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

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

June 25, 1996

MEMORANDUM:

SUBJECT: **5F4440/5H5713**. Clethodim in/on Alfalfa, Dry Beans, and Peanuts. Evaluation of Residue Data and Analytical Methodology. MRID#'s 438489-00, 434482-01, 434482-02, 434482-03, 438489-01, 434717-02, 434717-03.

DP Code: D210424, D210427, D221693
Case #: 286167, 286168
Chem #: 121011
Caswell: 721F

Trade Name: Select® 2 EC and Select® 0.94 EC
Reg #: 59639-3 and 59639-78
40 CFR: §180.458
Class: Herbicide

FROM: José J. Morales, Chemist
Pilot Interdisciplinary Risk Assessment Team
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

José J. Morales 6/25/96

THROUGH: Michael Metzger, Acting Chief
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

Michael L. Metzger

TO: Joanne I. Miller/Dan Kenny, PM 23
Fungicide-Herbicide Branch
Registration Division (7505C)

Valent U.S.A. is requesting the establishment of tolerances for the combined residues of the herbicide clethodim [(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as clethodim) in/on alfalfa forage at 10 ppm; alfalfa hay at 15 ppm; dry bean seeds at 2 ppm; dry bean forage at 5 ppm; dry bean straw and hay at 7 ppm; peanut nutmeat at 3 ppm; peanut hulls at 2 ppm; and peanut hay at 5 ppm.

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Permanent tolerances were established for the combined residues of the herbicide clethodim and its metabolites containing the 2-cyclohexen-1-one moiety under 40 CFR §180.458 for the fat, meat, and mbyp of cattle, goats, hogs, horses, poultry, and sheep at 0.20 ppm; milk at 0.05 ppm; eggs at 0.20 ppm; cottonseed at 1.0 ppm; and soybeans at 10.0 ppm.

Feed additive tolerances were established for the combined residues of the herbicide clethodim and its metabolites containing the 2-cyclohexen-1-one moiety under 40 CFR §186.1075 for cottonseed meal at 2.0 ppm; and soybean soapstock at 15.0 ppm.

CONCLUSIONS

1. The manufacturing process of technical grade clethodim has been adequately described. We do not foresee any residue problems from impurities in the technical.

2a. PIRAT concludes that the nature of the residue in plants is adequately understood for the purposes of the subject petition. Studies have been conducted in a root crop (carrots) and two oilseeds (soybean and cotton). The residue of concern is clethodim and its metabolites containing the 2-cyclohexen-1-one moiety. However, the petitioner should be reminded that for future petitions on crops other than root crops, legumes, or oil seeds additional metabolism data should be provided on a crop such as a leafy vegetable, or fruit crop. Until there are plant metabolism data for clethodim on at least 3 widely different representative commodities; e.g., tree nut, leafy vegetable, small grain, legume, root/tuber crop, oil seed, etc., which reflect a similar metabolism profile, PIRAT can not conclude that the nature of the residue is understood in all plants.

2b. PIRAT concludes that the nature of the residue in ruminants and poultry is adequately understood for the purposes of the subject petition. The residue of concern is clethodim and its metabolites containing the 2-cyclohexen-1-one moiety.

3a. Analytical methods are available for enforcement. Method EPA-RM-26D-2, "Confirmatory Method for the Determination of Clethodim and Clethodim Metabolites in Crops, Animal Tissues, and Milk and Eggs", which distinguishes clethodim residues from residues of the structurally similar herbicide Poast®, and method RM-26B-2 ,"Analytical Method for the Determination of Clethodim Residues", the common moiety method, have undergone successful EPA Method Validation.

3b. The submitted chromatographic data showed high apparent residues in control samples, erratic recovery values, and problems in the cleanup steps of the method. Therefore, PIRAT has requested the Analytical Chemistry Branch to pre-review, without method validation, the enclosed above methods for clethodim determination in/on alfalfa, peanuts, and dry beans. Attached is the ACB pre-trial review of the analytical methods (E. Greer's memo of 4/3/96). The registrant should refer to this review for guidance on revisions needed in the analytical method. These revisions are not iterated here in the interest of brevity.

