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

EXPEDITE

FEB 8 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Memorandum

Subject: PP #5F3180. (RCB #331) Cyromazine in/on lettuce and celery. Evaluation of the analytical method and residue data. Accession No. 073084

From: Cynthia Deyrup, Ph.D., Chemist
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Hazard Evaluation Division (TS-769)

Thru: Charles L. Trichilo, Chief
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Hazard Evaluation Division (TS-769)

To: Timothy A. Gardner, Product Manager No. 17
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Note: This review has been expedited per the request of the Director of the Registration Division, Mr. Douglas D. Campt (see memo of 1/29/85).

Ciba-Geigy proposes the establishment of tolerances for the combined residues of the insecticide cyromazine (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine) and its metabolite melamine (1,3,5-triazine-2,4,6-triamine) in or on celery and lettuce at 10.0 and 5.0 ppm respectively.

The petitioner should revise Section F to read "...tolerances for combined residues of cyromazine (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine) and its principle metabolite, melamine (1,3,5-triazine-2,4,6-triamine), calculated as cyromazine..." (See also Analytical Methodology Section of this review)

Cyromazine tolerances for eggs, meat, fat, and meat by-products of poultry at 0.4 ppm (PP #2F2707) resulting from a feed-through use of cyromazine on poultry feed are pending. Tolerances

for residues of cyromazine and its metabolite melamine in/on mushrooms at 10 ppm (PP #5F3177) are also pending.

No permanent tolerances for residues of cyromazine have been established on any raw agricultural commodities.

Conclusions

1. The petitioner needs to provide more experimental details for the lettuce and celery metabolism studies. RCB will need the following articles cited by the petitioner in order to evaluate the metabolism studies.
   a. Seim, V., et al., Biological Report for the Metabolism of Δ^{14}C-CGA-72662 Applied as a Multiple Foliar Treatment on Greenhouse Grown Celery and Lettuce.
   b. Brown, G., et al., BIOL-82015, Biological Report for the Metabolism of Δ^{14}C-CGA72662 Applied as a Multiple Foliar Treatment on Greenhouse Grown Celery and Lettuce.
   c. Procedures for Balance and Characterization of Radioactive Components in Plants and Soil; consists of AG-214, AG-223, AG-252, AG-254, and AG-276.

   Until references a, b, and c have been provided by the petitioner, RCB cannot conclude at this time that the nature of the residue in plants is adequately understood.

2a. Since the residue levels of melamine are calculated as cyromazine equivalents, the petitioner should revise Section F to read "...tolerances for combined residues of cyromazine (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine) and it principle metabolite, melamine (1,3,5-triazine-2,4,6-triamine), calculated as cyromazine..."

2b. The petitioner has submitted representative chromatograms of cyromazine and melamine standards, one check sample of celery, and one celery sample fortified with cyromazine and melamine at levels of 0.05 and 2.0 ppm. The petitioner also needs to provide chromatograms of lettuce check samples and of lettuce samples fortified with cyromazine and melamine for RCB's evaluation of method AG-402. In order for RCB to validate the methodology, we will need more than one chromatogram of check samples.

2c. The petitioner needs to provide chromatograms of check

samples of lettuce and samples of lettuce fortified with cyromazine and melamine so that RCB can more adequately evaluate Method AG-408. RCB will need more than one chromatogram of check samples to validate method AG-408.

2d. The petitioner needs to show that Method AG-376, which has undergone a successful method trial on chicken feed, is suitable for the analysis of cyromazine and melamine on lettuce and celery; if not, then methods AG-402 and/or 408 will have to be subjected to a method trial after the petitioner has indicated which method(s) should be used for regulatory purposes.

3a. Celery and lettuce samples were stored and shipped frozen. Celery was stored up to 16 months before analysis, and lettuce was stored up to 12 months before analysis. No storage stability data were submitted. The petitioner needs to provide storage stability data for residues of cyromazine and melamine on an appropriate crop for storage periods of at least 16 months.

3b. The petitioner needs to submit residue data on celery and lettuce which reflect analyses of samples that have received the minimum trimming expected of these crops as they enter interstate commerce.

