



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

SUBJECT 1401

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Product and Residue Chemistry Data Requirements for Zineb
Registration Standard

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The Residue Chemistry Branch (RCB) has reviewed the available product and residue chemistry data for zineb (MRIDs and Branch petition files) and determined that insufficient product and residue chemistry data have been submitted to support any uses of this active ingredient. No data are available regarding (i) product chemistry, (ii) metabolism in livestock animals, (iii) potential residue concentration on processing of raw agricultural food and feed commodities, (iv) storage stability, (v) residues of ethylene thiourea (ETU), a known metabolite of toxicological concern, in raw agricultural commodities (RACs) treated with zineb, or (vi) specific analytical methods for enforcement of tolerances. Minimal and inadequate data are available depicting the metabolism of zineb in plants and residues of zineb per se in or on RACs. In order to obtain a complete product and residue chemistry data base for zineb, Registrant(s) must submit all requirements for these topics as outlined in 40 CFR Parts 158.120 and 158.125. Specific data requirements are described in detail in "data gap" tables for Product and Residue Chemistry, attached to this memorandum (Attachments 2-4).

Due to the magnitude and complexity of residue chemistry data requirements for zineb, the Product Manager should urge Registrant(s) to submit detailed protocols for approval prior to initiation of required studies. Furthermore, Registrant(s) should complete and submit all plant

metabolism data to the Agency for review prior to initiation of residue field trials and processing studies. This approach may prevent unnecessary expense and repetition of tests. Registrant(s) should also be informed that they are still expected to comply, in a timely manner, with all requirements cited in the Data Call-In Notice(s) for Zineb.

It should be noted that, due to time constraints, registered 24(c) and intrastate uses of zineb were not reviewed nor considered in the development of specific residue chemistry data requirements (see Attachment 4). In the past we have found that these state uses occasionally permit use on crops having no tolerances for residues, or lower preharvest intervals and/or higher rates on crops which do have established tolerances for residues. Registrants should be encouraged to review these state uses and submit appropriate data to support them or request their cancellation if (i) the uses are such that they could result in residues higher than those resulting from Section 3 uses or (ii) they specify use on crops on which no tolerances have been established. Registrant compliance with this request will help avoid Agency imposition of additional data requirements at some future date to support these state uses.

Tolerances for residues in/on the following commodities listed in 40 CFR 180.115 should be revoked since no Section 3 uses on them exist: rutabagas (with or without tops), rutabaga tops, salsify, parsley, Romaine lettuce, quinces, dewberries, loganberries, youngberries, and guava. However, if any of the 24(c) or intrastate registrations permit use on these crops, the Registrant(s) may submit data in support of such use and retain (or revise) the tolerance. The CFR entry "turnips (with or without tops)" should be revised to "turnip roots", the presently accepted commodity definition. Also, the tolerance for residues in/on radish tops should be deleted from the CFR since radish tops are not presently considered to be a raw agricultural commodity.

The U.S. tolerances for residues of zineb are currently expressed in terms of zineb per se. On receipt of required data, the tolerance definition will be revised to include ethylene thiourea (ETU) and any additional residues of toxicological concern. Attachment 1 lists all U.S. tolerances for zineb.

Attachment 1. U.S. Tolerances for Residues of Zineb.

Attachment 2. Product Chemistry Data Requirement Table for Technical Zineb Products

Attachment 3. Product Chemistry Data Requirement Table for Formulation Intermediate Zineb Products

Attachment 4. Residue Chemistry Data Requirement Table for Zineb.

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Attachment 1: U.S. Tolerances for Residues of Zineb, in ppm.

<u>Commodity</u>	<u>Tolerance¹</u>
Root and Tuber Vegetables:	
Beets (garden roots only)	7
Carrots	7
Potatoes	0.5 ²
Radishes (with or without tops)	7
Rutabagas (with or without tops)	7
Salsify	7
Turnips (with or without tops)	7
Leaves of Root and Tuber Vegetables:	
Beet tops	25
Radish tops	7
Rutabaga tops	7
Turnip greens	7
Bulb Vegetables:	
Onions	7
Leafy Vegetables:	
Celery	5
Endive	10
Lettuce	10
Parsley	7
Romaine lettuce	25
Spinach	10
Swiss chard	25
Brassica Leafy Vegetables:	
Broccoli	7
Brussels sprouts	7
Cabbage	7
Cauliflower	7
Chinese cabbage	25
Collards	25
Kale	10
Kohlrabi	7
Mustard greens	10
Legume Vegetables:	
Beans	7
Peas	7

Continued

Attachment 1 (Continued). U.S. Tolerances for Residues of Zineb, in ppm.

<u>Commodity</u>	<u>Tolerance¹</u>
Fruiting Vegetables:	
Eggplants	7
Peppers	7
Tomatoes	4
Cucurbit Vegetables:	
Cucumbers	4
Melons	4
Pumpkins	7
Squash	4
Summer Squash	7
Citrus Fruits	7
Pome Fruits:	
Apples	2
Pears	7
Quinces	7
Stone Fruits:	
Apricots	7
Cherries	7
Nectarines	7
Peaches	7
Plums	7
Small Fruits and Berries:	
Blackberries	7
Boysenberries	7
Cranberries	7
Currants	7
Dewberries	7
Gooseberries	7
Grapes	7
Loganberries	7
Raspberries	7
Strawberries	7
Youngberries	7
Cereal Grains:	
Corn grain	0.1
Sweet corn (kernels plus cob w/husk removed)	5
Wheat	1

Continued.

Attachment 1 (Continued). U.S. Tolerances for Residues of Zineb, in ppm.

<u>Commodity</u>	<u>Tolerance¹</u>
Miscellaneous Commodities:	
Guavas	7
Hops	60
Mushrooms	7
Peanuts	7

¹Residues of zineb per se.

²Interim tolerance (40 CFR 180.319).

ATTACHMENT 2. DATA REQUIREMENTS FOR ZINEB TECHNICAL PRODUCTS (EPA Reg Nos. 2749-20, 4581-267, 7969-12, 19713-58, 19713-58, 19713-186, and 43981-6).

Data Requirement	Composition ^a	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^b
<u>158.120 Product Chemistry</u>				
<u>Product Identity and Composition:</u>				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	No		Yes
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No		Yes ^c
61-3 - Discussion of Formation of Impurities	TGAI	No		Yes ^d
<u>Analysis and Certification of Product Ingredients</u>				
62-1 - Preliminary Analysis of Product Samples	TGAI	No		Yes ^e
62-2 - Certification of Ingredient Limits	TGAI	No		Yes ^f
62-3 - Analytical Methods to Verify Certified Limits	TGAI	No		Yes ^g
<u>Physical and Chemical Characteristics</u>				
63-2 - Color	TGAI	No		Yes ^h
63-3 - Physical State	TGAI	No		Yes ^h
63-4 - Odor	TGAI	No		Yes ^h
63-5 - Melting Point	TGAI	No		Yes ^h
63-6 - Boiling Point	TGAI	No		Yes ^h
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No		Yes ^h

(Continued).

