT/MILK/POULTRY/EGGS

Deficiency

Judgment is deferred on the appropriateness of the existing livestock feeding studies and secondary metalaxyl tolerances in meat/milk/poultry/eggs until questions relating to animal metabolism, analytical methods, and additional crop field trial data are all resolved.

Petitioner's Response

The petitioner did not respond in this amendment.

DEB Comments

Since questions relating to animal metabolism, analytical methods, and additional crop field trial data have all been resolved, this deficiency is resolved.

DEB recognizes that the livestock diets based on previously submitted feeding studies are artificial, but nonetheless maximizes possible exposure to metalaxyl residues. Based on feeding studies previously reviewed (see memorandum PP#8F3617 by F.D. Griffith, Jr., dated November 28, 1988), these studies have demonstrated the presence of low levels of metalaxyl in liver and kidney; thus any feed use of a metalaxyl-treated rac or its byproducts must necessarily be categorized within 40 CFR 180.6(a)(1) or (a)(2). Since real residues have been found in livestock tissues from feeding exaggerated levels of metalaxyl, DEB characterized the proposed use as (a)(2). DEB now concludes that previous metalaxyl feeding studies used to support the secondary metalaxyl tolerances are adequate for this petition only. DEB points out that questions raised by the FRSTR relating

to the nature of the residue in livestock may engender the need for additional livestock metalaxyl feeding studies.

OTHER CONSIDERATIONS - HARMONIZATION OF TOLERANCES

An International Residue Limit (IRL) Status Sheet is attached to this petition. There are no problems of compatibility with Canadian or Mexican metalaxyl tolerances in sugar beets as these countries have not established tolerances. There is a Codex tolerance for parent only metalaxyl on sugar beet roots at 0.05 ppm. Because the tolerance is expressed for residues of parent only, compatibility cannot be achieved at this time.

Attachment: International Residue Limit Status Sheet

cc: R.F.,Circu(7),Reviewer(FDG),PP#8F3617/8H5554,
FDA(Corneliussen, HFF-426),PIB/FOD(Furlow),
DRES/SCAB(Kariya).

H-7509C:DEB:Reviewer(FDG):CM#2:Rm814B:5570828:JOB:57275:I:C.Disk:
KENCO:04/18/90:de:sw:vo:de:ed:fdg:4/24/90.

RDI:Section Head:R.S.Quick:4/26/90:R.A.Loranger:4/26/90.

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INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Metalaxyl (Ridomil®)

CODEX NO. 138

I. Kerns 4/17/90

CODEX STATUS:

☐ No Codex Proposal Step 6 or above

Residue(if Step 8): Metalaxyl per se

Crop(s)	Limit (mg/kg)
Sugar beet (roots)	0.05

PROPOSED U.S. TOLERANCES:

Petition No. 8F3617/8H5554

RCB Reviewer F.D.Griffith,Jr. 17Apr90

Residue: Metalaxyl* and its metabolites

Crop(s)	Limit (mg/kg)
Sugar Beet (tops)	10.0
Sugar Beet (roots)	0.5
FAT	
Sugar Beet Molasses	5.0

CANADIAN LIMITS:

☑ No Canadian limit (on sugar beet)

Residue:

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

☑ No Mexican limit

Residue:

Crop(s)	Limit (mg/kg)

NOTES:

* N-(2,6-Dimethyl)-N-(methoxyacetyl) alanine methyl ester

Form revised 1986

END OF DOCUMENT

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

APR 25 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Leon Sawyer, Chemist
Pesticides and Industrial Chemicals Branch (HFF-426)
Division of Contaminants Chemistry
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Dear Leon:

Enclosed is the following Multiresidue Method (MRM) test information for updating a future addition of PAM-I, Appendix I:

Title: "Determination of the Metalaxyl Metabolites CGA-100255 and CGA-94689 (A and B Isomers) By U.S. Food and Drug Administration Multiresidue Procedures"
H. Lee Hubbard Author
February 24, 1989
78 pages
Laboratory Project ID ABR-88156

Chemical: Metalaxyl*

Type: Fungicide

Protocols: I, II, III, and IV

Company: Ciba - Geigy Corporation
Agricultural Division
Post Office Box 18300
Greensboro, N.C. 27419

Performing Laboratory: same

PP No: 8F 3617/8H 5554

MRID: 410552-03

40CFR References: 180.408, 185.4000, and 186.4000

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*N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester

These MRM data are for 2 metalaxyl metabolites. Previously DEB Had forwarded MRM data for parent metalaxyl and metabolites CGA-6286 and CGA-37734 through MRM Protocols I through IV (see letter from Dr. M.J. Nelson to L. Sawyer dated May 17, 1988, PP#5F3470/FAP#7H5520, Metalaxyl on Blueberries, Walnuts, Almonds, Almond, Hulls, Stone Fruits, Dried Apricots, and Prunes). In our review of that petition DEB requested these additional MRM recovery data for other metalaxyl metabolites.

I have scanned these data. These data were presented for Protocols I thru IV, not A through E. Much of the data can be translated from the Roman numeral protocols to the alphabet designation protocols. The petitioner has presented GC determination data using the various columns designated in protocols I, II, and III for EC and N/P, but not FPD-S detector as there is no S in the molecules. The metabolites could not be recovered through Florisil using either elution system. Adequate detection could not be obtained for these metabolites using post column OPA derivatization fluorescence detection. The metabolites can be recovered using the Luke method (and Storherr method) but not necessarily at very low sensitivity levels.

If upon examination these data you consider what has been submitted by Ciba Geigy Corporation to be deficient, please let me know what additional data FDA would require.

Sincerely,

Dick

Francis D. Griffith, Jr. Chemist
Dietary Exposure Branch
Health Effect Division (H-7509C)

Enclosure: Ciba Geigy Corporation, Project Identification ABR-88156.
"Determination of the Metalaxyl Metabolites CGA-100255 and CGA-94689 (A, and B Isomers) By U.S. Food and Drug Administration Multiresidue Procedures."
MRID# 410552-03

cc:(Without Enclosure): R.F., Circu (7), Reviewer (FDG), PP#8F3617/8H5554, PM-21 (Lewis), PAM-II Coeditor (M. Bradley), Metalaxyl Reg. Std. File, PP#5F3470/7H5520, PIB/FOB (Furlow)

H7509C:DEB:Reviewer (FDG):vg:CM#2:Rm814B:5570826:ed:fdg:4/16/90.
RDI:Section Head:R.S.Quick:4/16/90:R.D.Schmitt:4/18/90.

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To - Dick Griffith
for review on 4/6/90
RM

April 14, 1989

Ms. Susan Lewis
Acting Product Manager (21)
Registration Division (TS-767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M. Street, S.W.
Washington, D.C. 20460

Dear Ms. Lewis:

SUBJECT: METALAXYL REGISTRATION STANDARD
EPA POLICY REGARDING THE EXPANSION OF
METALAXYL LABELS DURING THE COURSE OF REREGISTRATION

In October, 1988, CIBA-GEIGY received the Final Registration Standard Tolerance Reassessment (FRSTR) for the active ingredient metalaxyl. In that document it states that "the Agency will consider registration of any significant new use on a case-by-case basis while data gaps are being filled and data evaluated".

Recently, CIBA-GEIGY has received several reviews completed in connection with pending petitions for new uses where the reviewer has concluded that certain data required under the Metalaxyl FRSTR will need to be submitted before these new uses can be approved.

Environmental Fate and Ground Water Branch

One case in point is the petition pending for metalaxyl in blueberries, stone fruits, walnuts, and almonds (PP7F3470, FAP7H5520) where the EAB reviewer in two cases (reviews dated 5/31/88 and 7/30/87) has recommended against these new uses for lack of data required under the Standard (aqueous photolysis, field dissipation, ground water monitoring). This occurred again recently in a review of pending petition PP8F3617 (review dated 8/17/88) where need for the ground water monitoring study was reiterated.

CIBA-GEIGY in its 90-Day Response (12/23/88) to the Standard committed to generate these required data according to the timeframes prescribed. CIBA-GEIGY believes that the continued expansion of metalaxyl for the pending crops does not present

an unreasonable risk to the environment. The only deficiency outstanding on PP7F3470 is this issue from the Environmental Fate and Groundwater Branch. The tolerances, when established, will allow the expanded use of metalaxyl on blueberries, stone fruits, walnuts, and almonds. CIBA-GEIGY does not consider these new crops to represent significant new uses as metalaxyl is already registered on another small berry crop, raspberries, and on other orchard crops. In the case of blueberries, Arkansas and Missouri have requested and been granted Section 18 Emergency Exemptions for the use of Ridomil 2E for the past two years. It is our understanding that requests will be made again this year. Since metalaxyl is already being used in some of the major blueberry producing states under these Section 18's, the granting of a conditional registration should not significantly increase the use of metalaxyl. Further, metalaxyl is not an oncogen, does not cause teratogenic or reproductive effects, is not mutagenic, and its acute toxicity is minimal (Category II for eye irritation).

CIBA-GEIGY requests that the management of the Environmental Fate and Ground Water Branch be consulted regarding the position taken by its reviewers. CIBA-GEIGY believes that registrations, issued conditionally, based upon the submission of satisfactory data, will be in the public interest and will not cause any undue risk to man or the environment.