3c. Also, we note that some of the deficiencies cited in the ACB review of 4/3/96, apply to PP#4F4340 [clethodim in/on sugar beets and onions (dry bulb)]; and PP#5F4572/5H5729 (clethodim in/on tomatoes). The petitioner should make sure that the suggested changes in the ACB review also incorporate the above crops.

4. Adequate recoveries of clethodim, clethodim sulfoxide, and 5-OH clethodim sulfone have been obtained under FDA's multiresidue protocols (PP#9F3743, M. Nelson's memo of 3/12/90).

5. PIRAT concludes that adequate geographical representation of the residue data has been submitted for the proposed use on alfalfa.

6. PIRAT cannot make any conclusion on the storage stability of total clethodim residues in frozen alfalfa macerates until the petitioner submits information on the fortification levels used in the submitted storage stability studies.

7. The maximum residues in alfalfa forage and hay were 5.7 ppm and 9.2 ppm respectively. The petitioner is proposing a 10 ppm tolerance for alfalfa forage and 15 ppm for alfalfa hay. Based on the residue data above, PIRAT considers a 6 ppm tolerance on alfalfa forage and 10 ppm tolerance on alfalfa hay to be more appropriate. The petitioner needs to submit a revised Section F proposing tolerances for residues of clethodim [(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, expressed as clethodim, in or on the following raw agricultural commodities at the indicated levels:

Alfalfa, forage	6.0 ppm
Alfalfa, Hay	10 ppm

8. PIRAT cannot draw any conclusion on the adequacy of the proposed tolerances on peanut hay and nutmeat at this time. Based on the 6/2/94 Field Trial Document, a total of 12 field trial sites are required for the registration of a chemical in/on peanuts. The document indicates that of the 12 field trials, 8 should be conducted in region 2. Based on the fact that only 4 studies conducted in this region were submitted by the petitioner, that the highest residue values found were in these field trials, and that substantial translocation of residues occurred in peanut nutmeat, PIRAT cannot recommend for a permanent tolerance at this time.

Also, the maximum residues in peanut nutmeat and hay were 2.7 ppm (highest single sample) and 2.6 ppm respectively. The concentration factor for peanut meal was 3X. The HAFT for peanut nutmeat is 1.75 ppm and the dilution factor for peanut meal as a not ready-to-eat feed item is 3. The petitioner is proposing a 3 ppm tolerance for peanut nutmeat, a 5 ppm tolerance for peanut hay, and a 10 ppm tolerance for peanut meal. Based on the residue data above, PIRAT considers a 3 ppm tolerance on peanut hay and a Section 701 MRL of 5 ppm on peanut meal to be more appropriate. The petitioner needs to submit a revised Section F proposing tolerances for residues of clethodim [(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, expressed as clethodim, in or on the following raw agricultural commodities at the indicated levels:

Peanut, Hay	3 ppm
Peanut, Meal	5 ppm (Section 701 MRL)

Also, the proposed tolerance for peanut hulls should be deleted from the Section F as they are no longer considered a significant livestock feed item.

However, pending submission of 4 field trials in region 2, conducted at the maximum use rate and proposed PHI, and a revised Section F, PIRAT can recommend for the establishment of Time Limited Tolerances for residues of clethodim in/on peanut nutmeat at 3 ppm, peanut hay at 3 ppm, and peanut meal at 5 ppm (Section 701 MRL).

9. PIRAT cannot make any conclusion on the storage stability of total clethodim residues in frozen dry bean seed macerates until the petitioner submits information on the fortification levels used in the submitted storage stability studies.

10. PIRAT cannot draw any conclusion on the adequacy of the proposed tolerance on dry bean seeds at this time. Based on the 6/2/94 Field Trial Document, a total of 12 field trial sites are required for the registration of a chemical in/on dry beans. The document indicates that of the 12 field trials, 5 should be conducted in region 5. Based on the fact that only 2 studies conducted in this region were submitted by the petitioner, and that significant residue values found were in the submitted field trials, PIRAT cannot recommend for a permanent tolerance at this time. Also, dry bean hay/straw and dry bean vines are no longer considered significant livestock feed items. Therefore, the PHI for dry bean hay/straw and dry bean vines should be deleted from the label. A revised Section B should be submitted reflecting this deletion. A revised Section F proposing tolerances for dry bean seeds only should be submitted by the petitioner. The tolerances for dry bean forage and straw/hay should be deleted from the Section F.