ATTACHMENT 2 (Continued).

Data Requirement	Composition ^a	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^b
158.120 Product Chemistry (continued)				
63-8 - Solubility	TGAI or PAI	No		Yes ^h
63-9 - Vapor Pressure	TGAI or PAI	No		Yes ^h
63-10 - Dissociation Constant	TGAI or PAI	No		Yes ^h
63-11 - Octanol/Water Partition Coefficient	PAI	No		Yes ^h
63-12 - pH	TGAI	No		Yes ^h
63-13 - Stability	TGAI	No		Yes ^h
Other Requirement:				
64-1 - Submittal of samples	N/A			N/A

a Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.

b Data must be submitted no later than 6-8 months from the date of this Standard.

c Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, a flow chart with chemical equations for each intended chemical reaction, equipment used to produce the product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material.

d A detailed discussion of all impurities that are or may be present at $\geq 0.1\%$, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

Continued.

ATTACHMENT 2 (Continued).

- e Five or more representative samples of each product must be analyzed for the amount of active ingredient and each impurity present at $>0.1\%$ (w/w). Complete validation data (accuracy, precision) for each analytical method used must be submitted.
- f Upper and lower limits for the active ingredient and upper limits for each impurity present at $>0.1\%$ (w/w) must be provided, certified, and validated using analytical procedures for which accuracy and precision data have been provided. Certifications must be submitted on EPA form 8570 Rev. 2-85.
- g Analytical methods are required to determine the active ingredient and each toxicologically significant impurity for which a certified limit is required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits. [RCB defers to the TOX Branch regarding the toxicological significance of impurities for which certified limits are required.]
- h Physical/chemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, K_{ow} , pH, and stability) as required in 49 FR No. 207, p. 42890 (Sec. 158.120) and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

ATTACHMENT 3. DATA REQUIREMENTS FOR ZINEB FORMULATION INTERMEDIATE PRODUCTS (EPA REG. NOS. 2749-6, 1439-237, 279-1863, 707-72, 2749-13, 2749-68, 8236-3).

Data Requirement	Composition ^a	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^b
<u>158.120 Product Chemistry</u>				
<u>Product Identity and Composition:</u>				
61-1 - Product Identity and Disclosure of Ingredients	MP	No		Yes ^c
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes ^d
61-3 - Discussion of Formation of Impurities	MP	No		Yes ^e
<u>Analysis and Certification of Product Ingredients</u>				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes ^f
62-2 - Certification of Ingredient Limits	MP	No		Yes ^g
62-3 - Analytical Methods to Verify Certified Limits	MP	No		Yes ^h
<u>Other Requirements:</u>				
64-1 - Submittal of Samples	N/A			N/A

^a Composition: MP = Manufacturing-use product.

^b Data must be submitted no later than 6-8 months from the date of this Standard.

^c The nominal concentration, purpose, CAS registry number, and chemical name of each intentionally-added inert must be provided.
Continued.

ATTACHMENT 3 (Continued).

- d Complete information must be provided regarding the relative amounts of beginning materials and the order in which they are added, equipment used to produce the product, purification procedures, and quality control measures. Also, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material.
- e A detailed discussion of all impurities that are or may be present at $>0.1\%$, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.
- f Five or more representative samples must be analyzed for the amount of active ingredient, each impurity present at $>0.1\%$, and each toxicologically significant intentionally added inert. Complete validation data (accuracy and precision) for the analytical method used must be submitted.
- g Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at $>0.1\%$ (w/w) must be provided, certified, and validated using analytical procedures for which accuracy and precision data have been provided. Certifications must be submitted on EPA form 8570 Rev. 2/85.
- h Analytical methods must be submitted to determine the active ingredient and each toxicologically significant impurity and intentionally added inert for which a certified limit is required. Each method must be accompanied by studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits. [RCB defers to the TOX Branch regarding the toxicological significance of impurities and intentionally-added inerts for which certified limits are required.]

ATTACHMENT 4. RESIDUE CHEMISTRY DATA REQUIREMENTS FOR ZINEB.

Data Requirement	Test Substance ^{1/}	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission ^{2/}
<u>158.125 Residue Chemistry</u>					
171-2. Chemical identity ^{3/}					
171-3. Directions for use		(See Index)			
171-4. Nature of the residue (Metabolism)					
- Plants	PAIRA	No		Yes ⁴	
- Livestock	PAIRA	No		Yes ⁵	
171-4. Residue analytical methods	TGAI and metabolites	No		Yes ^{6/7}	
171-4. Storage stability data	TEP, EP	No		Yes ⁸	
171-4. Magnitude of the Residue - Crop field trials					
- Root and Tuber Vegetables					
o Beets	EP	No		No ⁹	
o Carrots	EP	No		Yes ¹⁰	
o Potatoes	EP, TEP	No		Yes ^{11/12}	
o Radishes	EP	No		No ¹³	
o Turnips	EP	No		Yes ¹⁴	

Continued.

ATTACHMENT 4 (CONTINUED). RESIDUE CHEMISTRY DATA REQUIREMENTS FOR ZINEB.

Data Requirement	Test Substance ^{1/}	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission ^{2/}
- Leaves of Root and Tuber Vegetables					
o Beet tops	EP	No		No ¹⁵	
o Turnip greens	EP	No		Yes ¹⁶	
- Bulb Vegetables					
o Onions	EP	No		Yes ¹⁷	
- Leafy Vegetables					
o Endive	EP	No		No ¹⁸	
o Celery	EP	No		Yes ¹⁹	
o Lettuce	EP	No		Yes ²⁰	
o Spinach	EP	No		Yes ²¹	
o Swiss chard	EP	No		Yes ²²	
- Brassica leafy Vegetables					
o Broccoli	EP	No		Yes ²³	
o Brussels sprouts	EP	No		No ²⁴	
o Cabbage	EP	No		Yes ²⁵	

Continued.

ATTACHMENT 4 (CONTINUED). RESIDUE CHEMISTRY DATA REQUIREMENTS FOR ZINEB.

