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

MAY - 4 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#9F3743. Clethodim (SELECT®) in or on Soybeans, Cottonseed, and Animal Commodities.
Amendment of 2/5/90.
DEB#: **6412** HED#: 0-0783 MRID#: 413823-00, -01; 413899-01 thru -03

FROM: Maxie Jo Nelson, Ph.D., Chemist
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division (H7509C)

mjn

THRU: Richard D. Schmitt, Ph.D., Chief
Dietary Exposure Branch
Health Effects Division (H7509C)

Richard D Schmitt

TO: J. Miller/M. Erumsele, PM Team 23
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Toxicology Branch - HFA Support
Health Effects Division (H7509C)

BACKGROUND

This amendment is the petitioner's (Valent U.S.A. Corporation) response (**MRID# 413823-00**) to comments contained in DEB's memorandum (M. Nelson) of 10/25/89, regarding residue analytical methods (**MRID# 413899-01, -02**) and reference standards (**MRID# 413823-00**).

In addition, this amendment provides frozen storage stability data for residues of clethodim and two representative metabolites in cattle tissues and milk (**MRID# 413899-03**) and chicken tissues and eggs (**MRID# 413823-01**). The need for these data were two of the deficiencies identified by DEB in its review (M. Nelson) of 3/12/90 (see Conclusions 12 and 13).

SUMMARY OF DEFICIENCIES REMAINING TO BE RESOLVED FOR DEB
(See Conclusions this review and 3/12/90 review)

- **Address Product Chemistry deficiencies.**
- **Resubmit the compound-specific Confirmatory Procedure, revised in accordance with our requests (including an interference study and independent laboratory validation).**
- **Submit a quantity of the internal standard (cloproxydim sulfoxide) to the Pesticides Repository, RTP-NC.**
- **Run Method Validation Trial(s) by ACB/BEAD.**
- **Submit Multiresidue Test Data via FDA Protocol B. [Note: May be deferred until a future petition.]**
- **Submit freezer storage stability studies for soybean processing fractions and cottonseed processing fractions.**
- **Submit a revised Section F incorporating the following additions/changes: soybean soapstock @ 15 ppm; cottonseed @ 1.0 ppm; cottonseed meal @ 2.0 ppm; and, eggs @ 0.2 ppm.**

CONCLUSIONS

1. DEB has requested BEAD conduct a PMV trial of the revised version (Analytical Method RM-26B-1; MRID# 413899-01) of the proposed primary enforcement method ("common moiety"). DEB defers further judgment on the adequacy of this method pending receipt/review of BEAD's PMV report.

2. Representative analytical reference standards are available for PMV testing of RM-26B-1, and for use in the enforcement of the proposed tolerances. Samples of these standards are now obtainable from the Pesticides and Industrial Chemicals Repository, RTP-NC.

3. The "compound-specific" confirmatory procedure, RM-26C-1, is not adequate, as written. Various revisions, additions, an interference study, and an independent laboratory validation study are required; see body of this review, under **"DEB Conclusion(s) re Comment #4"**, for details.

4. A quantity of the internal standard, cloproxydim sulfoxide (reference grade), along with appropriate supporting documentation, should be submitted to the U.S. EPA Pesticides and Industrial Chemicals Repository, U.S. EPA Environmental Research Center, Research Triangle Park, NC, 27711.

5. Contingent upon the satisfactory resolution of analytical methods issues, DEB concludes that total clethodim residues are stable in cattle tissues (liver, kidney, fat, muscle) and milk stored frozen (-20°C) for up to 5 months.

   Subject to the favorable removal of this contingency, DEB can also consider Conclusions 12 and 18 of its 3/12/90 review to be resolved.

6. Contingent upon the satisfactory resolution of analytical methods issues, DEB concludes that total clethodim residues are stable in poultry tissues (liver, gizzard, fat, muscle) and eggs stored frozen (-20°C) for up to 2 months.

   Subject to the favorable removal of this contingency, DEB can also consider Conclusion 13 of its 3/12/90 review, this petition, to be resolved; re Conclusion 19, a revised Section F remains outstanding.

RECOMMENDATIONS

DEB recommends **against** the establishment of the proposed tolerances for combined residues of the herbicide clethodim and its metabolites containing the 2-cyclohexen-1-one moiety in or on the commodities of this petition for the reasons stated in Conclusions 1, 3, and 4, above, **AND** in the Recommendations section of our 3/12/90 review, which see.