Dietary Exposure Branch

This is also the case with the Dietary Exposure Branch where a recent review (PP8F3617, FAP8H5554, review dated 11/28/88) cited the need for animal metabolism studies required under the Metalaxyl FRSTR. Although there are other deficiencies identified in connection with this petition which CIBA-GEIGY needs to address, the requirement for replacement animal metabolism studies, although cited, should not hold up the registration of these new uses or others which may be pending. Again, CIBA-GEIGY has committed to conduct replacement goat and poultry metabolism studies. The Science Chapter prepared for the Metalaxyl FRSTR refers back to the 1981 Guidance Document for Metalaxyl where it was noted that for permanent tolerances, large animal feeding studies would be needed along with tolerance proposals in meat, milk, poultry, and eggs. Supporting data were reviewed and appropriate tolerances established in these commodities in January, 1983. Therefore, it would seem that in order to establish the tolerances in the animal commodities, metabolism was understood, at least in accordance with guidelines acceptable at the time. We would point out then that the Agency has data in its possession regarding metabolism of metalaxyl in animals and that this data, although perhaps not up to today's expectations, should be sufficient to recommend for new uses of metalaxyl, while new data meeting current guidelines is generated. It is also worth mentioning that additional tolerances were established

in November, 1985 for metalaxyl on a number of fruit, vegetable, and other crops.

CIBA-GEIGY requests that the management of the Dietary Exposure Branch be consulted regarding the need for animal metabolism studies before approving any expansion of metalaxyl's uses. It also can be pointed out that currently registered uses of metalaxyl only utilize 18.3001% of the Acceptable Daily Intake. Pending uses are expected to add approximately another 5%. That coupled with the safety profile of the chemical should alleviate any dietary exposure concern the Agency might have.

In addition, the Agency should consider the fact that metalaxyl has unique product performance in that it is systemic and specific for the Oomycete class of fungi. The delay in approving expanded registrations for metalaxyl will likely result in a number of Section 18 emergency exemption requests, as has already been seen with blueberries and strawberries. The reregistration process for other major fungicides may cause additional burdens on growers if use of these products on certain crops is curtailed and metalaxyl is not available either.

CIBA-GEIGY requests that the two scientific branches under discussion reevaluate their positions regarding the conditional approval of metalaxyl for new uses. After consulting with the appropriate Agency personnel, CIBA-GEIGY further requests that it be provided a response in writing regarding the Agency's position with respect to this issue.

Thank you for your consideration in this matter.

Sincerely,

Karen S. Stumpf
Senior Regulatoy Specialist
Regulatory Affairs

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

NOV 28

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8F3617/8H5554 - Metalaxyl on Sugar Beet Tops and Roots; Legume Vegetables (Dry and Succulent) Crop Groups; Legume Vegetables Foliage Crop Group; Grass Forage, Fodder, and Hay Crop Group; and Nongrass Animal Feeds Crop Group. Evaluation of Analytical Methods and Residue Data (MRID No. 405348-00 through -03 and 405693-01 through -03) [DEB Nos. 3908 through 3912]

FROM: Francis D. Griffith, Jr., Chemist
Dietary Exposure Branch
Health Effects Division (TS-769C)

TO: Lois A. Rossi, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Health Effects Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Dietary Exposure Branch
Health Effects Division (TS-769C)

EXECUTIVE SUMMARY OF CHEMISTRY DEFICIENCIES REMAINING TO BE RESOLVED:

- Revise the Ridomil^{R} 5G and 2E labels for rotational restrictions.
- Ruminant and poultry ^{14}C-metalaxyl metabolism studies are needed.

- Storage stability data for up to 36 months are needed.

- Revised Section F for metalaxyl molasses tolerance at 5 ppm.

- Additional metalaxyl crop field trial data needed on dried and succulent beans (phaseolus) and dried and succulent peas (pisum), and all representative commodities of the foliage of legume vegetables crop group.

- Provide complete description of legume vegetable processing study.

- Additional metalaxal crop field data needed for each representative commodity of the grass forage, fodder, and hay crop group.

CONCLUSIONS

CHEMICAL IDENTITY/MANUFACTURE AND FORMULATION

Impurities in technical mixtures of the levels given are not expected to present a residue in the subject crops.

DIRECTIONS FOR USE/LABELING

The petitioner needs to revise the Ridomil^{R} 5G label to make it in agreement with the Ridomil^{R} 2E label for rotational uses and plant back restriction relating to grass forages crop group and nongrass animal feeds crop group; ie, a 60 day rotational interval.

The petitioner has resolved the label deficiencies noted in the Final Registration Standard and Tolerance Reassessment (FRSTR). DEB notes there is a 7-day preharvest interval (PHI) for peppers and eggplants and a 28-day PHI for tomatoes; thus, PHIs are proposed for the fruiting vegetables (except cucurbits) crop group. On onions (dry bulb and seed) the petitioner now proposes a maximum of four foliar applications. For a rotational crop use on wheat the petitioner now proposes a 14-day plant back from the last Ridomil application on the primary raw agricultural commodity (RAC) to the planting of wheat.

The proposed Ridomil^{R} MZ-58 use for EBDC's on sugar beets is less liberal then the EBDC only currently approved use on sugar beets.

NATURE OF THE RESIDUE - PLANTS

The nature of the residue in plants is adequately understood. The residue of concern is metalaxyl, per se, and its metabolites containing the 2,6-dimethylaniline (DMA) moiety and N-[2-(hydroxymethyl)-6-methylphenyl]-N-(methoxyacetyl) alanine methyl ester.

NATURE OF THE RESIDUE - LIVESTOCK

Metabolism studies are needed utilizing ruminants and poultry in which animals should be dosed for a minimum of 3 days with ^{14}C-metalaxyl at a level sufficient to make residue identification and quantification possible. Milk and eggs should be collected twice daily during the dosing period. Animals should be sacrificed within 24 hours of the final dose. The distribution and characterization of residues should be determined in milk, eggs, liver, kidney, muscle, and in skin and gizzard for poultry. If the metabolism of metalaxyl in ruminants or poultry is different than that in rats or with each other, then a porcine metabolism study would be required.

ANALYTICAL METHOD

For the analytical method used to gather metalaxyl residue data on sugar beets, the petitioner needs to provide validation data at the 2 ppm to 15 ppm range where residues are reported. Additional supporting chromatographic data, especially control and spike samples are needed. The petitioner needs to provide reasons for variably positive controls.

For the nongrass animal feeds crop group and the grass forage crop group, the petitioner needs to supply additional supporting chromatographic data, an explanation for the variable positive control values, and additional method validation data (either repeat the original work or provide new data).

For legume vegetable (succulent or dried) crop group and legume vegetable foliage crop, the petitioner needs to provide additional recovery data for all pea (pisum) commodities and an explanation for variable positive control values.

Multiresidue method data are still needed for the metabolite CGA-94689.

MAGNITUDE OF THE RESIDUE - STORAGE STABILITY

Adequate metalaxyl storage stability exist for 18 months. Metalaxyl storage stability data are needed for up to 3 years for nongrass animal feeds crop group and the grass forage, fodder, and hay crop group.

MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALS

DEB defers judgment on the proposed metalaxyl tolerances for sugar beet root at 0.5 ppm and sugar beet top at 10 ppm until the petitioner resolves analytical method concerns noted above. No additional metalaxyl sugar beet field trial data are required. It appears that residues will not exceed the proposed tolerance under the conditions of the proposed use.

For the food additive tolerance (FAT) on sugar beet molasses, the petitioner needs to submit a revised Section F proposing total metalaxyl tolerances of 5 ppm (10X concentration factor x proposed metalaxyl sugar beet root tolerance). DEB reiterates FATs are not required for sugar, dried beet pulp, or the cossettes.

DEB defers judgment on the proposed metalaxyl tolerance on legume vegetable (succulent or dried) crop group and foliage of legume vegetables crop group until the petitioner resolves analytical method concerns relating to this crop group and provides additional geographically representative data for the representative commodities dry and succulent beans (phaseolus) and dry and succulent peas (pisum).

The petitioner needs to provide complete details of the legume vegetables processing study that generated the proposed 11 ppm metalaxyl tolerance on cannery waste.

DEB defers judgment on the proposed metalaxyl tolerance on the legume vegetable foliage crop group until the petitioner has resolved our analytical method concerns relating to this crop group and has provided satisfactory additional geographically representative crop field trial data on all representative commodities of the group.

DEB defers judgment on both the proposed rotational crop tolerances for the grass forage, fodder and hay crop group until the petitioner has resolved analytical method concerns for the crop group, provided adequate storage stability data for up to 3 years of sample storage, and provides satisfactory additional geographically representative crop field trial residue data for each representative commodity in this group.

DEB defers judgement on the proposed rotational crop tolerances for the non-grass animals feeds group until the petitioner has resolved our analytical method concerns, and provides adequate storage stability data for up to three years of sample storage.

MAGNITUDE OF THE RESIDUE - MEAT/MILK/POULTRY/EGGS

Judgment is deferred on the appropriateness of the existing livestock feeding studies and secondary metalaxyl tolerances in meat/milk/poultry/eggs until questions relating to animal metabolism, analytical methods, and additional crop field trial data are all resolved.

HARMONIZATION OF TOLERANCES

An International Residue Limit (IRL) Status Sheet is attached to this review that shows there is no problem harmonizing the proposed U.S. tolerance on these crop groups and commodities with Mexican or Canadian tolerances. The proposed U.S. crop group tolerances, FATs, and commodity crop group tolerances cannot be harmonized with Codex at this time as Codex tolerances are set for the parent only metalaxyl.

DEB RECOMMENDATION

DEB cannot recommend, at this time, for the requested metalaxyl crop group tolerances for the reasons cited above in our Executive Summary and further explained in our conclusions above.

For further consideration of the proposed tolerance of metalaxyl, the petitioner should be advised to resolve the deficiencies noted above.