3c. Since celery and lettuce may not be washed before entering interstate commerce, the petitioner needs to submit residue data reflecting analyses on unwashed samples. RCB is especially concerned because cyromazine and melamine are polar compounds which may partition into the aqueous layer.

3d. The celery analyses reflect analyses of stalks only. Celery leaves may be consumed by humans. According to 80 CFR 180.1 (j), the raw agricultural commodity to be examined for pesticide residues consists of the whole raw agricultural commodity. Therefore, the petitioner needs to provide residue data reflecting analyses of the whole celery plant (stalks and leaves).

3e. The petitioner needs to submit representative chromatograms of treated lettuce and celery from the field trials so that RCB can validate the residue data.

3f. Only one field trial involved leaf lettuce. Residue data from this trial reflected a 2X rate. Residue data on head lettuce should not be translated to leaf lettuce because the head grows from within the outer leaves which bear most of the residues (RCB cultural practices file). The petitioner will need to provide

residue data on leaf lettuce from the major leaf lettuce growing areas (CA and FL, according to the Leafy Greens Council).

3g. Problems associated with the pending feed-through use of cyromazine (PP #2F2707) must be resolved before RCB can judge whether the application of manure containing cyromazine/melamine (as a result of the feed-through use) will significantly increase levels of cyromazine and melamine in lettuce and celery.

3h. RCB can draw no conclusions on the appropriateness of the proposed tolerances for the reasons summarized below:

1) RCB can't evaluate the analytical methodology for Method AG-402 and Method AG-408 until chromatograms of lettuce check samples and samples of lettuce fortified with cyromazine and melamine have been submitted.
2) The petitioner needs to provide storage stability data for residues of cyromazine and melamine on an appropriate crop for periods up to 16 months.
3) The petitioner needs to provide residue data reflecting analyses of unwashed celery and lettuce which have received the minimum trimming expected of these crops as they enter interstate commerce.
4) The petitioner needs to submit residue data reflecting analyses of whole celery plants.
5) The petitioner needs to submit representative chromatograms of treated lettuce and celery samples from the field trials.
6) The petitioner needs to submit additional residue data on leaf lettuce.
7) Problems associated with the pending feed-through use of cyromazine (PP# 2F2707) must be resolved before RCB can judge whether the application of manure containing cyromazine and melamine as a result of the feed-through use will significantly increase levels of cyromazine and melamine in lettuce and celery.

After submittal and evaluation of the revised Sections D, and F, RCB may then be able to reach a conclusion on the appropriateness of the proposed tolerances for residues of cyromazine and melamine on lettuce and celery.

4. Since neither celery nor lettuce is a livestock feed item, there is little expectation of secondary residues of cyromazine/melamine occurring in meat, milk, poultry, and eggs from the proposed use.

5. Neither Codex, Mexico, nor Canada has established

tolerances for combined residues of cyromazine and melamine on lettuce and celery. There will be no compatibility problem.

Recommendations

RCB recommends against establishing the proposed tolerances for combined residues of cyromazine and its metabolite melamine on lettuce at 5 ppm and celery at 10 ppm for the reasons given above under our conclusions 1, 2a, 2b, 2c, 2d, 3a, 3b, 3c, 3d, 3e, 3f, 3g, and 3h.

Detailed Considerations

Manufacture and Formulation

The commercial synthesis of cyromazine was discussed in RCB's review of PP #9G2230 (memo of A. Rathman, 11/14/79). Technical cyromazine is 95% pure. The minor impurities present in technical cyromazine are not expected to present a residue problem.

The formulation proposed for use on celery and lettuce is Trigard 75 W, a wettable powder consisting of 75% of the active ingredient. The inerts have been cleared under 40 CFR 180.1001.

Proposed Use

For leafminer control, 0.125 lb. a.i./A is to applied as a foliar spray in 50 gal. of water with ground equipment or in 5 gal. of water with aerial application. Applications may be made at 7-day intervals with the stipulation that no more than 12 applications be made to one celery crop, and no more than 8 applications be made to one lettuce crop. A 7 day PHI is imposed.