Attention is also drawn to the contingencies in Conclusions 5 and 6, vide supra.

DETAILED CONSIDERATIONS

RESPONSE TO DEB MEMORANDUM OF 10/25/89

DEB COMMENT #1: DEB requested the petitioner submit a revised write-up of the proposed enforcement method (RM-26A-1, MRID# 410301-41) for determining residues of clethodim and its metabolites in plant and animal commodity matrices. The revision was to incorporate directions for analysis of animal products and a more specific title. It was also recommended the method be examined and revised (as needed) to provide detailed instructions for an analyst, using the sethoxydim enforcement method found in PAM II, §180.412, as a model.

Valent Response to Comment #1: A revised analytical method addressing the Agency's recommendations is submitted:

"The Determination of Clethodim Residues in Crops, Chicken and Beef Tissues, Milk, and Eggs." Method RM-26-B-1 (supersedes version RM-26A-1). 1/30/90. **(MRID# 413899-01)**

DEB Conclusion(s) re Comment #1: A petition method validation (PMV) trial of RM-26B-1 has now been requested (M. Nelson, 4/16/90 memo) of BEAD. DEB defers further judgment on the adequacy of RM-26B-1 pending receipt/review of BEAD's PMV report.

DEB COMMENT #2: DEB requested a complete list of the analytical reference standards available for clethodim, its metabolites, and derivatives.

Valent Response to Comment #2: The requested information is submitted **(MRID# 413823-00)**:

Standard	Code
Clethodim	RE-45601
Clethodim sulfoxide	RE-45924
5-OH clethodim sulfone	RE-51228
S-methyl clethodim sulfoxide	RE-47506
Dimethylester (DME) sulfone	RE-50525
DME-OH sulfone	RE-50562
S-methyl DME sulfone	RE-52243

DEB Conclusion(s) re Comment #2: Representative analytical reference standards are available for PMV testing of RM-26B-1, and for enforcement of the proposed tolerances via RM-26B-1.

DEB COMMENT #3: DEB requested quantities of each analytical reference standard (identified in #2 above), and accompanying documentation, be shipped to the Pesticides and Industrial Chemicals Repository, RTP-NC.

Valent Response to Comment #3: Reference standards and material safety data sheets (MSDS) have been sent to RTP-NC, as requested.

DEB Conclusion(s) re Comment #3: DEB has confirmed (FTS 629-3951) that RTP-NC has received a supply of the analytical reference standards (identified in #2 above), with an accompanying MSDS for each.

DEB COMMENT #4: DEB requested an estimated date of submission for the compound-specific confirmatory analytical procedure being developed for residues derived from clethodim.

Valent Response to Comment #4: A compound-specific confirmatory method is submitted:

> "Confirmatory Method for Determination of Clethodim Metabolites in Crops." Method RM-26C-1. 1/26/90. **(MRID# 413899-02)**

DEB Conclusion(s) re Comment #4: This method, as written and submitted, is not adequate for its intended purpose. The petitioner needs to:

a. Replace diazomethane with a safer derivatizing agent. (If that is not possible, documentation/data supporting the necessity for using diazomethane must be provided; see Attachment 1, "Use of diazomethane in analytical methods.") Revise method write-up accordingly.

b. Revise title to include clethodim per se: "... Determination of Clethodim and Clethodim Metabolites ...."

c. Expand matrices of applicability to include animal commodities (cattle tissues and milk; poultry tissues and eggs). Revise title and write-up accordingly.

d. Provide validation (recovery) data for animal commodity matrices, and representative HPLC chromatograms.

e. Provide information/data from an **interference study** run in the matrices beef liver, milk, and soybeans, to show the behavior (HPLC separation and relative retention times) of sethoxydim and representative sethoxydim metabolites, both alone and in combination with clethodim and representative clethodim metabolites. The internal standard (cloproxydim sulfoxide) should be included in all instances. Levels of fortification should be appropriate to the tolerance levels (requested and/or established) for those matrices. Revise the write-up of the confirmatory procedure to incorporate the findings of the interference study.

f. Provide information/data from an **independent laboratory** validation trial; see Attachment 2, PR Notice 88-5.