DETAILED CONSIDERATIONS

BACKGROUND

Ciba-Geigy Corporation proposes tolerances for residues of the fungicide metalaxyl, trade named Ridomil^{R} [N-(2-6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety and N-(2-hydroxymethyl)-6-methylphenyl]-N-(methoxyacetyl)alanine

methyl ester], each expressed as metalaxyl in or on the following RACs and commodity groups:

Sugar beet (tops)	10.0 ppm
Sugar beet (roots)	0.5 ppm
Foliage of legume vegetables crop group	10.0 ppm
Legume vegetables (dry or succulent) crop group	1.0 ppm
Nongrass animal feeds crop group	6.0 ppm
Grass forage, fodder, and hay crop group	2.0 ppm

The non-grass animal feeds crop group and the grass forage, fodder, and hay crop group are rotational crop tolerances.

Ciba-Geigy is also requesting the establishment of both feed additive and food additive tolerances for combined residues of metalaxyl and its two metabolites named above in the following processed commodities:

Legume vegetables, cannery waste	11 ppm
Molasses	4 ppm

Metalaxyl and its metabolite tolerances are established on a variety of RACs ranging from 0.02 ppm in milk; 0.05 ppm in eggs; 0.4 ppm in fat of cattle, goats, hogs, horses, sheep, and poultry; sugar beets (tops and roots) at 0.1 ppm; sugar beet molasses at 1.0 ppm; soybeans at 1.0 ppm; legume vegetable foliage at 8 ppm; legume vegetables (dry or succulent) crop groups at 0.2 ppm, to 1.0 ppm in fruiting vegetables (except cucurbits) crop group; 10 ppm in green onions; and 20 ppm in peanut vines and hay (see 40 CFR 180.408(a)). Inadvertent tolerances are established for metalaxyl on wheat commodities ranging from 0.2 to 2 ppm (see 40 CFR 180.408(b)). Combined metalaxyl tolerances are also established for animal feed items ranging from 0.4 ppm on wet apple pomace to 20 ppm on tomato pomace (wet or dry) and 5.0 ppm for metalaxyl on legume vegetable cannery waste (see 40 CFR 186.4000 or 21 CFR 561.273). Food additive tolerances are also established for combined residues of metalaxyl and its metabolites ranging from 1.0 ppm in wheat milling

fractions to 7 ppm on citrus oils and 50 ppm on dried hops (see 40 CFR 185.4000 or 21 CFR 193.277).

The legume vegetables foliage crop group is defined in 40 CFR 180.34(f)(9)(vii). The representative commodities are any variety of beans (phaseolus), field peas (pisum), and soybeans (glycine max.). The legume vegetables (succulent or dried) crop group is defined in 40 CFR 180.34(f)(9)(vi). The representative commodities are beans (phaseolus, one succulent variety and one dried variety), peas (pisum, one succulent variety and one dried variety), and soybeans.

The nongrass animal feeds crop group is defined in 40 CFR 180.34(f)(9)(xviii). Representative commodities of this group are alfalfa and clover. The grass forage, fodder, and hay crop group is defined in 40 CFR 180.34(f)(9)(xvii). The representative commodities are bermudagrass, bluegrass, and bromegrass or fescue.

Metalaxyl was the subject of a Registration Standard issued in December, 1981. Metalaxyl was also the subject of an FRSTR issued on June 22, 1987. Issues from the FRSTR that need to be addressed include labeling (directions for use), ruminant and poultry metabolism, storage stability, rotational crop data, and soybean tolerances.

RCB recommended favorably for metalaxyl on papaya at 0.1 ppm (see memorandum PP#8E3605, by F.D. Griffith, Jr., dated May 5, 1988). A proposed metalaxyl tolerance on strawberries remains in reject status (see memorandum PP#6F3337 by M.F. Kovacs, Jr., dated September 3, 1987) as does a proposed metalaxyl tolerance on grapes (see memorandum 6F3362/6H5493 by M.P. Firestone dated March 20, 1986).

CHEMICAL IDENTITY - MANUFACTURE AND FORMULATION

The manufacturing process for metalaxyl has been adequately described and previously discussed (see memorandum PP#1F2500 by P.V. Errico dated March 9, 1982 and summarized also in Confidential Appendix B to the FRSTR. Impurities in the technical mixture at the levels given are not expected to present a residue problem in the subject crops (see memorandum PP#8G2121 by G. Makhijani dated March 29, 1979 and PP#6F3387 by F.D. Griffith, Jr., dated September 26, 1986).

The petitioner proposes use on legume vegetables and their foliage crop groups and sugar beets with replanting and plant back (rotational) uses for nongrass animal feeds and grass forage, fodder, and hay crop groups of Ridomil^{R} 5G, a granular formulation that contains 5% metalaxyl a.i. (EPA Registration No. 100-628). The review of the inert ingredients

for this formulation is now under the purview of the Registration Division (RD).

The petitioner also proposes use on legume vegetables and their foliage (including soybeans) crop groups and sugar beets with replanting and plant back (rotational) uses for nongrass animal feeds crop group and grass forage, fodder and hay crop groups of Ridomil^{R} 2E, an emulsifiable concentrate that contains 2 lbs metalaxyl a.i. or 25.1 percent ai/gal (EPA Registration No. 100-607). The review of the inert ingredients for this formulation is now under the purview of RD.

Another formulation proposed for use on sugar beets only with plant back (rotational) uses for nongrass animal feeds and grass forage, fodder, and hay crop groups is Ridomil^{R} MZ58, a wettable powder that contains 10% metalaxyl ai and 48 % zinc ion and manganese ethylene bisdithiocarbamate (EPA Registration No. 100-629). The review of the inert ingredients for this formulation is now under the purview of RD.

PROPOSED USES

In general, the petitioner is proposing to use Ridomil^{R} as a systemic fungicide to control the Oomycetes class of fungi caused diseases in various crops. Examples of these diseases are pyrthium damping off and phylophthora crown rot.

Either Ridomil^{R} 5G or Ridomil^{R} 2E is proposed for soil application, preplant incorporation, or surface application at planting at a rate of 1 to 2 lbs ai (4 to 8 pts or 20 to 40 lbs)/acre for sugar beets and legume vegetables. Section B lists use of Ridomil^{R} for legume vegetables at 1 to 2 lbs ai/acre while the Ridomil^{R} 2E label lists 2 to 4 pints (0.5 to 1 lb ai/acre). The petitioner needs to have Section B and the labels in agreement with respect to the maximum proposed use rate. For the preplant broadcast application, work Ridomil^{R} into the top 2 inches of soil, and for surface at-planting application either natural rains move Ridomil^{R} into the seed germination zone, or use irrigation to get Ridomil^{R} 1 1/2 inches down into the seed germination zone before germination.

Ridomil^{R} 2E can be applied by irrigation sprinkler, ground application in water as a 20 gal/acre minimum application, or by air at 5 gal/acre water mix minimum application. For Ridomil^{R} 2E the petitioner suggests various tank mates with the clear warning it is the applicator's responsibility to be certain the tank mix partners of Ridomil^{R} are currently labeled for use on that crop (implying a tolerance) and the tank mate use pattern is compatible with Ridomil^{R}. Ridomil^{R} 2E is not to be used in foliar, late season applications, or

in plant dip solutions. Ridomil^{R} 2E is not to be used for greenhouse disease control.

Ridomil^{R} 5G application is at 20 to 40 lbs/acre, usually as a broadcast application. Banded applications in a 7-inch band are also recommended. Ridomil^{R} is not to be used for greenhouse disease control.

Both Ridomil^{R} 5G and Ridomil^{R} 2E have replanting and plant back (rotational) restrictions. Soybeans and other legume vegetables and sugar beets had zero days replanting times from last Ridomil^{R} application to the planting of non-grass animal feeds crop group and grass forages crop group. Similar rotational restrictions for the nongrass animal feeds and grass forages crop groups are not on the Ridomil^{R} 5G label. DEB suggests the petitioner correct this oversight by providing a revised Ridomil^{R} 5G label that is in agreement with the Ridomil^{R} 2E label for rotational restrictions on nongrass animal feeds and grass forage crop group replantings.

Ridomil^{R} MZ-58 is proposed for a foliar application to sugar beets at a rate of 1 1/2 to 2 lbs (0.15 to 0.2 lb metalaxyl) ai/acre in 20 to 150 gal water/acre ground application or 3 to 10 gal water/acre air applications. A maximum of four applications (0.8 lb ai metalaxyl) are permitted per sugar beat growing season with a 14-day repeat application interval and a 7-day PHI. Ridomil^{R} MZ-58 may be applied through irrigation systems. Ridomil^{R} MZ-58 should not be used for greenhouse crops disease control. Plant back or replanting instructions on the label are 0 days to replant after last Ridomil application for legume vegetables and sugar beets, and 60 days (2 months) for nongrass animal feeds group and grass forages crop group. The 1 1/2 to 2 lbs of Ridomil^{R} MZ-58 containing 48% EBDC would be 0.75 lb to 1 lb a.i. of EBDC per acre. This amount of EBDC is less then the currently approved use on sugar beets ;ie, 1.6 lbs ai pe acre.

In the Generic Data Requirements for Metalaxyl table in the FRSTR, RCB noted in the Directions for Use two deficiencies, both of them not germane to this petition. However, on review of the Ridomil^{R} 2E label, DEB notes the petitioner has proposed a 7-day PHI for peppers and eggplants and proposed a 28-day (4 weeks) PHI for tomatoes. Thus, members of the fruiting vegetables (except cucurbits) crop group have a proper PHI. On the Ridomil^{R} MZ-58 label for onion (dry bulb and seed) the petitioner proposes a maximum of four applications per crop growing season. For a rotational crop; that is wheat, RCB recommended a 14-day plant back restriction. Review of the Ridomil^{R} 2E label shows the petitioner has proposed the suggested rotational restriction of 14 days from the last Ridomil^{R} application on a primary crop to the replant-

ing (rotation) of wheat. DEB concludes the petitioner has resolved all of the label deficiencies noted in the FRSTR.