Data Requirement	Test Substance ^{1/}	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission ^{2/}
- Brassica Leafy Vegetables (continued)					
o Cauliflower	EP	No		No ²⁶	
o Chinese cabbage	EP	No		Yes ²⁷	
o Collards	EP	No		Yes ²⁸	
o Kale	EP	No		No ²⁹	
o Kohlrabi	EP	No		No ³⁰	
o Mustard greens	EP	No		Yes ³¹	
- Legume vegetables					
o Beans	EP	No		Yes ³²	
o Peas	EP	No		No ³³	
- Fruiting Vegetables					
o Eggplant	EP	No		No ³⁴	
o Peppers	EP	No		Yes ³⁵	
o Tomatoes	EP, TEP	No		Yes ^{36/37}	

Continued.

ATTACHMENT 4 (CONTINUED). RESIDUE CHEMISTRY DATA REQUIREMENTS FOR ZINEB.

Data Requirement	Test Substance ^{1/}	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission ^{2/}
- Cucurbit vegetables					
o Cucumbers	EP	No		Yes ³⁸	
o Melons	EP	No		Yes ³⁹	
o Pumpkins	EP	No		Yes ⁴⁰	
o Squash	EP	No		No ⁴¹	
o Summer Squash	EP	No		No ⁴²	
- Citrus fruits	EP, TEP	No		Yes ^{43/44}	
- Pome fruits					
o Apples	EP, TEP	No		Yes ^{45/46}	
o Pears	EP	No		Yes ⁴⁷	
- Stone Fruits					
o Apricots	EP	No		No ⁴⁸	
o Cherries	EP	No		Yes ⁴⁹	
o Nectarines	EP	No		No ⁵⁰	
o Peaches	EP	No		Yes ⁵¹	
o Plums	EP, TEP	No		Yes ^{52/53}	

Continued.

ATTACHMENT 4 (CONTINUED). RESIDUE CHEMISTRY DATA REQUIREMENTS FOR ZINEB.

Data Requirement	Test Substance ^{1/}	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission ^{2/}
- Small Fruits					
o Blackberries	EP	No		Yes ⁵⁴	
o Boysenberries	EP	No		No ⁵⁵	
o Cranberries	EP	No		Yes ⁵⁶	
o Currants	EP	No		Yes ⁵⁷	
o Gooseberries	EP	No		No ⁵⁸	
o Grapes	EP, TEP	No		Yes ^{59/60}	
o Raspberries	EP	No		No ⁶¹	
o Strawberries	EP	No		Yes ⁶²	
- Cereal Grains					
o Corn grain	EP, TEP	No		Yes ^{63/64}	
o Sweet corn	EP	No		Yes ⁶⁵	
o Wheat	EP	No		Yes ^{66/67}	

Continued.

ATTACHMENT 4 (CONTINUED). RESIDUE CHEMISTRY DATA REQUIREMENTS FOR ZINEB.

Data Requirement	Test Substance ^{1/}	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission ^{2/}
- Miscellaneous Commodities					
o Asparagus	EP	No		Yes ⁶⁸	
o Hops	EP, TEP	No		Yes ^{69/70}	
o Mushrooms	EP	No		Yes ⁷¹	
o Peanuts	EP, TEP	No		Yes ^{72/73}	
o Tobacco	EP	No		Yes ⁷⁴	
- Seed Treatments	EP	No		Yes ⁷⁵	
- Meat/Milk/Poultry/Eggs	EP	No		Reserved ⁷⁶	

1/ Test Substance: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product; EP = end-use product.

2/ Data must be submitted within the indicated time frame, based on the date of this Guidance Document.

3/ Refer to Product Chemistry Data Requirement tables.

Continued.

Attachment 4 (Continued).

- 4/ The uptake, distribution and metabolism of zineb must be studied in carrots, tomatoes, and corn following foliar treatment and lettuce following soil and foliar treatment with [¹⁴C-ethylene]zineb at rates sufficiently high to permit complete characterization of ¹⁴C-residues. Sampling intervals through at least 21 days following treatment must be included. The identities and quantities of residues in or on mature plant parts must be determined in order to elucidate terminal residues. Precautions must be taken to minimize EBDC degradation during analysis steps due to the presence of water, methanol, and atmospheric oxygen. Residue identities must be confirmed by a method such as GC, HPLC, and/or mass spectrometry. Data reflecting solvent extraction efficiency must be represented. Representative samples from these tests must also be analyzed by analytical methods proposed for enforcement to ascertain that the methods are capable of adequately recovering and quantifying all residues of concern.
- 5/ Metabolism studies using ruminants and poultry must be submitted. Animals must be dosed for 3 days with [¹⁴C-ethylene]zineb at a level sufficiently high to permit complete identification and quantification of ¹⁴C-residues. 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, muscle and fat. Precautions must be taken to minimize EBDC degradation during analysis steps due to the presence of water, methanol and atmospheric oxygen. Samples from these studies must also be analyzed using analytical methods proposed for enforcement to ascertain that the methods are capable of adequately recovering and quantifying all residues of concern. [It should be noted that if metabolism in ruminants or poultry is found to differ significantly from that in rats, additional metabolism data for swine may be required.]
- 6/ Residues of ethylenethiourea (ETU), zineb per se and any other residues of concern discovered in the required plant metabolism studies in or on crop samples must be subjected to analysis by multiresidue method protocols I-IV, available from NTIS under order No. PB203734/AS. If it is determined that tolerances must be established for residues of zineb in animal commodities, these data will also be required for representative animal commodities.
- 7/ All residue data required in this Standard must be accompanied by a complete description of all analytical methods used in data collection along with complete method validation data (accuracy, precision, sensitivity) for each residue in/on each commodity.

Continued.

Attachment 4 (Continued).