However, pending submission of 3 field trials in region 5, conducted at the maximum use rate and proposed PHI, a revised Section B and Section F, PIRAT can recommend for the establishment of Time Limited Tolerances for residues of clethodim in/on dry bean seeds at 2 ppm.

11. We expect no increase in the dietary burden of ruminants and poultry as a result of this use. Therefore, PIRAT anticipates that any secondary residues that might result in milk, eggs, and meat, fat, and mbyp of cattle, goats, hogs, horses, poultry, and sheep would be covered by the established tolerances on these commodities.

12. Due to the fact that the applications were made to bare soil in the submitted confined rotational crop study, and that this is a postemergence herbicide applied in part to weeds, PIRAT concludes that residues in rotated crops under actual use conditions are going to be lower than the ones in the confined study. Therefore, there is no need for limited crop field trials. However, due to the fact that there may be residues of concern close to or at the trigger value of 0.01 ppm, a rotational crop restriction of 1 month for crops rotated with alfalfa should be added to the label. A revised Section B is needed.

13. An International Residue Limits (IRL) Status Sheet is attached (see attachment 2). There are no Canadian, or Mexican tolerances for clethodim on alfalfa, peanuts, and dry beans. A Codex tolerance of 0.1 ppm on dry beans exists. As shown above, the highest residue values found on dry bean seeds was 1.6 ppm. Therefore, a compatibility problem exists.

However, once the deficiencies associated with this petition are resolved, PIRAT recommends that the petitioner consider submitting the petition information which supports the tolerance to Codex once the United States tolerance is approved.

RECOMMENDATION

Pending submission of revised Sections B and F as detailed in Conclusions 7, 8, 10, and 12, PIRAT can recommend for a **Time Limited Tolerance** with expiration date of 3 years for residues of clethodim in/on alfalfa forage at 6 ppm; alfalfa hay at 10 ppm; peanut nutmeat at 3 ppm; peanut hay at 3 ppm; peanut meal at 5 ppm (701 MRL); and dry bean seeds at 2 ppm. For a **Permanent Tolerance** recommendation, the registrant must resolve the deficiencies cited in Conclusions 3b, 3c, 6, 8, 9, and 10. Peanut meal Maximum Residue Limit (MRL) need to be established under Section 701 of the FFDCA. RD should contact OGC with regard to procedures for setting 701 MRL's.

NOTE TO THE PM: A DRES run has been initiated using the above values for alfalfa, dry beans, and peanuts.

DETAILED CONSIDERATIONS

PRODUCT CHEMISTRY

The manufacturing process for clethodim was submitted in support of PP#9F3743 (MRID#'s 409745-01 thru -05) and discussed in M. Nelson's memo of 3/12/90. There are no toxicological concerns for any of clethodim impurities.

PIRAT concludes that the manufacturing process of technical grade clethodim has been adequately described. We do not foresee any residue problems from impurities in the technical.

PROPOSED USE

Two registered formulations of clethodim are proposed for use: Select® 2 EC and Select® Herbicide. Select® 2 EC Herbicide (EPA Reg. No. 59639-3) is an emulsifiable concentrate containing 25% of ai and 75% of inerts. This formulation contains 2 pounds of ai per gallon. Select® Herbicide (EPA Reg. No. 59639-78) contains 12.6% of ai and 87.4% of inerts. The formulation contains 0.94 pounds of ai per gallon.

The registrant proposes use of Select® 2 EC herbicide for postemergence control of annual and perennial grasses in alfalfa (not grown for seed), dry beans, and peanuts. To control annual grasses apply Select® 2 EC at the rate of 4 fl. ozs./A (0.064 lbs. ai/A) to 16 fl. ozs./A (0.25 lbs. ai/A) by ground application in a minimum of 5 gallons and a maximum of 40 gallons of spray solution per acre. Air application should be made in a minimum of 3 gallons of spray solution per acre. Increase spray volume up to 10 gallons as grass or crop foliage becomes dense. To control perennial grasses apply at the rate of 6 fl. ozs./A (0.096