Nature of the Residue

Summaries of metabolism studies of ^{14}C cyromazine, uniformly labeled in the triazine ring, on lettuce, celery, and tomatoes were submitted with this petition. In one study, half mature lettuce and celery each received 2 treatments totaling 0.375

lb. a.i./A (0.250 lb., 2X rate, + 0.125 lb., 1X rate). In a second study, lettuce received up to 4 applications (0.25 lb. a.i./A per application, totaling 1 lb. a.i./A after the fourth dosage) and celery received up to 6 applications (totaling 1.5 lb. a.i./A after the sixth dosage). PHI's of 7 days were observed in both studies. Also, a tomato study involved 6 applications at 0.25 lb. a.i./A, totaling 1.5 lb. a.i./A after the sixth application. PHI's of 0, 7, and 14 days were observed in the tomato study.

According to the petitioner, in the lettuce and celery studies, "...plant samples were processed and analyzed according to a group of AG methods for balance and characterization of radioactive components in plants...." Radioactive residues were identified by TLC.

The tomato samples were subjected to biphasic extraction. The petitioner indicated that tomatoes were also extracted with methanol/water (9:1) for analysis by cation exchange chromatography. Identification of radioactive residues was by TLC.

The results of the metabolism studies on celery and lettuce are tabulated below.

Celery (7 day PHI)

Maximum proposed use = 12 x 0.125 lb. a.i./A
Total = 1.5 lb. a.i./A

Dose lbs. a.i./A	Total ppm Cyromazine Equivalents	% Total Radioactivity Cyromazine	Melamine
0.25 + 0.125 Total = 0.375	1.46	56	33
3 x 0.25 Total = 0.75	5.84	64	16
6 x 0.25 Total = 1.5	1.55	48	25

Lettuce (7 day PHI)

Maximum proposed use = 8 x 0.125 lb. a.i./A
Total = 1.0 lb. a.i./A

Dose lbs. a.i./A	Total ppm Cyromazine Equivalents	% Total Radioactivity Cyromazine	Melamine
0.25 + 0.125 Total = 0.375	2.55	56	16
2 x 0.25 Total = 0.50	4.05	74	12
4 x 0.25 Total = 1.0	3.69	74	11

Therefore, 73-89% of the total radioactive residue has been identified in the celery stalks, and 72-85% of the total radioactive residue has been identified in the lettuce at a 7-day PHI.

The results of the tomato metabolism study are tabulated below.

Tomatoes

Dose lb. a.i./A	PHI	Total ppm Cyromazine Equivalents	%Total Radioactivity Cyromazine	Melamine
4 x 0.25 Total = 1.0	0	0.19	76	11
4 x 0.25 Total = 1.0	7	0.08	41	22
4 x 0.25 Total = 1.0	14	0.12	39	26
6 x 0.25 Total = 1.5	14	0.37	37	44

Therefore, with PHI's of 7-14 days, 63-81% of the total radioactive residue in tomatoes has been identified.

However, the petitioner needs to provide more experimental details for the lettuce and celery metabolism studies. RCB will need the following articles cited by the petitioner in order to evaluate the metabolism studies.

a. Seim, V., et al., Biological Report for the Metabolism of ^{14}C-CGA-72662 Applied as a

Multiple Foliar Treatment on Greenhouse Grown Celery and Lettuce.

b. Brown, G., et al., BIOL-82015, Biological Report for the Metabolism of ^{14}C-CGA72662 Applied as a Multiple Foliar Treatment on Greenhouse Grown Celery and Lettuce.

c. Procedures for Balance and Characterization of Radioactive Components in Plants and Soil; consists of AG-214, AG-223, AG-252, AG-254, and AG-276.

One of the things that RCB expects to see in the original reports is accountability for ^{14}C activity not reported in the summaries submitted with this petition.

Until references a, b, and c have been provided by the petitioner. RCB cannot conclude at this time that the nature of the residue in plants is adequately understood.