- 8/ All required residue data must be accompanied by data regarding sample handling, including storage intervals and conditions of sample storage. These data must be accompanied by data depicting the stability of all residues of concern in samples under the conditions and for the time intervals specified. If residue samples are macerated prior to freezing, then samples for use in storage stability tests must be macerated also. One approach for the parent compound would be to analyze samples bearing field-weathered residues on the day of collection and at intervals between collection and analysis of the remainder of the samples; this would necessitate a large, uniform sample from which subsamples could be drawn at various intervals. Alternatively, fortification/recovery data could be submitted depicting the stability of zineb in appropriate sample substrate under the conditions and for the time intervals specified. In the case of ethylenethiourea (ETU), spiking of samples should be the approach taken because ETU residues are frequently very low in/on field samples but they may increase during storage as a result of zineb degradation.
- 9/ The data requested for turnip and carrot roots will be used to assess the established tolerance for residues in/on beets. All label revisions required for carrots and turnips must be implemented for beets also.
- 10/ Data must be submitted depicting residues of concern in or on carrots harvested immediately after the last of several foliar applications made at 7-day intervals of a WP and D formulation (in separate tests) at 3 lb ai/A. A maximum permissible seasonal application rate or number of applications per season must be proposed and reflected in the submitted data. Tests must represent all major geographic production regions according to the most recent edition of Agricultural Statistics (USDA).
- 11/ Data must be submitted depicting residues of concern in or on mature potatoes grown from seed pieces treated with a WP formulation at 1.5 lb ai/100 gal and, in separate tests, a D formulation at 0.15 lb ai/100 lb of seed pieces. [Data are also required relecting foliar treatments as specified on labels 1386-512, 1772-74, and 2169-45, unless these uses have been deleted from the labels - see Auxiliary Documentation to the 10/30/84 EPA Index to Pesticide Chemicals for Zineb.] Tests must represent all major geographic production regions for each crop according to the most recent edition of Agricultural Statistics (USDA). Since the present tolerance is an "interim" tolerance, a tolerance for inclusion in 40 CFR 180.115 must be proposed and, if supported, established concomitant with revocation of the interim tolerance in 40 CFR 180.319.
- 12/ Data must be submitted depicting residues in granules or flakes, chips, and wet and dry peel processed from potatoes bearing measurable weathered residues. If residues are found to concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

Continued.

Attachment 4 (Continued).

- 13/ The data required for turnip and carrot roots will be used to assess the established tolerance for residues in/on radishes. All label revisions required for carrots and turnips must be implemented also for radishes.
- 14/ Data must be submitted depicting residues of concern in or on turnip roots harvested immediately after the last of several foliar applications made at 7-day intervals of a WP and D formulation (in separate tests) at 3 lb ai/A. A maximum permissible seasonal application rate or number of applications per season must be proposed and reflected in the submitted data. Tests must represent all major geographic production regions according to the most recent edition of the U.S. Census of Agriculture (U.S. Department of Commerce).
- 15/ The data required for turnip greens will be used to assess the established tolerance for residues in/on beet tops. All label revisions required for turnip greens must be implemented for beet tops also.
- 16/ Data must be submitted depicting residues of concern in or on turnip greens harvested immediately after the last of several foliar applications made at 7-day intervals of a WP and D formulation (in separate tests) at 3 lb ai/A. Both ground and aerial application data from separate tests must be submitted. A maximum permissible seasonal application rate or number of applications per season must be proposed and reflected in the submitted data. The 7-day preharvest intervals (PHI) for tops only must be deleted from the labels or proposed also for roots because it is impractical to assume that growers will dispose of tops of roots harvested prior to the established PHI for tops. Tests must represent all major geographic production regions for each crop according to the most recent edition of the Census of Agriculture (U.S. Dept. of Commerce).
- 17/ Data must be submitted depicting residues in or on onions (bulb) harvested immediately and green onions (whole plant) harvested 7 days after the last of several foliar applications made at 7-day intervals of a WP and, in separate tests, a D formulation at 3 lb ai/A. A maximum permissible seasonal application rate or number of applications must be proposed and reflected in the submitted data. Tests must represent all major geographic production regions for each crop according to the most recent edition of Agricultural Statistics (USDA).
- 18/ The requested data for lettuce will be used to assess the established tolerance for residues in/on endive.

Continued.

Attachment 4 (Continued).

- 19/ Data must be submitted depicting residues of concern in/on unwashed, unstripped, and untrimmed celery harvested 14 days after the last of several foliar applications made at 7-day intervals with a WP and, in separate tests, a D formulation at 3 lb ai/A. Both ground and aerial application data must be submitted, representing separate tests. These field applications must be preceded by foliar plant bed applications beginning at emergence and continuing at 3-day intervals until transplanting. A maximum permissible seasonal application rate or number of applications must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to the most recent edition of Agricultural Statistics (USDA). [The EPA Index to Pesticide Chemicals for Zineb, dated 10/30/84 implies that the label gives instructions to remove residues by stripping, trimming, and washing. This instruction does not relieve the Registrant of submitting data for untrimmed, unwashed, and unstripped celery for purposes of tolerance assessment.]
- 20/ Data must be submitted depicting residues in/on lettuce (leaf and head) harvested 10 days after the last of several foliar applications made at 7-day intervals with a WP and, in separate tests, a D formulation at 3 lb ai/A. The submitted data must reflect both ground and aerial application data from separate tests. These field applications must be preceded by plant bed soil applications made as a drenching spray of a WP formulation at 3 lb ai/A beginning at planting and continuing a 7-day intervals until transplanting. A maximum permissible seasonal application rate or number of applications must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production areas according to the most recent edition of Agricultural Statistics (USDA).
- 21/ Data must be submitted depicting residues in/on spinach harvested 10 days after the last of several foliar applications made at 7-day intervals with a WP formulation at 3 lb ai/A. Both ground and aerial application data must be submitted from separate tests. A maximum permissible seasonal application rate or number of applications must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to the most recent edition of the Census of Agriculture (U.S. Dept. of Commerce).
- 22/ Data must be submitted depicting residues of concern in/on Swiss chard harvested 7 days after the last of several foliar applications made at 7-day intervals of a WP formulation at 3 lb ai/A. Both ground and aerial application data (from separate tests) must be submitted. A maximum permissible seasonal application rate or number of applications must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to the most recent edition of Agricultural Statistics (USDA).

Continued.

Attachment 4 (Continued).

- 23/ Data must be submitted depicting residues of concern in/on broccoli harvested 7 days after the last of several foliar applications made at 7-day intervals with a WP and, in separate tests, a D formulation at 4.8 lb ai/A. Both ground and aerial application data (from separate tests) must be submitted. These field treatments must be preceded by soil applications in the plant bed using a drenching spray of a WP formulation beginning when the seed is planted and continuing at 7-day intervals until transplant at 2.4 lb ai/100 gal. A maximum permissible seasonal application rate or number of applications must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to the most recent edition of Agricultural Statistics (USDA).
- 24/ The requested data for broccoli will be used to assess the established tolerance for residues in/on Brussels sprouts. All label revisions required for broccoli must be implemented for Brussels sprouts also.
- 25/ Data must be submitted depicting residues of concern in/on cabbage (with and without wrapper leaves) harvested 7 days after the last of several foliar applications made at 7-day intervals with a WP and, in separate tests, a D formulation at 4.8 lb ai/A. Both ground and aerial application data (from separate tests) must be submitted. These field treatments must be preceded by soil applications in the plant bed using a drenching spray of a WP formulation beginning when the seed is planted and continuing at 7-day intervals until transplant at 2.4 lb ai/100 gal. A maximum permissible seasonal application rate or number of applications must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to the most recent edition of the Census of Agriculture (U.S. Dept. of Commerce).
- 26/ The requested data for broccoli will be used to assess the established tolerance for residues in/on cauliflower. All label revisions required for broccoli must be implemented for cauliflower also.
- 27/ Data must be submitted depicting residues of concern in/on Chinese cabbage harvested 7 days after the last of several foliar applications made at 7-day intervals with the 7% D (MAI) formulation at the highest rate specified on the label. [The rate was not provided in the EPA Index to Pesticide Chemicals for Zineb, dated 10/30/84.] Both ground and aerial application data (from separate tests) must be submitted. A maximum permissible seasonal application rate or number of applications must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to the most recent edition of the Census of Agriculture (U.S. Dept. of Commerce).