lbs. ai/A) to 16 fl. ozs./A (0.25 lbs. ai/A) by ground application in a minimum of 5 gallons and a maximum of 40 gallons of spray solution per acre. Air application should be made in a minimum of 3 gallons of spray solution per acre. Increase spray volume up to 10 gallons as grass or crop foliage becomes dense. Apply only to actively growing grasses. Always use a crop oil concentrate containing at least 15% emulsifier at 1% v/v to the finished spray volume. Make second application to actively growing grass 2 to 3 weeks after emergence of new growth. The registrant also proposes a spot application treatment using Select® 2 EC and a crop oil concentrate at a 1:2 ratio (fl. oz:fl. oz). The PHI for alfalfa is 15 days. The PHI for dry bean vines is 15 days and for dry bean seeds and hay/straw is 30 days. The PHI for peanuts is 40 days. Do not exceed a total of 32 fl. ozs./A (0.50 lbs. ai/A) of Select® 2 EC herbicide per season.

The registrant proposes use of Select® herbicide for postemergence control of annual and perennial grasses in alfalfa (not grown for seed), dry beans, and peanuts. To control annual grasses apply Select® at the rate of 8 fl. ozs./A (0.06 lbs. ai/A) to 34 fl. ozs./A (0.25 lbs. ai/A) by ground application in a minimum of 5 gallons and a maximum of 40 gallons of spray solution per acre. Air application should be made in a minimum of 3 gallons of spray solution per acre. Increase spray volume up to 10 gallons as grass or crop foliage becomes dense. To control perennial grasses apply at the rate of 13 fl. ozs./A (0.09 lbs. ai/A) to 34 fl. ozs./A (0.25 lbs. ai/A) by ground application in a minimum of 5 gallons and a maximum of 40 gallons of spray solution per acre. Air application should be made in a minimum of 3 gallons of spray solution per acre. Increase spray volume up to 10 gallons as grass or crop foliage becomes dense. Apply only to actively growing grasses. Always use a crop oil concentrate containing at least 15% emulsifier at 1% v/v to the finished spray volume. Make second application to actively growing grass 2 to 3 weeks after emergence of new growth. The registrant also proposes a spot application treatment using Select® and a crop oil concentrate at a 1:2 ratio (fl. oz:fl. oz). The PHI for alfalfa is 15 days. The PHI for dry bean vines is 15 days and for dry bean seeds and hay/straw is 30 days. The PHI for peanuts is 40 days. Do not exceed a total of 68 fl. ozs./A (0.50 lbs. ai/A) of Select® herbicide per season.

NATURE OF THE RESIDUE

No new metabolism studies were submitted for clethodim.

Plants

A metabolism study in carrots, soybeans, and cotton was submitted with PP#9F3743 (MRID#410301-37) and discussed in M. Nelson's memo of 3/12/90. Immature plants of carrots, soybeans, and cotton were treated twice at a 14-day interval with a 50:50 tautomeric mixture of ring [6-^{14}C]-clethodim at a rate equivalent to 0.25 lbs. ai/A as a postemergence foliar spray; grown to maturity in a greenhouse; and, harvested with preharvest intervals of 20, 30, and 70 days. The major metabolic pathways of clethodim (C) in plant were initial

sulfoxidation to clethodim sulfoxide (CSO) followed by further oxidation to clethodim sulfone (CSO_2), elimination of the chloroallyloxy side chain to give the imine sulfoxide (ISO) and sulfone (ISO_2), and hydroxylation to form the 5-OH sulfoxide (5OH-SO) and sulfone (5OH-SO_2). Clethodim sulfoxide and clethodim sulfone conjugates were also detected as major or minor metabolites, depending on plant species and subfractions. Also present as a minor metabolite was the aromatic sulfone. A study designed to follow the fate of the chloroallyloxy group was done side-by-side with the ^{14}C-ring-labeled clethodim study discussed above. The results showed that the chloroallyloxy moiety cleaved from clethodim underwent extensive metabolism, eliminating the chlorine atom and incorporating the three carbon moieties into natural plant components (with some being evolved as $^{14}CO_2$).