NATURE OF THE RESIDUE - PLANTS AND LIVESTOCK

PLANT METABOLISM

No new plant metabolism studies were submitted. Radiolabeled metabolism studies using phenyl ring ^{14}C-metalaxyl on potato, grape, and lettuce have been previously submitted and adequately reviewed (see memoranda PP#1F2500, P. Errico, March 9, 1982 and PP#8G2121, G. Makhijani, March 29, 1979). Additional plant metabolism studies of metalaxyl on lettuce and spinach have also been previously submitted and adequately reviewed (see memorandum PP#2F2762, N. Dodd, December 8, 1983).

In summary, metalaxyl in plants is metabolized through one or more of the following processes: oxidation of the ring methyl to benzyl alcohol/benzoic acid, hydroxylation of the phenyl ring, hydrolysis of the methyl ester, cleavage of the methyl ether, N-dealkylation and subsequent conjugation of some of the metabolites.

The fate of metalaxyl in plants is adequately understood. The residues of concern are metalaxyl, its metabolites containing the 2,6-dimethylaniline (DMA) moiety and N-[2-(hydroxymethyl-6-methylphenyl]-N-(methoxyacetyl) alanine, methyl ester.

ANIMAL METABOLISM

Radiolabelled metabolism studies in rats, goats, and cows have been previously studied and reviewed (see memoranda PP#862121, G. Makhijani, March 29, 1979 and PP#1F2500, P. Errico, July 15, 1982).

In summary, metalaxyl is rapidly excreted in the urine and feces. From the studies we conclude metalaxyl degradation in animals follows the same mechanism as in plants, i.e., methyl ester hydrolysis, N-dealkylation, methyl ether cleavage, benzylic methyl oxidation with subsequent formation of glucuronic acid conjugates. In lactating goat, small amounts of radioactivity were detected in the milk, blood, and tissues.

The fate of metalaxyl in meat and milk is not adequately understood. Previously the residues of concern were metalaxyl, and metabolites containing the 2,6-dimethylaniline (DMA) moiety and N-[(2-hydroxymethyl)-6-methylphenyl]-N-(methoxyacetyl) alanine, methyl ester.

At that time, DEB noted that no poultry metabolism studies were available. DEB had considered the nature of the residue in poultry to be adequately understood by translation of the above animal studies. This is no longer the case. Poultry studies are required. Present studies show metalaxyl residues to be low in most tissue and transitory in liver and kidney.

Upon reconsideration of all available metalaxyl data on livestock metabolism, DEB (ne RCB) now concludes the nature of the residue in livestock is not adequately understood. We reiterate the livestock metabolism deficiency of the FRSTR as follows:

"Metabolism studies utilizing ruminants and poultry in which animals must be dosed for a minimum of 3 days with [^{14}C]metalaxyl at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, and muscle and also skin and gizzard for hen. If the metabolism of metalaxyl in ruminants or poultry is found to differ from that in rats, or with each other, then swine metabolism data may be required. Data reflecting solvent extraction of residues are also required. Representative samples from the above described tests must also be analyzed by current enforcement methods to ascertain the validity of these methods."

ANALYTICAL METHODS (see MRID No. 405348-03)

The method used to gather the metalaxyl residue data for the commodities in this petition is coded AG-395, dated December 7, 1982, by K. Balasubramanian and R. Perez and titled "Improved Method for the Determination of Total Residues of Metalaxyl in Crop as 2,6-dimethylaniline." This method has been previously submitted and reviewed (see memorandum PP#3F2918, K. Arne, December 13, 1983). RCB judged the method to be significantly different from methods 330 and 348, thus a method tryout (MTO) was requested. The results of the MTO (see memorandum PP#3F2918, P. Jung, July 9, 1984) showed EPA recoveries of total metalaxyl from peanuts and peanut hay range from 62 to 102 percent at spike levels of 0.05, 0.5, and 5 ppm. The method has been submitted to FDA as an enforcement method but is not presently in PAM-II.

A suitable enforcement procedure exists for total metalaxyl residues in liver and milk. The method also has had a successful MTO (op. cit.) and is in PAM-II as of November 1984, as Method II. The milk and liver (tissue) method is a modification of the tobacco method. The method

is coded AG-349. This method is essentially the same as method 348 except with different extraction solvents before hydrolysis: acetonitrile (ACN) for milk, 80% aqu. ACN for tissues, and hexane for eggs. The limit of metalaxyl detection in milk is 0.01 ppm, in liver and kidney at 0.1 ppm, and 0.05 ppm in eggs. Milk spiked at 0.01 ppm to 0.1 ppm total metalaxyl had recoveries ranging from 52 to 76 percent and the bovine liver samples spiked with metalaxyl at 0.1 to 0.4 ppm had recoveries ranging from 54 to 116 percent. Similar recoveries were noted for eggs and poultry products.

The petitioner has submitted ^{14}C-metalaxyl validation data for methods AG-348 and AG-395. The ^{14}C-metalaxyl method validation data for AG-348 and AG-395 had been previously submitted and adequately reviewed (ibid.) In summary, method AG-395 was validated by analyzing mature lettuce harvested 0 and 7 days PHI. Method AG-348 was also validated by analyzing mature lettuce leaves after treatment with ^{14}C-metalaxyl: 73 percent of the activity was accounted for on day 0 but a lower percentage activity was accounted for at day 7 (48%).

The petitioner has previously presented the results of two interference studies. They have been adequately reviewed in PP#6F3387 (memorandum dated September 29, 1986 by F.D. Griffith, Jr.).In summary, from method AG-348 none of the pesticides tested showed metalaxyl equivalents on the chromatograms to the 0.05 ppm screening level. DEB will translate the interference data from method AG-348 to method AG-395.

To summarize, method AG-395 involved blending 10 grams of high moisture samples like sugar beets, beans, or grass, 1 minute in a Polytron Homogenizer with 100 mL of methanol/ water (80/20, v/v). Filter through Whatman 2V filter paper then remove a 2 gram aliquot equivalent. Rotoevaporate to dryness then dissolve the residue in 10 mL H_2O and 10 mL of methanesolfonic acid. Reflux for 15 minutes. The petitioner cautions that a 20-minute reflux will degrade 2,6-dimethylaniline. Cool, then add 15 mL hexane and 25 mL of 25 percent NaOH through the top of the condenser. Be sure the pH > 8.0. The steam distillation apparatus is a modification of the equipment proposed by Veitch and Kiwus. The distillation time is approximately 1/4 hours. Next the solution is frozen. Cleanup is by silica SepPak^R. The hexane is poured off the frozen water into the syringe then forced through the SepPak^R. The 2,6-dimethylaniline is recovered from the SepPak^R with 18 mL CH_2Cl_2. The derivative is formed by adding 200 uL of trifluoroacetic acid then rotoevaporate in a 15 °C, not 18 or 20 C, water bath to just dryness. Take up in 2.0 mL toluene and transfer the toluene to a HP autosampler vial. The instrument used was a Hewlett Packard gas chromatograph,

model 5880, equipped with a N/P detector and a capillary column. The columns were either a fused silica 0.25 um coating of SE-54 in a 0.2 mm x 20 m column, or a wide bore 0.32 mm x 30 m fused silica column with a 0.25 um coating of DX-4. The petitioner had an adequate run table and used suitable temperature programming.

Confirmation of residues is by GC/MS using a Finnigan GC/MS, model 3200, operated in the CI mode with CH_4 as the reactant and carrier gas. The column is a glass 1.2 m x 2 mm (id) packed with 3 percent Dexsil-300 on Gas Chrom Q (80/100 mesh) operated at 100 C. The fragment ion DMA is measured at m/e of 122 (the M + 1 ion).

The limit of detection is < 0.05 ppm. Quantitation is by the HP-1000 Lab Automation computer system. The peak heights are used for comparison of standards to unknowns for software calculations. Corrections are made for recoveries and controls; and a factor 1.188 is used to convert DMA-TFA detected to metalaxyl equivalents.

The petitioner has provided extensive validation data attempting to show method AG-395 is suitable to gather the residue data submitted in this petition. Sugar beet roots and tops were spiked with metalaxyl ranging from 0.05 to 0.5 ppm. Recoveries from roots ranged from 61 to 134 percent . The method has been validated at the proposed sugar beet root tolerance and limit of detection. The petitioner needs to provide additional sugar beet top validation data at the 5 to 15 ppm range where residues are reported. The petitioner provided three sets of chromatograms; a set for sugar beet roots, tops, and for molasses. Each set contained three standards, a control, a spike, and two samples. DEB considers this insufficient as we have concerns for the positive controls, i.e., 0.29 and 0.24 ppm at 1.0 ppm spikes. DEB requests the petitioner not only explain how control samples became variably positive, but also provide copies of all control and spike samples of sugar beet roots and top. DEB defers judgment on the suitability of this method to gather metalaxyl residue data on sugar beet roots and tops until the petitioner provides additional validation data supporting chromatograms and a reason for variably positive controls.

The representative commodities of the nongrass animal feed crop group alfalfa and clover were spiked with metalaxyl ranging from 0.1 to 5.0 ppm. Forage recoveries ranged from 71 to 102 percent ($\bar{X}$ = 85.63 $\pm$ 0.03%, n = 8) and metalaxyl hay recoveries ranged from 68 to 150 percent ($\bar{X}$ = 99 $\pm$ 31.17%, n = 8). The petitioner presented two sets of chromatograms, a set for clover and a set for alfalfa. The amount of supporting chromatographic data are insufficient. The petitioner is requested to explain how/why control samples have

metalaxyl residues ranging from < 0.05 ppm to 2.9 ppm. We suggest additional chromatographic data for all controls and their spikes. The petitioner should repeat some of the recovery experiments or perform additional recovery experiments at his option. DEB defers judgment on the suitability of this method to gather metalaxyl residue data on the nongrass animal feeds crop group until we have the additional supporting chromatographic data, an explanation for the variably positive controls, and additional validation data, either repeat recoveries or new data.