Continued.

Attachment 4 (Continued).

- 28/ Data must be submitted depicting residues of concern in/on collards harvested 7 days after the last of several foliar applications made at 7-day intervals with a WP and, in separate tests, a D formulation at 3 lb ai/A. Both ground and aerial application data (from separate tests) must be submitted. A maximum permissible seasonal application rate or number of applications per season must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to the most recent edition of the Census of Agriculture (U.S. Dept. of Commerce).
- 29/ The data required for mustard greens will be used to assess the established tolerance for residues in/on kale. All label revisions required for mustard greens must be implemented for kale also.
- 30/ The data required for broccoli will be used to assess the established tolerance for residues in/on kohlrabi. [It should be noted, however, that the registered uses on kohlrabi - foliar applications at 1.63 lb ai/A at 7-day intervals until edible parts start to form - would most likely result in residues significantly below levels in/on broccoli. If the Registrant wishes to propose a lower tolerance for residues in/on kohlrabi, appropriate supporting data must be submitted.]
- 31/ Data must be submitted depicting residues of concern in/on mustard greens harvested 10 days after the last of several foliar applications made at 7-day intervals of a WP and, in separate tests, a D formulation at 3 lb ai/A. Both ground and aerial application data (from separate tests) must be submitted. A maximum permissible seasonal application rate or number of applications per season must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to the most recent edition of the Census of Agriculture (U.S. Dept. of Commerce).
- 32/ Data must be submitted depicting residues of concern in/on dry, lima, and snap beans harvested 7 days after the last of several foliar applications made at 4-day intervals of a WP and, in separate tests, a D formulation at 3 lb ai/A. Both ground and aerial application data (from separate tests) must be submitted. These foliar treatments must be preceded by an at-plant incorporated soil application with a WP/D formulation at 5.25 lb ai/A (broadcast) or 3.5 lb ai/A (row). A maximum permissible seasonal application rate or number of applications per season must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to the most recent edition of Agricultural Statistics (USDA). Separate tolerances must be proposed for dry, lima, and snap beans. Data must also be submitted and tolerances proposed for residues in/on bean vines and hay. Hay must be harvested at the PHI and vines immediately after the last foliar treatment or at a pregrazing interval to be proposed by the Registrant. Alternatively, feeding and grazing restrictions may be imposed. If feeding and grazing restrictions are imposed, data depicting residues in cannerly residue derived from beans bearing measurable weathered residues must be submitted. If the concentration of residues is higher in the cannerly residue than in the beans per se, an appropriate feed additive tolerance must be proposed.

Continued.

Attachment 4 (Continued).

- 33/ The data requested for beans (dry and snap) will be used to assess the established tolerance for residues in/on peas. Separate tolerances for residues in/on succulant and dried peas must be proposed based on the data collected for snap and dried beans, respectively. Data requested for bean vines and hay may be used to propose tolerances for residues in/on pea vines and straw, respectively. All label revisions required for beans, such as limitations on lb ai/A/season, and a pregrazing interval or feeding and grazing restrictions must be implemented also for peas.
- 34/ The data required for peppers will be used to assess the established tolerance for residues in/on eggplant.
- 35/ Data must be submitted depicting residues in/on peppers harvested immediately after the last of several foliar applications made at 7-day intervals of a WP formulation at 6.5 lb ai/A. Both ground and aerial application data (from separate tests) must be submitted. These field treatments must be preceded by plant bed (soil) treatments at 0.8 lb ai/50 gal using 0.5 gal/sq. yd. applied weekly after seeding until transplant. A maximum permissible seasonal application rate or number of foliar applications per season must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to the most recent edition of the Census of Agriculture (U.S. Dept. of Commerce).
- 36/ Data must be submitted depicting residues in/on tomatoes harvested 5 days after the last of several foliar applications made at 7-day intervals of a WP and, in separate tests, a D formulation at 3.8 lb ai/A. Both ground and aerial application data (from separate tests) must be submitted. A maximum permissible seasonal application rate or number of foliar applications per season must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to Agricultural Statistics (USDA).
- 37/ Data must be submitted depicting residues in wet and dry pomace, puree, catsup, and juice processed from tomatoes bearing measurable weathered residues. If residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.
- 38/ Data must be submitted depicting residues in/on cucumbers harvested 5 days after the last of several foliar applications made at 7-day intervals of a WP and, in separate tests, a D formulation at 3 lb ai/A. Both ground and aerial application data, from separate tests, must be submitted. A maximum permissible seasonal application rate or number of foliar applications/season must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to Agricultural Statistics (USDA).

Continued.

Attachment 4 (Continued).

- 39/ Data must be submitted depicting residues in/on melons (cantaloupes) harvested 5 days after the last of several foliar applications made at 7-day intervals of a WP and, in separate tests, a D formulation at 3.8 lb ai/A. Both ground and aerial application data, from separate tests, must be submitted. A maximum permissible seasonal application rate or number of foliar applications/season must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to the Census of Agriculture (U.S. Dept. of Commerce).
- 40/ Data must be submitted depicting residues in/on pumpkins harvested immediately after the last of several foliar applications made at 7-day intervals of a WP and, in separate tests, a D formulation at 3 lb ai/A. Both ground and aerial application data, from separate tests, must be submitted. A maximum permissible seasonal application rate or number of foliar applications/season must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to the Census of Agriculture (U.S. Dept. of Commerce).
- 41/ Data required for melons (cantaloupes) will be used to assess the established tolerance for residues in/on winter squash. [The commodity definition in the CFR should be changed from "Squash" to "Winter Squash".] All label revisions required for melons must be implemented for winter squash also.
- 42/ Data required for cucumbers will be used to assess the established tolerance for residues in/on summer squash. All label revisions required for cucumbers must be implemented for summer squash also.
- 43/ Data must be submitted depicting residues in/on oranges, grapefruit, and limes harvested immediately after the last of several foliar applications made at intervals to be specified by the Registrant using a WP formulation at 0.75 lb ai/100 gal to runoff. In addition, two foliar applications made 4 weeks apart must be applied in July/August at 1.5 lb ai/100 gal to runoff. The Registrant must propose a maximum permissible seasonal application rate or number of applications, and a minimum interval between applications for the lower foliar rate which must be reflected in the submitted data. Information regarding tree size and spacing, and the number of gallons/A applied must be provided for each test. Tests must be conducted in all major geographic production regions according to Agricultural Statistics (USDA).
- 44/ Data must be submitted depicting residues in/on dried pulp, oil, molasses and juice processed from oranges bearing measurable weathered residues. If residues are found to concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

Continued.