Soil Uptake Studies--Aged Residues

Tolerances for combined residues of cyromazine and melamine in poultry tissues and eggs resulting from a feed-through use to control flies are pending (PP #2F2707). Since chicken manure is a common fertilizer, the uptake of cyromazine and melamine residues by wheat, sugar beets, and lettuce grown in soil amended with cyromazine was studied in conjunction with this petition (PP #5F3180). Before planting the indicator crops, the top 3 inches of soil had been amended with chicken manure (equivalent to 5 tons/A) and aged for 30 days after treatment with ^{14}C-triazine ring labeled cyromazine at 0.05 lb. a.i./A. This treatment corresponds to 5 ppm in the chicken manure. The results of the soil uptake study are tabulated below.

	Lettuce	Sugar Beets		Spring Wheat		
		Tops	Beets	Straw	Hulls	Grain
Total ppm (Cyromazine equivalents)	<0.009	<0.009	<0.009	0.112	0.078	<0.009

The radioactive residues in wheat straw were cyromazine (72% of the total radioactive residue) and melamine (6% of the total radioactive residue).

The 5 ppm cyromazine in manure may not adequately reflect residue levels expected from the proposed feed-through use. Data submitted in conjunction with PP #2F2707 show that chickens fed a diet 5 ppm in cyromazine (1 X rate) yield

manure with maximum combined residues of cyromazine and melamine of 22 ppm, or ca. 0.2 lb. a.i./A if 5 tons of manure are applied.

Soil Uptake--Fresh Residues

Celery was grown to maturity in muck soil top-dressed with ^{14}C-cyromazine at a level of 0.9 lb. a.i./A. Celery stalks contained 0.75 ppm cyromazine equivalents six weeks after transplant and 0.34 ppm at maturity. Cyromazine comprised 43% of the total radioactive residue of mature stalks, and melamine comprised 30% of the total radioactivity.

Animals

Since the proposed use on lettuce and celery does not involve feed items, the nature of the residue in animals will not be discussed here. Animal (goat and chicken) metabolism of cyromazine was discussed in our review of PP #2F2707 (memo of P. Errico, 2/23/83).

Analytical Methodology

The petitioner has submitted 2 methods, AG-402 and AG-408, which differ in clean-up techniques.

Analytical Method AG-402

Residues of cyromazine and melamine are extracted from chopped crop samples by refluxing in 10% water/methanol for 2 hours. The extract is concentrated by removal of methanol, and diluted with 0.1 M hydrochloric acid. The acidic extract is partitioned with dichloromethane (2 X) and hexane (1 X). The organic layers are discarded, and the aqueous layer is loaded onto a Dowex 50W-X4 column. Cyromazine and melamine are eluted from the column with 5% concentrated ammonia/methanol. The solvent is removed, the residue is dissolved in methanol, and quantitation is achieved with a HPLC equipped with a LiChrosorb-NH_2 column using 95% acetonitrile/water as the mobile phase and a UV detector set at 214 nm. Additional clean-up by automated gel permeation gel chromatography on Bio-Gel P-2 may be necessary. The GPC column may be calibrated using ^{14}C-labeled or non-radioactive standards. This method determines both cyromazine and melamine. The residue level of melamine in ppm is multiplied by a factor (1.317) which allows for the

difference in molecular weights between melamine and cyromazine and converts the residue level of melamine to cyromazine equivalents.

Recoveries of cyromazine from celery stems fortified at levels of 0.05-2.0 ppm cyromazine ranged from 66-115% Recoveries of melamine from celery stems fortified at levels of 0.05-2.0 ppm melamine ranged from 60-120%.

Recoveries of cyromazine from lettuce fortified at levels of 0.05-4.0 ppm ranged from 81-148%. Recoveries of melamine from lettuce fortified at levels of 0.05-2.0 ppm ranged from 65-133%.

A sensitivity of 0.05 ppm cyromazine and 0.04 ppm melamine (equivalent to 0.05 ppm cyromazine) is claimed.