The representative commodities of the grass forage, fodder, and hay crop group bromegrass, fescue, and bluegrass, were fortified with metalaxyl ranging from 0.5 to 5.0 ppm. No recovery data were presented for metalaxyl from bermudagrass. When the petitioner presents additional crop field trial data for bermudagrass (see following discussion in Magnitude of the Residue - Crop Field Trials) method validation data should be submitted for metalaxyl in/on bermudagrass. Metalaxyl recoveries from grass fodder or hay, and forage ranged from 66 to 134 percent For the grass hay the controls all had higher metalaxyl values than the spiked levels. An explanation is requested as are additional method validation data. For the grass forage recovery data, 7 out of 17 controls have positive metalaxyl values. DEB requests an explanation as well as method validation data; either new data or repeat experiments. Supporting chromatographic data were presented for a set of fescue samples and a set of bromegrass samples. Each set of chromatograms contains one standard, a spike, a control, and two or three samples (at least one hay and one forage). The petitioner needs to supplement these chromatographic data with copies of all spike and control chromatograms. DEB cannot conclude that this method is suitable to gather metalaxyl residue on the grass forage, fodder and hay crop group without additional supporting chromatographic data, additional validation data (either repeat recoveries or new data), and an explanation for all of the variably positive controls.

For the forage of legume vegetables, bean forage from phaseolus and vigna beans and pea vines were fortified with metalaxyl ranging from 0.2 ppm to 2 ppm. Metalaxyl recoveries ranged from 63 to 130 percent ($X = 81.08 \pm 17.11\%$, $n = 13$ for bean forage). Dry bean fodder was fortified with metalaxyl ranging from 0.2 ppm to 1.0 ppm. Recoveries ranged from 70 to 108 percent ($X = 89.11 \pm 14.80\%$, $n = 9$). Supporting chromatographic data were presented for bean vines, garden pea vines, Great Northern bean forage and fodder, and blackeye peas forage and fodder. The chromatograms show some unidentified analytical responses (UARs) but these do not interfere with metalaxyl. We agree that 0.2 ng metalaxyl is the lowest level that should be quantified. For this crop group, additional supporting chromatographic data are not necessary. DEB concludes that the

method is suitable to gather metalaxyl crop field trial data for the legume vegetables forage crop group. There are five dry bean fodder controls that were positive for metalaxyl. If satisfactory explanations are offered for the other variably positive control samples, then DEB is willing to translate these answers to the dry bean fodder control samples.

The representative commodities of the legume vegetables, succulent beans and dry beans, and succulent peas were spiked with metalaxyl ranging from 0.05 to 0.2 ppm. Metalaxyl recoveries from succulent green beans and peas ranged from 60 to 82 percent. From dried beans (kidney, pinto, blackeye peas, and Great Northern) metalaxyl recoveries ranged from 63 to 119 percent ($\bar{X}$ 88.57 $\pm$ 21.8%, n = 7). No recovery data were presented for dried peas from pisum and should be. When the petitioner presents additional crop field trial data for dried peas (see following discussion in MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALS) method validation data should be submitted for metalaxyl in dried peas. Supporting chromatographic data were presented for succulent green beans and garden peas, and for dried beans, i.e., Great Northern and Pinto. A few UARs were present, none of which would interfere with metalaxyl. DEB agrees with the petitioner's level of detection. For the representative commodities presented, additional supporting chromatographic data are not necessary. DEB concludes the method is suitable to gather residue data on succulent beans and peas and dried beans. The method is not suitable to gather residue data for the legume vegetable crop group without validation for dried peas (pisum).

The FRSTR noted the following multiresidue method deficiency:

> Metalaxyl metabolites containing the 2,6-dimethylaniline moiety and CGA-94689 in or on crop samples must be subjected to analysis by multiresidue protocols. Protocols for Methods I, II, III, and IV are available from the National Technical Information Service under order No. PB203734/AS.

In the RCB review of May 13, 1988 by M.J. Nelson for PP#5F3470/FAP#7H5520 - Metalaxyl on Blueberries, Walnuts, Almonds, Almond Hulls, Stone Fruits, Dried Apricots, and Prunes, we had the following conclusions related to MRM data:

> Data have now been submitted on the recovery/behavior of metalaxyl and two of its metabolites (CGA-6286 and CGA-37734) tested through FDA Multiresidue Protocols I through IV of PAM I.

Note: These data have been forwarded to EPA for publication in a future revision of Appendix I to PAM-I (see letter dated May 17, 1988 by M.J. Nelson to L. Sawyer, FDA [HFF-426]).

> For approval of future metalaxyl tolerances (and to support the continued registration of metalaxyl-containing products), FDA Multiresidue test information must also be supplied for the metabolite CGA-94689.

In this petition, no MRM data were presented to resolve this deficiency. For a favorable DEB recommendation the petitioner will need to supply the MRM data for metabolite CGA-94689 through each of the four protocols or provide sound defensible reasons why this metabolite cannot be recovered.

MAGNITUDE OF THE RESIDUE - FIELD CROP TRIALS

STORAGE STABILITY (See MRID No. 405348-02)

Storage stability studies for metalaxyl and its metabolites have been previously submitted and adequately reviewed (ibid). In summary, from either fortified or field incurred residues recoveries ranged 71% to 119% for residues at the 0.2 ppm and around 100 ppm levels.

DEB concludes there are adequate storage stability data to support the residue data presented in this petition for sugar beets and tops, legume vegetables crop group, and legume vegetables forage crop group. Metalaxyl and its metabolites determined as 2,6-DMA are stable for at least 18 months at 5 F.

DEB concludes there are no storage stability data to support the residue data presented in this petition for the nongrass animal feeds crop group and the grass forage, fodder, and hay crop groups. Metalaxyl storage stability data are needed at various times beyond 18 months up to 36 months to cover the storage time of samples for these two crop groups. These data are needed to support the crop field trial metalaxyl residue data from the grass forage, fodder, and hay crop group and the nongrass animal feeds crop group. This request for additional storage stability data is consistent with the metalaxyl storage stability deficiencies that were noted in the FRSTR. These two deficiencies are reiterated as follows:

> The storage intervals and conditions of samples used to support all established tolerances for residues must be submitted. These data must be accompanied

by data depicting the percent decline in residues at the times and under the conditions specified. (No additional stability studies are required for plant commodities stored at 5 F (-15 C) for up to 12 months.) On receipt of these data, the adequacy of the aforementioned tolerances will be reevaluated.

All residue data requested in this Standard must be accompanied by data regarding storage length and conditions of storage of samples analyzed. These data must be accompanied by data depicting the stability of residues under the conditions and for the time intervals specified, with the exception of plant commodities stored at 5 F (-15 C) for up to 12 months.

SUGAR BEET ROOTS, TOPS, AND PROCESSED COMMODITIES (See MRID No. 405693-01)

Metalaxyl and its 2,6-DMA metabolite residue data were presented from 13 field trials (including one for a sugar beet processing study) for the 1985 and 1986 crop years from CA (4), MN (2), WA, NE, OH, TX, ND, ID, and MI. Residue data from these 9 states represent sugar beet production on 816,000 acres in 1985 out of a national production on 1,124,520 acres (see Agricultural Statistics 1986).

Sugar beets were treated at planting with one application of Ridomil^{R} 2E or Ridomil^{R} 5G at the rate of 2.0 lbs ai (1X)/acre, then four foliar applications of 0.2 lb a.i. for a total application of 2.8 lbs ai (1X)/acre/sugar beet growing season. Exaggerated rate residue data were presented from six trials which were treated at planting with 4 lbs ai metalaxyl, then four foliar applications of 0.4 lb ai metalaxyl, for a total of 5.6 lbs ai (2X rate) metalaxyl.

Residues of metalaxyl and its 2,6-DMA metabolites on sugar beet roots from the 1X application ranged from < 0.05 ppm (n = 2) to 0.26 ppm with five samples of roots having total metalaxyl residues above 0.1 ppm. From the 2X application rate the maximum total metalaxyl residues were 0.22 ppm with two of the six samples having residues above 0.1 ppm. On sugar beet tops metalaxyl residues from the 1X proposed use ranged from 0.64 ppm to 9.3 ppm with 5 out of 25 results being above 5 ppm. Exaggerated rate 2X application produced total metalaxyl residue maximums of 14 ppm with three of six samples having residues about 10 ppm.

It appears the petitioner has provided an adequate amount of geographically representative crop field trial data over several growing seasons. However, before DEB accepts these data to support the proposed sugar beet root metalaxyl tolerance of 0.5 ppm and the proposed sugar beet top metalaxyl tolerance of 10 ppm the petitioner needs to resolve the analytical method concerns noted above, i.e., additional validation data, additional supporting chromatographic data, and reasons for the variable positive controls. Any tolerance established will cover residues resulting from the already registered seed treatment use on sugar beets as well as residues resulting from the use proposed in this petition.