The petitioner is also requested to generally scrutinize the level of detail provided to the analyst for the running of the confirmatory procedure, and to provide additional (more specific) details and information, as needed.

Lastly, the petitioner is requested to send a quantity of the internal standard, cloproxydim sulfoxide (reference grade), along with appropriate supporting documentation, to the U.S. EPA Pesticides and Industrial Chemicals Repository, U.S. EPA Environmental Research Center, Research Triangle Park, North Carolina, 27711.

FROZEN STORAGE STABILITY STUDIES WITH ANIMAL COMMODITIES

Valent U.S.A. Corporation has now submitted the following two studies:

(1) **"Storage Stability of S-Methyl Clethodim Sulfoxide, Clethodim, and 5-OH Clethodim Sulfone in Bovine Milk and Tissues"**, Analytical Development Corporation, Lab Project ID# ADC1124SSA, 12/13/89, 43 pp. **(MRID# 413899-03)**

Background: This study is a supplement to the "Cow Feeding Study: Determination of Residues of Clethodim in Bovine Tissues and Milk", 1/9/89, Lab Project ID# ADC1124, MRID# 410302-22. That feeding study was discussed by DEB (M. Nelson) in its 3/12/90 review, this petition, which see.

Conclusion 12 of that 3/12/90 review cites as a data deficiency the need for the petitioner to demonstrate via a freezer storage stability study that total clethodim residues (DME + DME-OH + S-MeDME) are stable in bovine tissues (liver, muscle, kidney, and fat) and milk stored frozen (-20°C) for up to 3¼ months.

Discussion: Bovine tissue (fat, kidney, liver, and muscle) and milk samples were fortified with clethodim (**C**), 5-OH clethodim sulfone (**5OH-SO_2**), and S-methyl clethodim sulfoxide (**SMSO**) at a level of 0.05 ppm each in milk and 0.25 ppm each in tissues.

Spiked samples and controls were maintained under frozen storage (≤20°C) for a period of 0-5 months prior to analysis in duplicate for total clethodim residues (DME + 5-OH DME + S-MeDME) by a modified version of RM-26A (adapted for milk and cattle tissues).

Recovery results from those fortified samples are summarized in the Table below.

No significant decline in recoveries of **C**, **5OH-SO_2**, or **SMSO** was observed in milk or cattle tissue matrices (liver, kidney, fat, and muscle) during the 5-month frozen storage period.

Control values were reported as <0.0125 ppm of **C**, **SMSO**, or **5OH-SO_2** in milk, and <0.05 ppm each in tissues, at all intervals.

Contingent upon the satisfactory resolution of analytical methods issues, DEB concludes that total clethodim residues are stable in cattle tissues (liver, kidney, fat, muscle) and milk stored frozen (-20°C) for up to 5 months.

Subject to the favorable removal of this contingency, DEB can also consider Conclusions 12 and 18 of its 3/12/90 review, this petition, to be resolved.

STORAGE STABILITY IN CATTLE MILK AND TISSUES

Matrix	Month	Spike (ppm)	SMSO Recovery (%) Range	SMSO Avg.	C Recovery (%) Range	C Avg.	5OH-SO_2 Recovery (%) Range	5OH-SO_2 Avg.
Milk	0	0.05	92,98	95	91,94	92	109,117	113
	1	"	88	88	80	80	102	102
	2	"	C O N T A M I N A T E D				S A M P L E S	
	3	"	84,89	86	79,83	81	90,95	92
	4	"	78,92	85	74,80	77	91,107	99
	5	"	72,114	93	70,94	82	80,116	98
Fat	0	0.25	83,85	84	79,79	79	99,107	103
	1	"	93,96	94	82,83	82	101,106	104
	2	"	78,82	80	71,82	76	82,82	82
	3	"	75,82	78	75,77	76	83,88	86
	4	"	89,92	90	80,83	82	98,100	99
	5	"	85,97	91	78,90	84	89,104	96
Kidney	0	0.25	77,90	84	77,88	82	94,113	104
	1	"	82,85	84	80,84	82	98,98	98
	2	"	67,74	70	69,71	70	81,81	81
	3	"	83,87	85	78,81	80	85,88	86
	4	"	79,84	82	79,84	82	95,95	95
	5	"	86,93	90	80,82	81	86,91	88
Liver	0	0.25	78,78	78	70,70	70	72,79	76
	1	"	70,70	70	69,71	70	80,97	88
	2	"	75,81	78	65,71	68	79,84	82
	3	"	77,87	82	68,76	72	91,103	97
	4	"	75,95	85	75,90	82	93,113	103
	5	"	74,87	80	72,82	77	85,89	87
Muscle	0	0.25	88,88	88	80,80	80	91,98	94
	1	"	89,90	90	73,76	74	94,100	97
	2	"	86,92	89	76,80	78	92,97	94
	3	"	86,106	96	74,94	84	103,111	107
	4	"	90,92	91	78,79	78	103,110	106
	5	"	95,99	97	76	76	98,98	98