Attachment 4 (Continued).

- 45/ Data must be submitted depicting residues of concern in/on apples harvested 15 days after the last of several foliar applications made at intervals to be specified by the Registrant using a WP formulation at 1.6 lb ai/100 gal to runoff and 12 lb ai/A [maximum rate currently specified on label]. The Registrant must propose a maximum permissible seasonal application rate or number of applications and a minimum interval between applications which must be reflected by the submitted data. Information regarding tree size and spacing, and the number of gallons/A applied must be provided for each test. Tests must be conducted in IL, PA, and VA, major apple production states where the 15-day PHI is permitted. [In more major production states such as WA, NY, MI and CA, the PHI is 30 days.]
- 46/ Data must be submitted depicting residues in wet and dry pomace and juice processed from apples bearing measurable weathered residues. If residues are found to concentrate in any of these commodities, appropriate food/feed additive tolerances must be proposed.
- 47/ Data must be submitted depicting residues in/on pears harvested 7 days after the last of several foliar applications made at intervals to be specified by the Registrant using a WP formulation at 1 lb ai/100 gal to runoff. In addition, three foliar applications at 1.6 lb ai/100 gal to runoff must be applied at 10% bloom, full bloom, and at petal fall. The Registrant must propose a maximum permissible seasonal application rate or number of applications, and a minimum interval between applications for the lower foliar rate which must be reflected in the submitted data. Information regarding tree size and spacing and the number of gal/A applied must be provided for all tests. Tests must be conducted in all major geographic production regions according to Agricultural Statistics (USDA).
- 48/ The required data for peaches will be used to assess the established tolerance for residues in/on apricots.
- 49/ Data must be submitted depicting residues of concern in/on cherries (sweet and sour) harvested after two foliar applications of a WP formulation made at petal fall and 20 days after petal fall at 0.8 lb ai/100 gal [7.5 lb ai/A, the maximum rate specified on the label must be represented; i.e., 7.5 lb ai/940 gal/A]. Information regarding tree size and spacing, and the number of gal/A applied must be provided. Tests must be conducted in all major geographic production regions according to Agricultural Statistics (USDA). [It should be noted that this requirement assumes that the labels specify the last application to be made 20 days after petal fall, as stated in the EPA Index to Pesticide Chemicals for Zineb. Thus, the 7-day PHI is unnecessary. However, if additional applications are, in fact, permitted up to the 7-day PHI, data reflecting such use must be submitted.]

Continued.

Attachment 4 (Continued).

- 50/ The required data for peaches will be used to assess the established tolerance for residues in/on nectarines.
- 51/ Data must be submitted depicting residues in/on peaches harvested 30 days after the last of several foliar applications made at 7-day intervals using a WP formulation at 1.5 lb ai/100 gal to runoff. A maximum seasonal application rate or number of applications per season must be proposed and reflected in the submitted data. Information regarding tree size and spacing and the number of gal/A applied must be provided for each test. Tests must be conducted in all major geographic production regions according to Agricultural Statistics (USDA).
- 52/ Data must be submitted depicting residues in/on plums harvested 30 days after the last of several foliar applications made at 7-day intervals using a WP formulation at 1.5 lb ai/100 gal to runoff. A maximum seasonal application rate or number of applications per season must be proposed and reflected in the submitted data. Information regarding tree size and spacing, and the number of gal/A applied must be provided for each test. Tests must be conducted in all major geographic production regions according to Agricultural Statistics (USDA).
- 53/ Data must be submitted depicting residues in or on prunes dried from plums bearing measurable weathered residues. If residues are found to concentrate on drying, an appropriate food additive tolerance must be proposed.
- 54/ Data must be submitted depicting residues in/on blackberries harvested 14 days after the last of several foliar applications of a WP formulation made 10 days apart at 1.2 lb ai/A. Both ground and aerial application data (from separate tests) must be submitted. The 75% WP registrant(s) giving a label direction of 1.5 lb ai/100 gal must specify a maximum lb ai/A to be placed on the label. If this lb ai/A rate is higher than 1.2, residue data representing it's use, in lieu of that required above, must be submitted. A maximum seasonal application rate and/or number of applications per season must be proposed and supported by the submitted data. Tests must be conducted in all major geographic production regions according to the U.S. Census of Agriculture (U.S. Dept. of Commerce).
- 55/ The data required for blackberries will be used to assess the established tolerance for residues in/on boysenberries. All label revisions required for blackberries must be implemented for boysenberries also.
- 56/ Data must be submitted depicting residues in/on mature cranberries treated with a WP formulation at 6 lb ai/A in ground applications in 250 gal/A and, in separate tests, in aerial applications in 13 gal/A at 5% bloom and at midbloom. Tests must be conducted in all major geographic production regions according to the Census of Agriculture (U.S. Dept. of Commerce).

Continued.

Attachment 4 (Continued).