Sugar beets in CA in 1985 treated at the proposed metalaxyl 1X use rate were grown expressly for a processing study. On review it appears this processing study has been previously submitted and adequately reviewed (see PP#6F3387/6H5499 by J.D. Griffith, Jr., on March 13 and 23, 1987). The planting date, harvest date, treatments and rates at planting, and four foliar applications of metalaxyl plus mancozeb are all the same. The actual processing has been adequately described and reviewed. The method used to generate total residue is AG-395. This method with its supporting validation data has been previously reviewed (ibid). The study results are slightly different in this report from the previous report. Sugar beet roots at the proposed use still contain 0.035 ppm total metalaxyl and the sugar beets from the exaggerated rate application contain 0.07 ppm, not 0.08 ppm. DEB does not consider this difference significant. DEB reiterates that FATs are not required for metalaxyl in sugar and dehydrated beet pulp. DEB does not require total metalaxyl residue data or tolerances on slices of sugar beets; i.e., the cossettes.

When the sugar beets containing 0.07 ppm were processed into molasses the total metalaxyl is 0.28 for a 4X concentration factor. The sugar beets from the proposed use application rate containing 0.035 ppm were processed into molasses containing 0.25 ppm total metalaxyl for a concentration of about 7X. This 7X concentration is slightly less than the 10X concentration observed in our March 1987 reviews. The 7X confirms that concentration of metalaxyl from sugar beet roots to molasses does occur. The FATs are based on the highest concentration from the RAC to the processed commodity; thus, DEB will use 10X. Based on the proposed tolerance of 0.5 ppm in sugar beet roots the appropriate FAT for total metalaxyl in molasses is 5 ppm. When the petitioner has resolved the analytical method concerns, then a revised Section F is appropriate for total metalaxyl in sugar beet molasses at 5 ppm, not 4 ppm.

LEGUME VEGETABLES CROP GROUP AND PROCESSED COMMODITIES

Metalaxyl and its 2,6-DMA metabolites residue data were presented on succulent green beans for the crop year 1986 from NY, MI, and CA. DEB does not consider this is an adequate amount of data, nor geographically representative data over several growing seasons for a crop group tolerance. The petitioner should consider presenting additional succulent bean crop field trial data from OR/WA, PA/NJ, WI, AR, and NC/VA. The varieties of the green succulent bean should be identified in all field trials.

From one preplant/planting incorporation of 2 lbs ai at PHIs of 55, 57, and 78 days, total metalaxyl residues ranged from 0.12 ppm to 0.87 ppm with 2 of 12 samples having residues above 0.3 ppm. A 2X application at preplant/planting incorporation of 4 lbs ai (same PHIs), total metalaxyl residues ranged from 0.31 ppm to 0.66 ppm with two of six samples at or above 0.5 ppm.

Metalaxyl and its 2,6-DMA metabolite residue data were presented on succulent peas for the crop year 1986 from NY and FL. DEB does not consider this an adequate amount of data, nor geographically representative data over several pea growing seasons for a crop group tolerance. DEB notes at this time no dried peas (pisum) total metalaxyl residue data were presented. DEB cannot consider a crop group tolerance for metalaxyl on legume vegetables without adequate amounts of geographically representative residue data on all representative commodities of the crop group under consideration. The petitioner should consider presenting both succulent and dried pea (pisum) metalaxyl crop field trial data from DE/MD, MN, OR/CA, WA, WI, and IA/IL. The variety of peas should be identified in each field trial.

From one preplant/planting incorporation of 2 lbs ai/acre at 55 and 59 days PHI, total metalaxyl residues on peas with pod ranged from < 0.05 ppm to 0.22 ppm with two out of eight samples having residues above 0.1 ppm. A 2X application at preplant/planting incorporation of 4 lbs ai/acre (same PHIs), total metalaxyl residues ranged from 0.05 ppm to 0.54 ppm with two of the four samples having total metalaxyl residues above 0.3 ppm.

Metalaxyl and its 2,6-DMA metabolites residue data were presented on dried beans (phaseolus) for the 1986 crop from MS, CA, MI, and ID. Total metalaxyl residue data were presented for dried blackeye peas (vigna) from TX and MS grown in 1986. DEB considers this is neither an adequate amount of data nor geographically representative data over several growing seasons for a crop group tolerance. The petitioner should consider presenting dried beans (phaseolus) crop field trial data from

CO/WY, KS/NE, ND/MT, WA, and WY. Data should be presented for dry large lima beans and dry baby lima beans. Each variety of dry beans should be identified.

From one preplant/planting incorporation of 2 lbs ai/acre at PHIs of 89, 90, 91, 105, 119, 161, and 186 days total metalaxyl residues on dried beans ranged from < 0.05 ppm to 0.18 ppm with only 1 sample out of 27 having residues above 0.1 ppm. A 2X application at preplant/planting incorporation of 4 lbs ai/acre, same PHI, total metalaxyl residues ranged from less than 0.05 ppm to 0.14 ppm with 2 out of 10 samples having residues above 0.1 ppm.

DEB defers judgment on the proposed metalaxyl legume vegetables (succulent or dried) crop group tolerance at 1.0 ppm until the petitioner resolves analytical method concerns relating to this crop group, and has provided satisfactory additional geographically representative crop field trial data for representative commodities of beans/succulent and dried, phaseolus) and peas (succulent and dried, pisum).

The petitioner is proposing a feed additive tolerance for total metalaxyl residue in legume vegetables cannery waste at 11 ppm. DEB is unable to decide which field trial(s) were used for this study; what method was used to generate the data; find a description of the processing study, sample handling and storage, and validation of results. DEB defers judgment on this tolerance request until the petitioner has presented an adequately described legume vegetable processing study that can generate valid residue data.

FOLIAGE OF LEGUME VEGETABLES CROP GROUP (See MRID No. 405693-03)

Metalaxyl and its 2,6-DMA metabolites data were presented on the foliage, forage, vines, and/or fodder of phaseolus beans and pisum peas. The field trials used for these samples are all described above (which see) under legume vegetables. For this crop grouping, DEB reiterates we need additional geographically representative crop field trial data for the foliage of succulent beans from OR/WA, PA/NJ, WI, AR, and NC/VA. Additional foliage, forage, and fodder crop field trial data for peas (pisum) should be presented from DE/MD, MN, OR/CA, WA, WI, and IA/IL. For dry beans additional crop field trial data showing total metalaxyl residues on foliage/forage and fodder should be from CO/WY, KS/NE, ND/MT, WA, and NY. The variety of the bean and pea should be identified.

The metalaxyl (Ridomil^{R}) application for 1X and 2X with PHIs is described above under legume vegetables (which see). Basically the petitioner has presented companion foliage,

forage, vine, and fodder metalaxyl crop field trial data matching the succulent and dry bean data and succulent peas metalaxyl residue data.

On succulent pea vines from the 2X rate all four metalaxyl residues were above 3 ppm with the maximum residue being 5.2 ppm. From a 1X application, total metalaxyl residues on pea vines ranged from 1.2 ppm to 3.6 ppm with only one out of eight samples being above 3 ppm.

On green bean foliage/forage from the exaggerated rate application (2X) residues ranged from 0.71 ppm to 11 ppm with three out of six samples having total metalaxyl residues above 3 ppm. From the 1X or proposed use application rate, total metalaxyl residues on succulent bean vines ranged from 0.46 ppm to 10 ppm with 4 out of 13 samples having residues above 3 ppm.

Forage from beans grown for dry beans treated at the proposed use rate had metalaxyl residues ranging from 0.3 to 9.2 ppm with 7 out of 32 samples having residues above 3 ppm. Forage from exaggerated rate application (2X) to beans grown for dry beans had total metalaxyl residues ranging from 0.4 to 28 ppm, with 4 out of 12 samples having residues above 3 ppm and two of these were above the proposed 10 ppm tolerance.

Once the beans were harvested, the dry fodder was sampled and analyzed. On bean fodder from the exaggerated rate application (2X) total metalaxyl residues ranged from 0.7 to 3.5 ppm. From the 1X or proposed use application rate, metalaxyl residue on dry bean fodder ranged from 0.12 to 4.9 ppm with only 3 out of 32 samples having residues above 3 ppm.

DEB defers judgment on the proposed metalaxyl legume vegetable foliage crop group tolerance at 10 ppm until the petitioner resolves our analytical method concerns relating to this crop group and has provided satisfactory additional geographically representative crop field trial data for the forages of the representative commodities beans succulent and dried (phaseolus) and peas succulent and dried (pisum).

NONGRASS ANIMAL FEEDS (FORAGE, FODDER, STRAW, HAY) CROP GROUP (See MRID No. 405693-02).

Metalaxyl and its 2,6-DMA metabolites residue data were presented on the nongrass animal feed crop group representative commodities alfalfa and clover following soybean production from 14 trials for the crop years 1983 and 1984 from CA, MS, NE, and NY. The petitioner is proposing a rotational crop tolerance, not treating the RAC directly. Thus, alfalfa or clover could follow soybeans, sugar beets, fruiting vegetables

(except cucurbits), etc. DEB considers that the amount of data presented are adequate and geographically representative. The variety of alfalfa and clover should be identified in all field trials.

Soy beans were treated with Ridomil^{R} 2E at a rate of 2.0 lbs ai metalaxyl preplant, broadcast, then one application of 1 lb ai metalaxyl either layby or foliar for a total of 3 lbs ai/acre/soybean growing season. Companion plots were treated at a 2X rate (exaggerated), i.e., 4 lbs ai metalaxyl preplant broadcast followed by one application of 2 lbs ai either layby or foliar application for a total of 6 lbs ai metalaxyl/acre/soybean growing season. Following soybean harvest alfalfa or clover were planted. The interval from last Ridomil^{R} application to soybeans to planting of alfalfa and clover ranged from 29 days in NY, 43/47 days in MS, to 69 days in CA and 268 days in NE. The petitioner presented crop field trial from clover and alfalfa for a fall forage value in two of three States with fall planting followed by the spring foliage and hay samples. A 60-day rotational crop plant back restriction is proposed.