PIRAT concludes that the nature of the residue in plants is adequately understood for the purposes of the subject petition. Studies have been conducted in a root crop (carrots) and two oilseeds (soybean and cotton). The residue of concern is clethodim and its metabolites containing the 2-cyclohexen-1-one moiety. However, the petitioner should be reminded that for future petitions on crops other than root crops, legumes, or oil seeds additional metabolism data should be provided on a crop such as a leafy vegetable, or fruit crop. Until there are plant metabolism data for clethodim on at least 3 widely different representative commodities; eg, tree nut, leafy vegetable, small grain, legume, root/tuber crop, oil seed, etc., which reflect a similar metabolism profile, PIRAT can not conclude that the nature of the residue is understood in all plants.

Animals

Ruminants

A metabolism study in goats was submitted with PP#9F3743 (MRID#410301-39) and discussed in M. Nelson's memo of 3/12/90. Following a one day acclimation period, a lactating goat (39 kg) was dosed with 1.16 mg/kg/day of [propyl-1-^{14}C]-clethodim in gelatin capsules for 4 consecutive days, receiving 3 equal daily doses (14.2 mg/dose) for 3 days and 1 dose (14.2 mg) on the morning of day 4. A control goat received the same number of empty gelatin capsules. Both animals were sacrificed within 4 hours after the final dose. The dominant metabolic process in ruminants (goat) is oxidation of clethodim to clethodim sulfoxide and, to a lesser extent, clethodim sulfone. Clethodim can also be converted to S-methyl, which can be oxidized to S-methyl sulfoxide and S-methyl sulfone. Cleavage of the oxime N-O bond in clethodim produces the imine, which is rapidly oxidized to imine sulfoxide. In a minor process, clethodim can be hydroxylated to 5-OH, which can be oxidized to 5-OH sulfoxide. Alternately, clethodim sulfoxide may be hydroxylated to 5-OH sulfoxide (S-methyl is formed only from clethodim; the literature does not support the formation of S-methyl sulfoxide from clethodim sulfoxide. Thus, the S-methyl metabolites have significance only if animals are exposed to clethodim and this is limited because clethodim is rapidly oxidized to sulfoxides and sulfones in plants).

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PIRAT concludes that the nature of the residue in ruminants is adequately understood for the purposes of the subject petition. The residue of concern is clethodim and its metabolites containing the 2-cyclohexen-1-one moiety.

Poultry

A metabolism study laying hens was submitted with PP#9F3743 (MRID#410301-40) and discussed in M. Nelson's memo of 3/12/90. Young laying hens were assigned to one of two test groups (8 hens each) or the control group (12 hens). Following a 12-day acclimation period, each hen in the test groups received an oral dose of a 50:50 tautomeric mixture of ring [6-^{14}C]-clethodim:[4-^{14}C]-clethodim (either 2.1 mg/kg/day or 51.3 mg/kg/day) contained in a gelatin gel capsule filled with commercial poultry feed, once daily for 5 consecutive days. Controls received gelatin capsules containing only poultry feed. Clethodim metabolism in hens was not as complex as in goats. The chicken tissues and eggs contained only clethodim (C), clethodim sulfoxide (CSO), and clethodim sulfone (CSO_2). None of the imine analogs, 5-hydroxy analogs, or S-methyl analogs which were identified in the goat were seen in the chicken.

PIRAT concludes that the nature of the residue in poultry is adequately understood for the purposes of the subject petition. The residue of concern is clethodim and its metabolites containing the 2-cyclohexen-1-one moiety.

ANALYTICAL METHODOLOGY

The analytical method used to gather the magnitude of the total clethodim residue data on alfalfa, dry beans, and peanuts was Chevron Chemical Method RM-26B-1, "Analytical Method for the Determination of Clethodim Residues". This method is one of 2 methods recommended to enforce the clethodim tolerances. The registrant has revised this method at CBTS's request and designated the revision as Method RM-26B-2 (MRID#413899-01). This revised method has successfully completed a Petition Method Validation (PMV) in EPA Laboratories (M. Nelson's memo of 5/4/90). Briefly, the method involves extraction with aqueous methanol, cleanup by alkaline precipitation and acidic back extraction, oxidation to the pentanedioic acid moieties, derivatization to the corresponding dimethyl esters (DME and/or DME-OH), partition of the dimethyl esters in CH_2Cl_2, and determination by GC-FPD-S. The total residue is expressed as clethodim equivalents. The limit of quantitation is 0.10 ppm. The minimum detection limit for residues measured as the dimethyl esters is 0.01 ppm for milk; 0.05 ppm for other animal commodities including eggs; and 0.05 ppm for crops.