- 57/ Data must be submitted depicting residues in/on currants harvested 7 days after the last of several foliar applications of a WP formulation at a maximum lb ai/A rate to the proposed by the Registrant [the established maximum lb ai/100 gal rate of 1.6 may be maintained provided a maximum gal/A rate is specified]. Treatments must be made two and three weeks after bloom and at 10-day intervals thereafter. A maximum seasonal application rate or number of applications per season must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to the Census of Agriculture (U.S. Dept. of Commerce).
- 58/ The required data for currants will be used to assess the established tolerance for residues in/on gooseberries.
- 59/ Data must be submitted depicting residues in/on grapes treated with a D and, in separate tests, a WP formulation at 3 lb ai/A just before and just after bloom, 10 days after bloom, and 3 weeks later. Both ground and aerial application data must be submitted (from separate tests). Tests must be conducted in all major geographic production regions according to Agricultural Statistics (USDA). [It should be noted that this requirement assumes that the labels specify the last application to be made approximately 31 days after bloom, as stated in the EPA Index to Pesticide Chemicals for zineb. Thus, the 7-day PHI is unnecessary. However, if additional applications are, in fact, permitted up to the 7-day PHI, data reflecting such use must be submitted.]
- 60/ Data must be submitted depicting residues in/on raisins, wet and dry pomace, raisin waste and juice processed from grapes bearing measurable weathered residues. If residues are found to concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.
- 61/ The data required for blackberries will be used to assess the established tolerance for residues in/on raspberries. All label revisions required for blackberries must be implemented for raspberries also.
- 62/ Data must be submitted depicting residues in/on strawberries harvested 7 days after the last of several foliar applications of a WP formulation made 7 days apart at 2.6 lb ai/A. Both ground and aerial application data (from separate tests) must be submitted. The 75% WP registrant(s) giving a label direction of 1.5 lb ai/100 gal must specify a maximum lb ai/A to be placed on the label. If this lb ai/A rate is higher than 2.6, residue data representing its use, in lieu of that required above, must be submitted. A maximum seasonal application rate and/or number of applications per season must be proposed and supported by the submitted data. Tests must be conducted in all major geographic production regions according to Agricultural Statistics (USDA).

Continued.

Attachment 4 (Continued).

- 63/ Data must be submitted depicting residues in/on field corn grain harvested 40 days after the last of several foliar applications at 7-day intervals of a D formulation at 2.6 lb ai/A and, in separate tests, of a 75% WP at a lb ai/A rate to be proposed by the Registrant [the established maximum lb ai/100 gal rate of 1.5 for the 75% WP may be maintained provided a maximum gal/A rate is specified]. Both ground and aerial application data (from separate tests) must be submitted. If the proposed lb ai/A rate for the 75% WP is significantly lower than 2.6 lb ai/A, the WP tests need not be submitted. On the other hand, if the proposed rate is significantly higher than 2.6 lb ai/A, no D formulation tests need be submitted. A maximum seasonal application rate or number of applications per season must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to Agricultural Statistics (USDA).
- 64/ Data must be submitted depicting residues in starch and refined oils from wet milling; in grits, meal, flour, and crude and refined oil from dry milling; and in grain dust. These products must be prepared from field corn grain bearing measurable weathered residues. If residues concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.
- 65/ Data must be submitted depicting residues in/on sweet corn (kernels plus cob with husks removed) harvested immediately after the last of several foliar treatments made at 3-day intervals with a WP formulation at 3 lb ai/A. Both ground and aerial application data (from separate tests) must be submitted. A maximum lb ai/A rate must be proposed for the 75% WP label(s) [the established 1.5 lb ai/100 gal rate may be maintained provided a maximum gal/A rate is specified]. If the proposed lb ai/A rate is higher than 3, the tests required above must be conducted at the higher rate. A maximum permissible seasonal application rate or number of applications per season must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic regions according to Agricultural Statistics (USDA). Data must also be submitted and a tolerance proposed for residues in/on forage. Forage must be harvested immediately after the last treatment or at a pregrazing interval to be proposed by the Registrant. Alternatively, a grazing restriction may be imposed. If a grazing restriction is imposed, data depicting residues in cannery waste derived from sweet corn bearing measurable weathered residue must be submitted. If the concentration of residues in cannery waste is higher than in the sweet corn per se, an appropriate feed additive tolerance must be proposed.

Continued.

Attachment 4 (Continued).

- 66/ Data must be submitted depicting residues in/on wheat grain harvested 3 weeks after the last of several foliar applications made at 7-day intervals of, in separate tests, a WP formulation at 2.06 lb ai/3-6 gal/A using aerial equipment and a D formulation at 2.24 lb ai/A using ground equipment. A maximum permissible seasonal application rate or number of applications per season must be proposed and reflected in the submitted data. Tests must be conducted in all geographic production regions according to Agricultural Statistics (USDA). Data must also be submitted and tolerances proposed for residues in/on wheat forage, hay and straw. Forage must be harvested immediately after the last treatment or at a pregrazing interval to be proposed by the Registrant. Hay and straw must be harvested 3 weeks after the last treatment. Alternatively, grazing and feeding restrictions may be imposed.
- 67/ Data must be submitted depicting residues in bran, flour, middlings, shorts, and grain dust prepared from grain bearing measurable weathered residues. If residues concentrate in any of these products, appropriate food/feed additive tolerances must be proposed.
- 68/ Data must be submitted depicting residues in/on mature asparagus harvested the following season after a postharvest application of a WP/D formulation at 1.365 lb ai/A. Tests must be conducted in all major geographic production regions according to the Census of Agriculture (U.S. Dept. of Commerce). If measurable residues are detected, an appropriate tolerance must be proposed.
- 69/ Data must be submitted depicting residues in/on fresh hops harvested 14 days after the last of several foliar applications made at 5-day intervals of a WP formulation at 3 lb ai/A. The Registrant(s) for the 75% WP label(s) bearing directions for a 1.5 lb ai/100 gal rate must propose a maximum lb ai/A rate [the lb ai/100 gal rate may be maintained provided it is accompanied by a maximum gal/A rate]. If the proposed lb ai/A rate exceeds 3, the higher rate should be used in the tests required above. A maximum permissible seasonal application rate and/or number of applications/season must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions according to Agricultural Statistics (USDA).
- 70/ Data must be submitted depicting residues in dried and spent hops processed from fresh hops bearing measurable weathered residues. If residues are found to concentrate in these processed products, appropriate food/feed additive tolerances must be proposed.
- 71/ Data must be submitted depicting residues in/on commercial mushrooms treated with several soil applications of a D formulation beginning shortly after casing soil is applied and continuing at 3-day intervals thereafter until buttons begin to form at 0.15 lb ai/4000 sq. ft. of bed.

Continued.

Attachment 4 (Continued).