Alfalfa forage, either fall or spring cutting, had total metalaxyl residues from its 1X application ranging from 0.15 ppm to 4.9 ppm. The exaggerated rate application produced total metalaxyl residues on alfalfa ranging from 0.41 ppm to 4.9 ppm. Clover forage either fall or spring cutting, had total metalaxyl residues from the 1X application rate ranging from 0.12 ppm to 3.7 ppm. The exaggerated rate application produced total metalaxyl residues on clover ranging from 0.1 ppm to 3.8 ppm.

Alfalfa hay produced in the spring after either a fall planting or a spring planting had total metalaxyl residues from the proposed use application rate ranging from 0.24 ppm to 1.8 ppm. The exaggerated rate application produced total metalaxyl residues on alfalfa hay ranging from 0.41 ppm to 1.8 ppm. Clover hay produced in the spring after either a fall planting or a spring planting had total metalaxyl residues ranging from 0.05 ppm to 1.8 ppm. The exaggerated rate application produced total metalaxyl residues on clover hay ranging from 0.28 to 3.4 ppm.

DEB defers judgment on the proposed metalaxyl on Nongrass Animal Feeds crop group tolerance at 6 ppm until the petitioner resolves our analytical method concerns, provides adequate storage stability to cover the period of storage up to 3 years, and provides the names of alfalfa and clover varieties used.

the proposed use treatment had metalaxyl residues ranging from 0.29 ppm to 0.60 ppm (n = 6) while the exaggerated use application generated residues of 0.5 ppm, 0.59 ppm, and 1.0 ppm. The change in metalaxyl residue values from mature forage to cured hay is not solely due to loss of moisture.

Metalaxyl residue data were presented from two crop field trials for fescue. Fall forage fescue metalaxyl residues from the proposed use application were 0.57 ppm and 0.27 ppm and from the exaggerated 2X application was 1.2 ppm. The spring forage metalaxyl residue was 0.6 ppm from the proposed use application and 0.2 ppm from the exaggerated rate application. Mature fescue forage from the proposed use application had total metalaxyl residues ranging from 0.07 ppm to 0.83 ppm (n = 4). The exaggerated 2X rate generated metalaxyl residues of 0.16 ppm and 0.87 ppm. When the mature fescue was processed into hay, metalaxyl residues ranged from 0.08 ppm to 0.64 ppm (n = 4) at the proposed use application and from the exaggerated rate application the total metalaxyl residues were 0.07 ppm and 0.84 ppm. The change in metalaxyl residue values from mature fescue forage to cured values from mature fescue forage to cured fescue hay is not solely due to a loss of moisture.

Metalaxyl residue data were presented from two crop field trials for bluegrass. Fall forage bluegrass metalaxyl residues from the proposed use application were 0.27 ppm and 0.37 ppm while the residue value from the exaggerated application was 1.2 ppm. The spring forage metalaxyl residues on bluegrass ranged from 0.07 ppm to 0.43 ppm (n = 4) from the proposed use application and were 0.21 ppm and 0.92 ppm from the exaggerated rate (2X) application. Mature bluegrass forage from the proposed application had total metalaxyl residue ranging from 0.14 ppm to 0.32 ppm (n = 4). The corresponding metalaxyl residues from the exaggerated rate application were 0.29 ppm and 0.71 ppm. When the mature bluegrass was "processed" into cured hay, metalaxyl residues ranged from 0.14 ppm to 0.58 ppm (n = 4) and ranged from 0.09 ppm to 0.81 ppm from the exaggerated use application. The change in metalaxyl residues from mature bluegrass forage to cured bluegrass hay is not due to a loss of moisture.

DEB defers judgment on the proposed metalaxyl on grass forage, fodder, and hay crop group tolerance at 2 ppm until the petitioner resolves our analytical method concerns, provides adequate storage stability data to cover the period of storage, and provide satisfactory additional geographically representative crop field trial residue data for each representative commodity.

GRASS FORAGE, FODDER, AND HAY CROP GROUP (See MRID No. 405693-02)

Metalaxyl and its 2,6-DMA metabolites residue data were presented on the forage and hay of fescue, bluegrass, and bromegrass, but no crop field trial metalaxyl residue data were presented for the representative commodity bermudagrass. These data were presented for the crop years 1983 and 1984 from NY, NE, MS, and CA representing six field trials. The petitioner is proposing a rotational crop tolerance, not treating the RAC directly. Thus, bluegrass, bromegrass, fescue and/or bermudagrass could follow soybeans, sugar beets, fruiting vegetables (except cucurbits), etc. DEB does not consider the amount of data presented either adequate or geographically representative. The petitioner should consider presenting additional crop field trial data of metalaxyl on bermudagrass, bromegrass, fescue, and bluegrass from the major sugar beet and soybean growing areas such as, but not limited to, the following: IA/KS, TN/KY, OK/TX, NE, CO/ID, IL/IN, PA/NJ, MT/ND, SD, SC/NC, WI/MN. The crop field trial metalaxyl residue data should be for each representative commodity from each area.

Soybeans were treated with Ridomil^{R} 2E at a rate of 2.0 lbs ai metalaxyl at preplant, broadcast then one application of 1 lb ai metalaxyl either at layby or as a foliar application for a total of 3 lbs ai/acre/soybean growing season. Companion plots were treated at a 2X rate (exaggerated); i.e., 4 lbs ai metalaxyl at preplant, broadcast, followed by one application of 2 lbs ai either at layby or as a foliar application for a total of 6 lbs ai metalaxyl per acre/soybeans growing season. Following soybean harvest, bromegrass, bluegrass, or fescue were planted. The interval from the last Ridomil^{R} application to soybeans to planting of the representative commodities varied from 29 days, 32 days, 47 days to 69 days and 268 days. A 60-day rotational crop plant back restriction is proposed. The petitioner presented metalaxyl crop field trial residue data in three out of six for fall forage values followed by spring forage and cured hay residue values.

Residue data were presented from two crop field trials of metalaxyl on bromegrass. Fall forage bromegrass metalaxyl residues at the 1X proposed use application were 0.98 ppm and 1.1 ppm. The 2X residue value was 1.5 ppm.

Metalaxyl on spring forage bromegrass ranged from 0.20 ppm to 0.32 ppm (n = 4) from the proposed use rate. The exaggerated rate application generated values of 0.47 ppm and 0.36 ppm. Mature bromegrass forage from the proposed use application had total metalaxyl residues ranging from 0.19 ppm to 0.23 ppm (n = 4). The exaggerated 2X rate generated metalaxyl residues on mature bromegrass of 0.28 ppm and 0.33 ppm. The cured hay from

MAGNITUDE OF THE RESIDUE - MEAT/MILK/POULTRY/EGGS (See MRID No. 40538-01)

Our conclusion on the magnitude in meat, milk, poultry, and eggs in the FRSTR is as follows: "Presently, the nature of the residue in animals is not adequately understood. On receipt of the data requested in the section entitled 'Nature of the Residue in Animals,' the appropriate nature of tolerances for residues in animal products will be determined and, with consideration for any newly found metabolites of toxicological concern, the adequacy of the available data regarding the magnitude of the residue in animal commodities (milk, poultry, eggs, fat, meat, liver, and kidney) will be determined. The metabolism studies may engender new feeding studies."

Thus, DEB's discussion on possible diets and previously submitted feeding studies are all tentative. DEB recognizes the following livestock diets are artificial but they nonetheless maximize possible exposure to metalaxyl residues. Based on tolerances established when the FRSTR was prepared, the dietary intake of residues of metalaxyl by beef cattle would be up to 16.1 ppm if: (i) the diet consisted of 25 percent peanut hay, 20 percent peanut vine, 25 percent dry tomato pomace, 15 percent dry citrus pulp, and 15 percent citrus molasses; (ii) residues in or on peanut hay and vines were each 20 ppm; and (iii) residues in citrus molasses, dry citrus pulp, and dry tomato pomace were 7 ppm, 7 ppm, and 20 ppm, respectively. The potential dietary intake of residues of metalaxyl by swine would be up to 2.91 ppm if: (i) the diet consisted of 10 percent peanut oil, 5 percent peanut soapstock, 50 percent processed potato waste, 1 percent dry citrus pulp, 20 percent soybean meal, 5 percent each of soybean hulls and soapstock, and 4 percent wheat milled byproducts; (ii) residues in peanut meal and soapstock were 1 ppm and 2 ppm, respectively; (iii) residues in processed potato waste, wheat milled byproducts, and dry citrus pulp were 4 ppm, 1 ppm, and 7 ppm, respectively; and (iv) residues in or on soybean meal, hulls, and soapstock were each 2 ppm.

The dietary intake of residues of metalaxyl by dairy cattle would be 18.1 ppm if: (1) the diet consisted of 60 percent peanut hay, 25 percent dry tomato pomace, 10 percent citrus molasses, and 5 percent dry citrus pulp; (ii) residues in or on peanut hay and dry tomato pomace each amounted to 20 ppm; and (iii) residues in citrus molasses and dry citrus pulp each amounted to 7 ppm.

The dietary intake of residues of metalaxyl by laying hens would be up to 1.73 ppm if: (i) the diet consisted of 20 percent cull potatoes, 50 percent soybean seed, 20 percent soybean meal, and 10 percent processed potato waste; (ii) residues in or on soybean seed, soybean meal, and processed

potato waste amounted to 1 ppm, 2 ppm, and 4 ppm, respectively; and (iii) cull potatoes contain 23 percent dry matter ([0.5 ppm/ 0.23] x 0.20 = 0.43 ppm). The dietary intake of turkeys and broilers would be up to 0.94 ppm if: (i) the diet consisted of 30 percent soybean meal, 15 percent soybean seed, 5 percent soybean soapstock, 7 percent cull potatoes, and 43 percent wheat grain; (ii) residues in or on soybean meal, grain, and soapstock amounted to 1 ppm, 2 ppm, and 2 ppm, respectively; (iii) residues in or on wheat grain amounted to 0.2 ppm; and (iv) cull potatoes contain 23 percent dry matter ([0.5 ppm/0.23] x 0.07 = 0.15 ppm).