The second method recommended to enforce clethodim tolerances is the compound specific residue analytical method, EPA-RM-26D-2, "Confirmatory Method for the Determination of Clethodim and Clethodim Metabolites in Crops, Animal Tissues, and Milk and Eggs" (MRID#429245-02). This method distinguishes clethodim residues from residues of the structurally similar herbicide Poast®, which contains sethoxydim as the active ingredient. The registrant has revised and rewritten this compound specific method as ACB has suggested and has included additional modifications from current method development. This method has successfully completed a Petition Method Validation (PMV) in EPA Laboratories (F. Griffith's memo of 9/29/93). In summary, a 50 gram sample is extracted with 150-200 ml of methanol/water (1/4, v/v), filtered through Whatman # 42 paper, and precipitated with 2 grams of calcium hydroxide. The solution is partitioned 3 X 100 mL CH_2Cl_2, dried through a bed of anh. Na_2SO_4, and rotary evaporated to just dry. The derivatized solution is base washed with 10 mL of 0.1N NaOH, then methylated with CH_2N_2 with silica gel catalysis before it is oxidized with 2 mL of a 10% solution of m-chloroperbenzoic acid. The solution is quenched with 10% sodium thiosulfate, washed with sat. sodium bicarbonate solution, dried through anh. sodium sulfate, and concentrated with a rotary evaporator. Clean-up is through a 10 gram silica-gel column with the clethodim metabolites eluted off in 200 mL of acetone:methylene chloride (3/7, v/v). Determination is by HPLC using a Hewlett-Packard, model 1090 HPLC, equipped with a Hypersil ODS, 3 um, 15 cm X 4.6 mm column. The mobile phase is a water-ACN gradient at a flow rate of 1 ml per min. The detector is UV at 266 mn with 254 mn as the alternate wavelength. The petitioner's data show the limit of quantitation (LOQ) is 0.05 ppm for crops and tissues, and 0.02 ppm for milk. Quantification is by external standards. The minimum detection limit (MDL) is 0.03 ppm for crops and 0.01 ppm for milk. This method has been shown to be suitable to be a quantitative procedure to enforce the total clethodim tolerances in crops and animal tissues. The method is a qualitative confirmatory method for total clethodim tolerances in milk. However, this method is not quantitative for milk and is not suitable for enforcing the total clethodim tolerance in milk. The common moiety method, RM-26B-2, is quantitative for milk and is the enforcement method for milk (F. Griffith's memo of 9/29/93).

As noted in F. Griffith's memo of 11/16/92, company generated method validation data are required for any new total clethodim tolerance (s) on all matrices; ie, the rac (s), food and/or feed processed commodities, and if appropriate for meat, milk, poultry, and eggs, on which tolerances are proposed. These company generated validation data are necessary for both the common moiety method and the compound specific method. Therefore, in support of the subject tolerance petition, the petitioner submitted the following reports:

> "Determination of Clethodim Residues in Alfalfa Commodities by the Confirmatory Method, EPA-RM-26D-2"; 10/13/94; J. C. Lai; Laboratory Project ID: VP10269; Performing Laboratory was Valent U.S.A. Corporation, Valent Dublin Laboratory, Dublin, CA (MRID# 434482-01).

"Determination of Clethodim Residues in Dry Bean Commodities by the Confirmatory Method, EPA-RM-26D-2"; 10/13/94; J. C. Lai; Laboratory Project ID: VP10905; Performing Laboratory was Valent U.S.A. Corporation, Valent Dublin Laboratory, Dublin, CA (MRID# 434482-02).

"Determination of Clethodim Residues in Peanut Commodities by the Confirmatory Method, EPA-RM-26D-2"; 10/11/94; J. C. Lai; Laboratory Project ID: VP10697; Performing Laboratory was Valent U.S.A. Corporation, Valent Dublin Laboratory, Dublin, CA (MRID# 434482-03).

The submitted chromatographic data showed high apparent residues in control samples, erratic recovery values, and problems in the cleanup steps of the method. Therefore, PIRAT has requested the Analytical Chemistry Branch to pre-review, without method validation, the enclosed above methods for clethodim determination in/on alfalfa, peanuts, and dry beans. Attached is the ACB pre-trial review of the analytical methods (E. Greer's memo of 4/3/96). The registrant should refer to this review for guidance on revisions needed in the analytical method. These revisions are not iterated here in the interest of brevity.