(2) **"Storage Stability of Clethodim Residues in Frozen Chicken Eggs and Tissue"**, EPL-Analytical Services, Inc., Lab Project ID# 129-003, 3/6/89, 46 pp. **(MRID# 413823-01)**

Background: This study is a supplement to the "Clethodim (5%) and Clethodim Sulfoxide (95%): Meat and Egg Residue Study in White Leghorn Chickens", 12/29/88, Lab Project ID# 88 EM 9, MRID# 410302-21. That feeding study was discussed by DEB (M. Nelson) in its 3/12/90 review, this petition, which see.

Conclusion 13 of that 3/12/90 review cites as a data deficiency the need for the petitioner to demonstrate via a freezer storage stability study that total clethodim residues (DME + DME-OH + S-MeDME) are stable in poultry tissues (liver, muscle, gizzard, and fat) and eggs stored frozen (-20°C) for up to 2 months.

Discussion: Poultry tissue (fat, gizzard, liver, and muscle) and egg samples were fortified with clethodim (**C**), 5-OH clethodim sulfone (**5OH-SO_2**), and S-methyl clethodim sulfoxide (**SMSO**) at a level of 1 or 2 ppm each in eggs and 1 ppm each in tissues.

Spiked samples and controls were maintained under frozen storage (≤20°C) for a period of 0-8 weeks prior to analysis in triplicate for total clethodim residues (DME + 5-OH DME + S-MeDME) by a modified version of RM-26A (adapted for egg and poultry tissues).

Recovery results from those fortified samples are summarized in the Table below.

FROZEN STORAGE STABILITY IN CHICKEN EGGS AND TISSUES

			SMSO		C		5OH-SO_2	
		Spike	Recovery (%)		Recovery (%)		Recovery (%)	
Matrix	Week	(ppm)	Range	Avg.	Range	Avg.	Range	Avg.
Egg	0	1	65-77	71	69-83	76	75-90	83
	4	1	71-85	78	78-92	85	75-84	79
	8	2	78-80	79	83-85	84	83-89	86
Fat	0	1	69-77	72	68-83	75	69-88	79
	3	1	69-76	72	72-79	75	80-89	84
	6	1	66-71	68	74-78	76	71-76	74
Gizzard	0	1	70-77	74	76-84	80	81-85	83
	3	1	67-75	72	70-78	75	77-82	79
	6	1	70-77	74	77-85	81	70-74	72
Liver	0	1	76-78	77	82-84	83	83-84	84
	3	1	76-80	78	80-83	82	81-85	83
	6	1	67-77	72	71-85	79	69-76	72
Muscle	0	1	63-70	67	68-75	71	70-77	73
	3	1	66-70	68	70-74	72	72-76	74
	6	1	66-75	70	74-82	77	54-73	64

No appreciable decline in recoveries of **C**, **5OH-SO_2**, or **SMSO** was observed in eggs or poultry tissue matrices (fat, gizzard, liver, and muscle) during the 6-8 week frozen storage period.

Control values were reported as ND-0.07 ppm; the limit of detection is 0.05 ppm each for **C**, **SMSO**, or **50H-SO_2** in eggs and poultry tissues.

Contingent upon the satisfactory resolution of analytical methods issues, DEB concludes that total clethodim residues are stable in poultry tissues (liver, gizzard, fat, muscle) and eggs stored frozen (-20°C) for up to 2 months.

Subject to the favorable removal of this contingency, DEB can also consider Conclusion 13 of its 3/12/90 review, this petition, to be resolved; re Conclusion 19, a revised Section F remains outstanding.