Substitution of sugar beet molasses or spent hops would not change the potential maximum dietary livestock uptake.

With this petition a feeding study was submitted titled "Residue of Metalaxyl and Metabolites in Tissues and Milk of Dairy Cows Receiving Metalaxyl in their Diets" by D.E. Burnett dated August 31, 1982, and coded by Ciba-Geigy Laboratory as Project Number ABR-82052. This study has been previously reviewed in the FRSTR on page 104.

In summary, five grade Holstein-Freisan cows were purchased in Okeechokee, FL, then acclimated for 21 days at Ciba-Geigy's Research Station in Vero Beach, FL. These cows were producing 12 kg to 15 kg of milk per day. The weights of these cows were from 445 to 698 kg at the start of the study. Feed intake was about 20 kg per cow per day. The test cows were on 1 acre of poor grass but it had shade, fresh drinking water, ad libitum, and a feed through and hay rack. The cows received 1.5 gram of metalaxyl per day by mixing the compound with 1 kg of untreated commercial feed. Three lactating cows were orally dosed at 75 ppm in the diet with metalaxyl for 14, 21, or 28 consecutive days and were sacrificed within 24 hours of the final dose. An additional two cows served as controls and were sacrificed at 14 and 28 days. Total metalaxyl residues in five samples each (including two control samples) of omental and perirenal fat were < 0.05 ppm. Total metalaxyl residues in three muscle samples from dosed cows ranged from < 0.05 ppm to 0.09 ppm. Combined metalaxyl residues in six round muscle samples from dosed cows and four samples from control cows were 0.06 ppm to 0.14 ppm and 0.05 to 0.08 ppm, respectively. Samples were analyzed using the GLC method AG-349). The limit of detection was 0.05 ppm. Control samples from cow kidney and liver (four samples each) bore < 0.10 ppm (nondetectable) of apparent metalaxyl. Cow kidney samples contained 5.3 ppm to 5.5 ppm, 0.11 ppm to 0.13 ppm, and 0.11 ppm of combined metalaxyl at dosing days 14, 21, and 28, respectively (two samples/dosing day). Cow liver samples contained 0.82 ppm to 1.1 ppm, 0.14 ppm, and < 0.10 ppm (nondetectable) to 0.12 ppm of combined metalaxyl at dosing days 14, 21, and 28, respectively (two samples/dosing day).

All milk residues plateaued after day 1 at 0.02 ppm. The levels neither rose or declined through day 27. The petitioner reported total metalaxyl residue in whole blood at 320 ppb at day 13 but dropped to < 50 ppb at days 21 and 28.

Other ruminant metalaxyl feeding studies were reviewed as part of PP#GF3387/6H5499 (which see). In summary, dairy cows were fed metalaxyl at 0 (control), 1.5 ppm, 7.5 ppm, and 15 ppm in their feed for up to 40 days. Milk samples were collected at the end of weeks 1, 2, 3, 4, then at 40 days. These milk samples were analyzed for total metalaxyl. No metalaxyl residues to the limit of detection (0.01 ppm) were detected in the milk. Cows were sacrificed 3 to 5 hours after the last feeding of metalaxyl at the end of weeks 2, 3, and 4, and at 40 days. Various muscle and fat samples were removed and analyzed for metalaxyl. No metalaxyl residues were detected in any of the muscle or fat samples to the limit of detection, 0.05 ppm. Liver samples at all feeding levels showed metalaxyl levels ranging from 0.11 ppm to 0.22 ppm. Kidney samples at these same metalaxyl feeding levels showed residues ranging from 0.16 ppm to 0.70 ppm. The anomalous higher residue levels in liver and kidney in the cold study when compared to the hot study are explained as being due to the short time from last feeding to slaughter. Additional feeding studies discussed previously (op. cit.) substantiate the transitory nature of metalaxyl residues in liver and kidney.

Poultry feeding studies have been previously submitted and adequately reviewed (op. cit.). Poultry feed items are associated with the use proposed in this petition.

In summary, hens were fed either a control diet, 0.05 ppm, 1.5 ppm, or a 5.0 ppm metalaxyl diet for 4 weeks. Eggs were collected and hens were selectively sacrificed at the end of weeks 1, 2, 3, and 4. Metalaxyl analysis of eggs, skin, fat, breast, and thigh muscle from each sacrifice showed no metalaxyl residues at the 5.0 ppm feeding level to the level of detection; < 0.1 ppm.

Since animal feeding studies have demonstrated the presence of low levels of metalaxyl in liver and kidney any feed use of a metalaxyl-treated RAC or its byproducts must necessarily be categorized within 40 CFR 180.6(a)(1) or (a)(2). Since real residues have been found in livestock tissues from feeding exaggerated levels of metalaxyl, DEB characterizes the proposed use as (a)(2).

DEB defers judgment on the adequacy of all previous metalaxyl feeding studies used to support secondary tolerance until the questions raised by the FRSTR relating to the nature of the residue in livestock are resolved. In addition, our analytical method concerns and the suggested additional crop

field trial data should be submitted before DEB decides on the adequacy of the feeding studies.

OTHER CONSIDERATIONS - HARMONIZATION OF TOLERANCES

An International Residue Limit Status Sheet is attached to this petition. There are no problems of compatibility with Mexican or Canadian metalaxyl tolerances as these countries have not been established metalaxyl tolerances for the legume vegetables (succulent or dried) crop group; legume vegetables foliage crop group; nongrass animal feeds crop group; grass forage, food, and hay crop group; and sugar beet tops, roots and molasses. There is a Codex tolerance for parent only metalaxyl on sugar beets at 0.05 ppm, on peas (shelled) at 0.05 ppm, and on soybeans (dry) at 0.05 ppm. These are method limit of detection tolerances.

The United States has objected to the exclusion of metabolites in the Codex metalaxyl tolerance expression. In a future meeting, Codex may reconsider and include the metalaxyl metabolites in the tolerance expression.

Attachment 1: INTERNATIONAL RESIDUE LIMIT STATUS SHEET

TS-769C:DEB:Reviewer (FDG):CM#2:Rm 814B:557-0826:KENCO:JOB: 53847:I:Griffith:C.Disk:KENCO:10/14/88:de:vo:de:edited:fdg: 11/28/88.

cc: Reviewer (FDG):PP#8F3617:Circ(7):R.F.:ISB/PMSD (Eldridge).

RDI:Section Head:R.S. Quick:11/22/88:R.D. Schmitt:11/28/88.

END OF DOCUMENT

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Metalaxyl (Ridomil®)

CODEX NO. 138

[signature] 4/29/89

CODEX STATUS:

[ ] No Codex Proposal Step 6 or above

Residue(if Step 8): Metalaxyl only

Crop(s)	Limit (mg/kg)
sugar beet	0.05**
Peas, shelled	0.05**
soya bean (dry)	0.05**

PROPOSED U.S. TOLERANCES:

Petition No. 8F3617/8H5554

RCB Reviewer F.D. Griffith, Jr 28 Sept 88

Residue: Metalaxyl* and its 2 metabolites

Crop(s)	Limit (mg/kg)
Sugar beet (tops)	10.0
Sugar beet (roots)	0.5
Nongrass Animal Feeds Crop Group	6.0
Grass Forage Fodder and Hay Crop Group	2.0
Legume Vegetables (Dry or Succulent) Crop Group	1.0
Legume Vegetables Foliage Crop Group	10.0

CANADIAN LIMITS:

[✓] No Canadian limit (on these commodities)

Residue: parent (to potato negligible residue tolerance)

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

[✓] No Mexican limit

Residue:

Crop(s)	Limit (mg/kg)

NOTES:

* N-(2,6-Dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester

** [illegible]

Form revised 1986

END OF DOCUMENT

1. PP#8F3617

2. Petitioner:

   CIBA-GEIGY
   Corporation

3. Pesticide: Metalaxyl

4. Related Petition

5. Rec'd RD 3/9/88

   See Index Card

6. Rec'd Chem. Br. 6/3/88

7. Tolerances Requested:

8. Amendments and
   Pertinent
   Correspondence

   10.0 ppm - Sugar beet (tops) and Legume vegetables, foliage;
   0.5 ppm - Sugar beet (roots)
   6.0 ppm - Nongrass animal feeds group
   2.0 ppm - Grass forage, fodder and hay group
   1.0 ppm - Legume vegetables (dry or succulent) group
   11.0 ppm - Legume vegetables, cannery waste
   4.0 ppm - Molasses

9. Filing Date:

10. F.R. Notice of Filing

11. Method Tryout:

12. Results of Tryout:

13. Anal. Standards Rec'd Chem. Br.:

14. Certif. of Usefulness (date
    of letter to Company):

15. Deadlines: 45 days _____

    90 days _____

    Due Date 10/20/88

16. TOX Br. Recommendation:

17. Petition Assigned to: Griffith

18. Chem. Br. Recommendation

19. Tolerances Established (F.R.)

ROI
8/24/88

END OF DOCUMENT

13544

R060237

Chemical:	**Metalaxyl**
PC Code:	**113501**
HED File Code	**11500 Petition Files Chemistry**
Memo Date:	**03/10/2003 12:00:00 AM**
File ID:	**00000000**
Accession Number:	**412-04-0141**

HED Records Reference Center
04/22/2004