Also, we note that some of the deficiencies cited in the ACB review of 4/3/96, apply to PP#4F4340 [clethodim in/on sugar beets and onions (dry bulb)]; and PP#5F4572/5H5729 (clethodim in/on tomatoes). The petitioner should make sure that the suggested changes in the ACB review also incorporate the above crops.

MULTIRESIDUE TESTING

The petitioner has determined recoveries of clethodim, clethodim sulfoxide, and 5-OH clethodim sulfone under FDA's multiresidue protocols (PP#9F3743, M. Nelson's memo of 3/12/90).

RESIDUE DATA

Alfalfa

Residue data reflecting the application of clethodim to alfalfa appear in the following report:

> "Magnitude of Clethodim Residues in Alfalfa Raw Agricultural Commodities and Processed Parts"; J. C. Lai; 11/2/95; Laboratory Project ID No. TSR5072AL; Performing Laboratory was Chevron Chemical Corporation, Agricultural Chemicals Division, Richmond, CA (MRID# 438489-01).

Twelve field trials on alfalfa were conducted, eight in 1989 and four in 1990. The 1989 field trials were conducted in CA (1), IA (1), MI (1), MN (1), NE (1), ND (1), SD (1), and WI (1). The 1990 field trials were conducted in CA (1), WI (1), NY (1), and ID (1). The formulation used for the 1989 trials was Select® 2 EC herbicide; for the 1990 trials the formulation used was Select® 0.94 EC. In all trials, one application per cutting for two or three consecutive cuttings of alfalfa were made, using ground equipment and aerial equipment, at the rate of 0.25 lbs. ai/A with PHI's ranging from 15 to 20 days. Duplicate samples of treated alfalfa forage were collected from each trial and were immediately frozen. Hay samples were allowed to dry one to ten days before collection and freezing. For the determination of residue carryover from applications to previous cuttings of alfalfa, duplicate samples from a third cutting were collected 43 to 68 days after the last application in seven trials. Duplicate samples from a fourth cutting were also collected 71 to 76 days after the last application in one trial. After collection, samples were frozen and shipped to Chevron Chemical Company, Agricultural Chemicals Division, Richmond, CA.

PIRAT concludes that adequate geographical representation of the residue data has been submitted for the proposed use on alfalfa.

A freezer storage stability study was conducted using frozen (-20°C) alfalfa macerates. No information was provided for the fortification levels used. Reanalysis of these samples at intervals ranging from 0 to 16 months resulted in clethodim recoveries (as total residue of DME and DME-OH) which ranged from 75% to 93% for alfalfa forage. For alfalfa hay, reanalysis of the samples at intervals ranging from 0 to 16 months resulted in clethodim recoveries (as total residue of DME and DME-OH) which ranged from 84% to 141%. Alfalfa samples were analyzed for total clethodim residues up to 14 months after sampling. Maximum interval between extraction and analyses was 8 days.

PIRAT cannot make any conclusion on the storage stability of total clethodim residues in frozen alfalfa macerates until the petitioner submits information on the fortification levels used in the submitted storage stability studies.

Recovery data were obtained from untreated samples of alfalfa forage, analyzed concurrently with the field trial samples, fortified with clethodim at the level of 0.05 ppm to 5.0 ppm. Overall recoveries of 60% to 154% were obtained. Recovery data for 5-OH clethodim sulfone at fortification levels of 0.05 ppm to 5.0 ppm ranged from 66% to 158%. Recovery data for hay samples, analyzed concurrently with the field trial samples, fortified with clethodim at the levels of 0.05 ppm to 2.0 ppm ranged from 76% to 204%. Recovery data for 5-OH clethodim sulfone at fortification levels of 0.05 ppm to 2.0 ppm ranged from 66% to 248%.

Table I summarizes the amount of residues on alfalfa forage resulting from 1 or 2 applications of clethodim at the rate of 0.25 lbs. ai/A.