Method AG-402 was compared to the methodology used in the radiolabeled metabolism studies (TLC and liquid scintillation counting). Samples of celery had been subjected to 2 foliar applications (0.375 lb. a.i./A, 7 day PHI) or one soil application (0.9 lb. a.i./A, 42 and 84 day PHI's). The results of the comparison are tabulated below.

Comparison of Radiodiochemical Analysis and Method AG-402

Radiochemical Analysis	Foliar Application ppm	Soil (42 day PHI) ppm	Soil (84 day PHI) ppm
Cyromazine	0.9	0.6	0.2
Melamine	0.4	0.1	0.1
Method AG-402			
Cyromazine	0.9	0.5	0.2
Melamine	0.4	0.3	0.1

Since the residue levels of melamine are calculated as cyromazine equivalents, the petitioner should revise Section F to read "...tolerances for combined residues of cyromazine (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine) and its principle metabolite, melamine (1,3,5-triazine-2,4,6-triamine) calculated as cyromazine..."

The petitioner has submitted representative chromatograms of cyromazine and melamine standards, one check sample of

celery, and one celery sample fortified with cyromazine and melamine at levels of 0.05 and 2.0 ppm. Since many varieties of lettuce contain higher amounts of chlorophyll and some other plant constituents (which need to be removed during clean-up) than may occur in celery, the petitioner also needs to provide chromatograms of check samples and samples of lettuce fortified with cyromazine and melamine for RCB's evaluation of method AG-402. In order for RCB to validate the methodology, RCB will need more than one chromatogram of check samples.

Method AG-408

Method AG-408 differs from Method AG-402 in that anion exchange chromatography is used for additional clean-up rather than gel permeation chromatography. Following cation exchange chromatography on Dowex 50W-X4 and removal of solvent, the residue is dissolved in water and subjected to anion exchange chromatography on a Bio Rex 9 column. Cyromazine and melamine are eluted from the column with 25% concentrated ammonia/methanol. Solvent is removed, and quantitation is achieved with HPLC as in Method AG-402.

Recoveries of cyromazine from lettuce fortified at levels of 0.05-1.0 ppm ranged from 62-99%. Recoveries of melamine from lettuce fortified at levels of 0.05-1.0 ppm ranged from 67-104%. Recoveries of cyromazine from celery fortified at levels of 0.05-1.0 ppm ranged from 62-131%. Recoveries of melamine from celery fortified at levels of 0.05-1.0 ppm ranged from 62-112%.

A sensitivity of 0.05 ppm cyromazine and 0.04 ppm melamine (equivalent to 0.05 ppm cyromazine) is claimed.

Out of 22 field trials, residue levels of ca. 0.1 ppm or greater were reported in 12 cyromazine analyses of check samples of celery and lettuce. The highest cyromazine residue level found in one check sample was 0.3 ppm. Residue levels of ca. 0.1 ppm or greater were found in 5 melamine analyses of check samples of celery and lettuce. The highest melamine residue level found in a check sample was 0.2 ppm. These high check values were found in samples analyzed either by Method AG-402 or with Method AG-408 and may be due to matrix interference rather than drift during application. Therefore, RCB considers more realistic sensitivities to be 0.3 ppm for cyromazine and 0.2 ppm for melamine.

The petitioner has submitted representative chromatograms of cyromazine and melamine standards, one check sample of carrots and one of celery, and samples of carrots fortified at 0.05 ppm cyromazine and melamine and celery fortified at 0.05 and 2.0 ppm cyromazine and melamine. The petitioner needs to provide chromatograms of lettuce check samples

and of lettuce samples fortified with cyromazine and melamine so that RCB can evaluate Method AG-408. However, RCB needs more than one chromatogram of check samples to validate Method AG-408

The petitioner's Method AG-376, submitted previously, has undergone a successful method trial on chicken feed. The petitioner needs to show that Method AG-376, which has undergone a successful method trial on chicken feed, is suitable for the analysis of cyromazine and melamine on lettuce and celery; if not, then methods AG-402 and/or 408 will have to be subjected to a method trial after the petitioner has indicated which method(s) should be used for regulatory purposes.