- 72/ Data must be submitted depicting residues in/on peanut nutmeats, hulls, and vines harvested immediately after the last of several foliar applications made at 7-day intervals of, in separate tests (i) a WP formulation applied by ground equipment at 1.125 lb ai/10-30 gal/A; (ii) a WP formulation applied by aerial equipment at 1.125 lb ai/5-10 gal/A; and (iii) a D formulation applied at 1.3 lb ai/A. A maximum seasonal application rate or number of applications per season must be proposed and reflected in the submitted data. Tests must be conducted in all major geographic production regions as specified in Agricultural Statistics (USDA). Separate tolerances must be proposed for residues in/on nutmeats, hulls, and vines. However, no vine data need be submitted or a tolerance for residues in/on vines proposed if the Registrant imposes a grazing restriction.
- 73/ Data must be submitted depicting residues in/on meal, crude and refined oil and soapstock processed from nutmeats bearing measurable weathered residues. If residues are found to concentrate in any of these products, an appropriate food/feed additive tolerance must be proposed.
- 74/ Data must be submitted depicting residues in/on green tobacco harvested immediately after the last of weekly foliar applications made from transplant to harvest with a D formulation at 4 lb ai/A. These field treatments must be preceded by plant bed foliar treatments beginning when plants are dime size and continuing at 3-day intervals until transplanting at 0.845 lb ai/100 sq. yd. If residues >0.1 ppm are detected, residues in or on cured or dried tobacco must be determined. If residues in/on cured or dried tobacco are >0.1 ppm, tobacco must be treated foliarly with [^{14}C -ethylene]zineb, cured or dried, and pyrolysis products derived from the ai characterized. Also, the level of residue in smoke must be quantified.
- 75/ To determine whether zineb seed treatment uses may be considered "non-food" uses, the following crops must be seed-treated with [^{14}C -ethylene]zineb formulated as a WP/D and all mature raw agricultural commodities (RACs) harvested from each crop and analyzed to determine whether uptake of ^{14}C -residues of concern from treated seed occurs: alfalfa (5.67 oz ai/ 100 lb seed), barley (0.525 oz ai/bushel), bluegrass (5.67 oz ai/100 lb seed), cotton (1.05 lb ai/100 lb acid delinted seed, 2.94 oz ai/100 lb machine delinted seed, and 1.47 oz ai/100 lb fuzzy seed), flax (1.26 oz ai/bu), sorghum (0.79 oz ai/bushel), soybeans (1.05 oz ai/bu), and sugar beets (4.2 oz ai/100 lb seed). The data required for alfalfa, soybeans, and barley will be used to assess seed treatment uses on clover, cowpeas, and oats, respectively. If uptake of residues of concern occurs, appropriate tolerances for residues in/on all RACs must be proposed.
- 76/ On receipt of the data required for animal metabolism and residues in feed items, appropriate feeding study requirements for ruminants and poultry will be determined.



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

1664

JUL 1 1987

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Meeting Held on 6/30/87 Between Representatives of
MicroFlo Co. and EPA, to Discuss DCI Requirements
for Zineb

FROM: Debra F. Edwards, Ph.D. *Debra Edwards*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

THRU: William J. Boodee, Supervisory Chemist *WJB*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: RCB Files
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

On 6/30/87, a meeting was held, at the request of the Registrant, to discuss the data call-in requirements for zineb. Participants are listed below:

<u>EPA</u>	<u>MicroFlo</u>
H. Jacoby (SIS/HED)	Keith L. Branley
G. Werdig (DCI/RD)	(MicroFlo Co.)
M. Kovacs (RCB/HED)	
E. Zager (RCB/HED)	Edwin Woolson
D. Edwards (RCB/HED)	(EPL Bio-Analytical Services)
W. Boodee (RCB/HED)	
S. Lewis (DCI/RD)	Milton Ganyard Jr.
J. Warshawsky (SRB/RD)	(Environmental Technologies International, Inc.)

The following residue chemistry issues were addressed:

1. Uses to be supported: The Registrant plans to support uses on citrus, apples, pears, cherries, peaches, plums, apricots, nectarines, cranberries, grapes, strawberries, radishes, potatoes, mushrooms, tomatoes, melons, ornamentals and turf. Susan Lewis informed the Registrant that all other uses must be deleted from the label.
2. Crops selected for field trials: The Registrant plans to conduct field trials on all of the crops listed above, except apricots and nectarines (data will be translated from peaches). Citrus trials will be conducted on grapefruit, oranges, and limes.

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3. Field trial sites: The Registrant requested guidance as to the requirements regarding field trial locations, number of trials/location and number of replications/trial. Bill Boodee recommended a minimum of three replications/trial and three trials/state for all crops. Ed Zager gave preliminary guidance regarding locations based on R. Perfetti's memo of 12/8/83. He clearly stated, however, that protocols should be submitted for formal Agency approval.
4. Geographic limitations for certain crops: The Registrant asked whether limited geographic field trial data could be submitted for strawberries, melons, tomatoes, and radishes if the label restricted use to the specific areas from which data were generated. EPA participants deferred comment but assured the Registrant that the Agency's policy on tolerances with regional registration would be routed to them via Susan Lewis as soon as possible [51 FR 63: 11341-11346 (4/2/86) and 51 FR 218:40988-40989 (11/12/86)].
5. Processing data: Ed Zager informed the Registrant that processing data (cooking, canning, etc.) are needed for apples, cranberries, potatoes, and tomatoes in addition to the data required in the DCI.
6. Metabolism in plants: The Registrant asked if it would be acceptable to conduct metabolism studies on radishes, tomatoes, and oranges, as representatives of the crop uses they plan to support. They also asked if it would be acceptable to conduct the metabolism studies indoors under controlled environmental conditions so that the trials could be started earlier. D. Edwards replied that indoor metabolism studies on these crops would be acceptable.
7. Whole fruit vs. peel and pulp analysis: The Registrant asked whether analyses of peel and pulp separately or whole fruit is desirable for metabolism and residue studies. Ed Zager replied that it would be best to present data in both ways.
8. Percent ¹⁴C accounted for in metabolism studies: The Registrant asked if, for example, it would be adequate to identify 92% of the ¹⁴C-residues in metabolism studies. M. Kovacs replied that this level of accountability is usually acceptable but a final conclusion will depend on the results of the metabolism study submitted.

9. Storage stability: The Registrant was advised by M. Kovacs that residue, processing, and feeding studies must be supported by storage stability data. For residue trials, a representative member of every major crop group on which use is to be supported must be subjected to storage stability tests. For the parent (zineb), storage stability data must be generated using both field-weathered and laboratory-fortified samples. For ethylenethiourea, only laboratory-fortification is required. The Registrant was referred to the DCI for additional guidance.
10. Protocols: The Registrant was strongly urged to submit protocols for expedited review prior to initiation of any metabolism or field trials.

TS-769C:RCB:Reviewer:D.Edwards:CM#2:RM:812:557-4353

cc:H. Jacoby (SIS/HED):G. Werdig (DCI/RD):M. Kovacs (RCB/HED):
E. Zager (RCB/HED):W. Boodee (RCB/HED):S. Lewis (DCI/RD):
J. Warshawsky (SRB/RD): Registration Standards File:
Reading File: Reviewer: Circu

RDI:Section Head:W.Boodee:7/87:R.Schmitt:7/87