OTHER CONSIDERATIONS

Several other data deficiencies remain outstanding for this petition; see listing and discussions in DEB's review of 3/12/90.

ATTACHMENTS:

1. DEB Memorandum, "Use of **diazomethane** in analytical methods", 2/15/89.

2. PR Notice 88-5, "Tolerance Enforcement Methods - Independent Laboratory Confirmation by Petitioner", 7/15/88.

cc (with attachments):

M. Nelson, Reading File, Circulation (7), PP#9F3743, Clethodim Registration Standard File, Clethodim Subject File, R. Schmitt, PIB/FOD (C Furlow).

H7509C:DEB:Reviewer(MJN):CM#2:Rm810:557-7484:typist(mjn):
CLET3743.RC2:5/1/90.

RDI:SecHd:RSQuick:5/2/90:BrSrScientist:RALoranger:5/2/90.

Attachment 1

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

FEB 15 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Use of **diazomethane** in analytical methods.

FROM: Richard D. Schmitt, PhD, Acting Chief
Dietary Exposure Branch
Health Effects Division (TS-769C)

Richard D Schmitt

TO: Dietary Exposure Branch Staff

The methylating agent diazomethane is carcinogenic and explosive. For these reasons the Beltsville laboratory has requested that we attempt to reduce its use in analytical methods as much as possible. Therefore, if any method is received which uses diazomethane, it should be returned to the petitioner with a request to find a safer methylating agent. If they can not find an alternative, documentation should be provided supporting the need for diazomethane. This procedure should ensure that this agent will be used only when absolutely necessary and reduce exposure to EPA chemists and enforcement personnel.

The Beltsville lab has pointed out that the above approach has been successful in reducing use of benzene (another carcinogen) in analytical methods. We should continue to discourage use of this solvent and other hazardous reagents so that safe enforcement methods are developed.

cc:Reading File
TS-769:DEB:CM#2:Room 810:Date:2/13/89

RCB

Attachment 2

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

JUL 15 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

PR NOTICE 88-5

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Federal Registration of Pesticides or Submission of Petitions for Tolerance or Exemption from Tolerance for Pesticides

SUBJECT: TOLERANCE ENFORCEMENT METHODS - INDEPENDENT LABORATORY CONFIRMATION BY PETITIONER

This notice is to inform all petitioners for pesticide tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA) of submission requirements for pesticide analytical methods. A petition involving new analytical methods for determining pesticide residues in agricultural commodities or processed foods must include results of a successful confirmatory method trial by an independent laboratory. A petition received by the Agency after August 1, 1989, which does not include this information will be considered incomplete and will be returned to the petitioner without further review.

I. BACKGROUND

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires the registration of all pesticides. Additionally, if a proposed use of a pesticide may result in residues in or on agricultural commodities or processed foods, a tolerance (or exemption from tolerance) is required under the FFDCA. A person seeking a tolerance must petition the Agency to establish the tolerance.

EPA regulations in 40 CFR 158.240, 180.7 and 180.34 require petitioners for pesticide tolerances to furnish adequate analytical methods to determine the total toxic residue for pesticides in agricultural commodities, and as appropriate, in processed foods. The total toxic residue includes the parent pesticide and its degradation products, metabolites (free or bound), and impurities which are of toxicological concern. These methods enable EPA to establish tolerances after determining the maximum pesticide residues which could be consumed by humans. The analytical methods are subsequently used by the Food and Drug Administration, U.S. Department of Agriculture and individual States for tolerance enforcement. Guidance on analytical methods is provided in the Pesticide Assessment Guidelines (Subdivision O, Reference 171-4). EPA's review of pesticide petitions

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for tolerances includes validation of new methods in EPA laboratories to ensure their suitability as enforcement methods. An enforcement method must be reproducible and suitable for use in Federal and state laboratories throughout the country. Moreover, sufficient information must be submitted about the analytical method to permit a competent analyst to apply it successfully.

Currently, the EPA validations are often confounded by poorly written and incomplete descriptions of the analytical procedures. In addition, the proposed enforcement method may not include determination of metabolites of toxicological concern. This creates delays in evaluating petitions and unnecessarily ties up Agency laboratory resources while the methods are rewritten and consultations occur between EPA chemists and the method developers. The Agency intends to reduce delays in petition review and conserve resources by requiring submission of results of independent, confirmatory trials as part of the pesticide petition. Petitioners are advised to consult with the Agency regarding the need for methods for pesticide metabolites.