Residue Data

Thirteen celery field trials were conducted in FL, CA, MI, NY, and TX. These states produce 99% of the nation's celery. Nine lettuce field trials were conducted in CA, FL, NY, TX, and WI which produce 79% of the nation's lettuce. Cyromazine was applied to celery or lettuce at a rate of 0.125 and 0.25 lb. a.i./A per application (1 X-2 X application rate). Applications were repeated at 7 day intervals. Ten to fifteen applications were made to celery, and and 7-9 applications were made to lettuce. Aerial application as well as ground equipment application was employed in one lettuce trial and one celery trial. PHI's ranging from 0-21 days were observed (proposed PHI, 7 days). Either Trigard 75 W or a formulation referred to as 0.4E was applied in the field trials.

Celery and lettuce samples were stored and shipped frozen Celery was stored up to 16 months before analysis, and lettuce was stored up to 12 months before analysis. No storage stability data were submitted. The petitioner needs to provide storage stability data for residues of cyromazine and melamine on an appropriate crop for storage periods of up to 16 months.

With 10-13 applications (0.125 lb. a.i./A, 1 X rate) and with PHI's of 0-2 days, cyromazine residue levels on celery ranged from 0.05-19.0 ppm, and levels of melamine ranged from 0.09-6.3 ppm. The highest level of combined residues of cyromazine/melamine was 20.9 ppm.

With 10-15 applications (0.125 lb. a.i./A, 1 X rate) and with PHI's of 7 days, which is the proposed PHI, cyromazine residue levels on celery ranged from <0.05-4.3 ppm. The highest level of combined residues of cyromazine/melamine was 9 ppm.

With 10-15 applications (0.25 lb. a.i./A, 2 X rate), and with a zero day PHI, cyromazine residue levels on celery ranged from 0.06-26 ppm, and melamine residue levels ranged

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from 0.08-2.0 ppm. The highest level of combined residues of cyromazine/melamine was 28 ppm. With a PHI of 7 days and the same application rate, cyromazine levels on celery ranged from 0.05-13 ppm, and melamine residue levels ranged from 0.1-4.4 ppm. The highest level of combined residues of cyromazine/melamine was 17.4 ppm.

With 7-9 applications (0.125 lb. a.i./A, 1 X rate) and with a zero day PHI, cyromazine residue levels on lettuce ranged from 0.3-8.8 ppm, and melamine residue levels ranged from 0.1-0.7 ppm. The highest level of combined residues of cyromazine/melamine was 9 ppm.

With 7-9 applications (0.125 lb. a.i./A, 1 X rate) and with PHI's of 7-8 days (proposed PHI, 7 days), cyromazine residue levels on lettuce ranged from 0.05-2.3 ppm, and melamine residue levels ranged from <0.05-1.3 ppm. The highest level of combined residues of cyromazine/melamine was 3.6 ppm.

With 7-8 applications (0.25 lb. a.i./A, 2 X rate) and with a zero day PHI (proposed PHI, 7 days), cyromazine residue levels on celery ranged from 0.6-16.0 ppm, and melamine residue levels ranged from 0.2-0.9 ppm. The highest level of combined residues of cyromazine and melamine was 16.4 ppm. With a 7 day PHI and the same application rate, cyromazine residue levels ranged from <0.05-2.3 ppm, and melamine residue levels ranged from <0.05-0.9 ppm. The highest level of combined residues of cyromazine/melamine was 6.1 ppm.

According to the petitioner, celery samples were washed and trimmed before analysis. According to EPA Guidelines, Subdivision O: Residue Chemistry, "Because certain crops (cabbage, celery, and lettuce) may be shipped without having been stripped or trimmed, samples of these crops should reflect both trimmed and untrimmed samples; only obviously decomposed outer leaves should be removed." Therefore, the petitioner needs to submit residue data on celery and lettuce which reflect analyses of samples that have received the minimum trimming expected of these crops as they enter interstate commerce.

The petitioner washed celery and lettuce samples before analysis. According to EPA Guidelines, Subdivision O: Residue Chemistry, "The sample should not be brushed, trimmed, or washed except to the extent that these are commercial practices before shipment or the extent allowable in Section 180.1 (j), Code of Federal Regulations, the PAM or the Codex Document Alinorm 81/24, appendix III. Since both celery and lettuce may not be washed before entering interstate commerce, the petitioner needs to submit residue data reflecting analyses on unwashed samples. RCB is especially concerned because cyromazine and melamine are polar compounds which are water soluble.

The celery analyses reflect analyses of stalks only. Celery leaves are a human food item. According to 80 CFR 180.1 (j), the raw agricultural commodity to be examined for pesticide residues shall consist of the whole raw agricultural commodity. Therefore the petitioner needs to provide residue data on the whole celery plant (stalks and leaves) rather than on stalks alone.

The petitioner needs to submit representative chromatograms of treated lettuce and celery so that RCB can validate the residue data.

Only one field trial involved leaf lettuce. Residue data from this trial reflected a 2X rate. Residue data on head lettuce should not be translated to leaf lettuce because the head grows from within the outer leaves which bear most of the residues (RCB cultural practices file). The petitioner will need to provide residue data on leaf lettuce from the major leaf lettuce growing areas (CA and FL, according to the Leafy Greens Council).

Problems associated with the pending feed-through use of cyromazine (PP #2F2707) must be resolved before RCB can judge whether the application of manure containing cyromazine/melamine (as a result of the feed-through use) will significantly increase levels of cyromazine and melamine in lettuce and celery.

RCB can draw no conclusions on the appropriateness of the proposed tolerances for the reasons summarized below.

1) RCB can't evaluate the analytical methodology for Method AG-402 and Method AG-408 until chromatograms of lettuce check samples and samples of lettuce fortified with cyromazine and melamine have been submitted.
2) The petitioner needs to provide storage stability data for residues of cyromazine and melamine on an appropriate crop for periods up to 16 months.
3) The petitioner needs to provide residue data reflecting analyses of unwashed celery and lettuce which have received the minimum trimming expected of these crops as they enter interstate commerce.
4) The petitioner needs to submit residue data reflecting analyses of whole celery plants.
5) The petitioner needs to submit representative chromatograms of treated lettuce and celery samples from the field trials.
6) The petitioner needs to submit additional residue data on leaf lettuce.

7) Problems associated with the pending feed-through use of cyromazine (PP# 2F2707) must be resolved before RCB can judge whether the application of manure containing cyromazine and melamine as a result of the feed-through use will significantly increase levels of cyromazine and melamine in lettuce and celery.

After submittal and evaluation of the revised Sections D and F, RCB may then be able to reach a conclusion on the appropriateness of the proposed tolerances for residues of cyromazine and melamine on lettuce and celery.

Meat, Milk, Poultry, and Eggs

Lettuce and celery are not livestock feed items. There is little likelihood of secondary residues of cyromazine and melamine occurring in meat, milk, poultry, and eggs from the proposed use.

Other Considerations

Neither Codex, Mexico, nor Canada has established tolerances for combined residues of cyromazine/melamine on lettuce or celery. There will be no compatibility problem.

cc: R.F., Circu, Reviewer, Deyrup, TOX, EEB, EAB, PP #5F3180
FDA, Robert Thompson
RDI: J. Onley, 2/5/85; R. Schmitt, 2/5/85
TS-769: C.D.:c.d.:Rm 810:CM2:2/6/85

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Cyromazine

CCPR NO. _____

PETITION NO. PP# 5F 3180

Reviewer: C Deyrup

Codex Status

☑ No Codex Proposal Step 6 or above

Proposed U.S. Tolerances

I thru 12/12/84

Residue (if Step 9): _____

_____

_____

Crop(s) Limit (mg/kg)

Residue: Cyromazine

Melamine

_____

Crop(s)	Tol. (ppm)
celery	10
lettuce	5

CANADIAN LIMIT

Residue: _____

_____

Crop	Limit (ppm)
NONE	

MEXICAN TOLERANCIA

Residue: _____

_____

Crop	Tolerancia (ppm
NONE	

NOTES:

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