II. DISCUSSION

A. Confirmatory Trial Required to Accompany Petitions for Tolerance

Results of confirmatory trials of new analytical methods are required for the parent pesticide including metabolites of toxicological concern and must accompany the following types of petitions:

1. The first tolerance petition for residues of a pesticide in a raw agricultural commodity or processed food.

2. Any new tolerance petition for residues of a pesticide with previously established tolerances if a new method is proposed for enforcement.

3. Any new tolerance for residues of a pesticide with previously established tolerances if the previously approved enforcement method has been significantly modified to accommodate the new commodity. If the registrant is uncertain whether a method change is "significant," the Agency should be contacted.

B. Confirmatory Trial must be Conducted by Independent Laboratory

The laboratory chosen to conduct the confirmatory trial must be unfamiliar with the method, both in its development and in its subsequent use in analyzing field samples. Provided this criterion is met, the laboratory chosen to conduct the confirmatory trial may be in the petitioner's organization. Other possibilities include laboratories at state enforcement agencies, at universities, or private laboratories. The petitioner should apply the same criteria of quality in selecting a laboratory for a confirmatory trial as he would for any analytical work. The laboratory

selected by the registrant must follow generally accepted good laboratory practices. A guidance document setting out good laboratory practices for residue chemistry studies is available from the contact person listed in Section IV.

C. Requirements for Confirmatory Trial

A successful confirmatory trial will require adequate results on at least one set of samples, and the laboratory conducting the confirmatory trial will be allowed to run up to three sets of samples using the method. A set consists of two control samples, two control samples fortified at the proposed tolerance, and two control samples fortified at 2-5 times the tolerance level. The method must be run as written with no modifications.

The laboratory conducting the confirmatory trial may not contact the developers or previous users of the method prior to running the first set of samples. If the first (or second) set is not successful, and the laboratory requires contact with the developers or other users of the method, this communication should be recorded. Any subsequent additions or modifications to the original method should be incorporated into the method write-up that is sent to the EPA for validation.

If tolerances for several pesticides are proposed, and one method is to be used for several commodities, the confirmatory trial should be carried out on that commodity the petitioner has had the most difficulty analyzing. The rationale for selection of the commodity should be provided. If, after three sets of samples, the confirmatory trial has failed to produce adequate results (see below), the petitioner must revise the method and run a second confirmatory trial using a different laboratory.

For a successful confirmatory trial, the results on one set of samples, after conducting no more than three sets, must be similar to those achieved by the petitioner. Recovery rates should be 70-120% and interference should be negligible compared to the proposed tolerance level.

D. Information to be Reported to the Agency

If the confirmatory trial is successful, the following should be submitted by the petitioner:

1. Address and contact person for confirmatory laboratory
2. Description of the analytical method
3. Recovery and control values
4. Representative chromatograms
5. Description of the instruments used
6. Description of any problems encountered

7. Any steps considered critical, i.e., steps where little variation is allowable or directions must be precisely followed

8. The number of person-hours required to complete one set of samples

9. The number of calendar days required for one set of samples.

10. Any contact between the confirmatory laboratory and the method developers or others familiar with the method, including the reasons for the contact, any changes in the method that resulted, and the time of this communication with respect to the progress of the confirmatory trial (i.e. after the first set, during the second set, etc).

E. The Agency will Continue to Conduct Method Validation

If the Agency determines that the petitioner has submitted results of a successful confirmatory trial by an independent laboratory, the method will be validated by Agency chemists. A petition that is not accompanied by results of a successful confirmatory trial will be returned to the petitioner.

III. Effective Date

All petitions received by the Agency after August 1, 1989, must include the results of an independent laboratory confirmatory trial.

IV. For Further Information

Persons wishing further information on this notice, a copy of the Agency's "Standard Evaluation Procedures for Petition Method Validation," or the Agency's guidance document on good laboratory practices for residue chemistry studies may contact:

Dallas P. Wright, Jr.
U.S. Environmental Protection Agency
Analytical Chemistry Laboratory
Building 306, Room 113 - ARC-East
Beltsville, Md. 20705.

Telephone number: (301) 344-1225

Edwin F. Tinsworth, Director
Registration Division