Table I. Clethodim Residues on Alfalfa Forage

Field Trial Location	No. of Applications	Formulation	Days After Last Application	Total Clethodim Equivalents (ppm)
MN	1	2 EC	21	1.4, 1.5
	2	2 EC	20	0.50, 0.55
	2	2 EC	61	<0.10
NE	1	2 EC	20	0.77, 0.87
	1	2 EC	57	<0.10
	2	2 EC	20	0.61, 0.63
	3	2 EC	20	0.31, 0.35
	3	2 EC	61	<0.10
MI	1	2 EC	20	1.1
	2	2 EC	20	1.6
	2	2 EC	63	<0.10
SD	1	2 EC	20	1.1, 1.2
	2	2 EC	20	0.96, 0.98
	2	2 EC	67	<0.10
ND	1	2 EC	15	1.4, 1.2

Field Trial Location	No. of Applications	Formulation	Days After Last Application	Total Clethodim Equivalents (ppm)
	2	2 EC	15	5.0, 5.7
	1	2 EC	19	0.90, 1.3
	2	2 EC	21	1.1, 1.3
WI	1	2 EC	15	2.8, 3.0
	2	2 EC	15	1.7, 2.3
	2	2 EC	44	<0.20
IA	1	2 EC	15	1.4, 1.5
	2	2 EC	17	1.1, 1.2
	2	2 EC	63	<0.20
CA	1	2 EC	15	1.3, 1.5
	2	2 EC	15	0.59, 0.81
	2	2 EC	43	<0.20
	2	2 EC	71	<0.10
WI	1	0.94 EC	15	1.3, 1.4
	2	0.94 EC	15	0.88, 0.86
NY	1	0.94 EC	15	2.5, 2.6
	2	0.94 EC	15	1.7, 2.1
CA	1	0.94 EC	15	0.25, 0.29
	2	0.94 EC	15	0.13, 0.19
ID	1	0.94 EC	15	1.8, 2.1
	2	0.94 EC	15	2.8, 3.2

Table II summarizes the amount of residues on alfalfa hay resulting from 1 or 2 applications of clethodim at the rate of 0.25 lbs. ai/A.

Table II. Clethodim Residues on Alfalfa Hay

Field Trial Location	No. of Applications	Formulation	Days After Last Application[1]	Total Clethodim Equivalents (ppm)
MN	1	2 EC	21+4	2.4, 3.2
	2	2 EC	20+7	1.0, 1.1
	2	2 EC	61+6	<0.10, 0.14
NE	1	2 EC	20+3	1.8, 2.3
	1	2 EC	57+4	<0.10, 0.40
	2	2 EC	20+2	1.2, 1.4
	3	2 EC	20+2	0.47, 0.56
	3	2 EC	61+6	<0.10, 0.16
MI	1	2 EC	20+3	2.6
	2	2 EC	20+3	3.0, 3.4
	2	2 EC	63+3	<0.10
SD	1	2 EC	20+2	3.1, 3.4
	2	2 EC	20+1	1.4, 1.6
	2	2 EC	67+3	<0.10
ND	1	2 EC	15+8	2.3
	2	2 EC	15+10	2.1, 3.7
	1	2 EC	19+8	1.7, 2.2
	2	2 EC	21+10	1.2, 1.4
WI	1	2 EC	15+4	3.8, 4.0
	2	2 EC	15+4	1.7, 2.0

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Field Trial Location	No. of Applications	Formulation	Days After Last Application[1]	Total Clethodim Equivalents (ppm)
	2	2 EC	44+5	<0.20
IA	1	2 EC	15+2	2.2, 3.1
	2	2 EC	17+2	1.7, 2.2
	2	2 EC	63+3	<0.20
CA	1	2 EC	15+6	4.3, 4.4
	2	2 EC	15+2	2.4, 2.8
	2	2 EC	43+5	<0.10, 0.13
	2	2 EC	71+5	0.36, 0.64
WI	1	0.94 EC	15+6	2.7
	2	0.94 EC	15+5	1.5, 1.8
NY	1	0.94 EC	15+3	3.2, 3.5
	2	0.94 EC	15+2	4.4, 4.5
CA	1	0.94 EC	15+3	0.45, 0.76
	2	0.94 EC	15+6	0.47, 0.58
ID	1	0.94 EC	15+5	4.6, 5.6
	2	0.94 EC	15+6	8.6, 9.2

1. Drying time is included.

In another trial, hay was allowed to field dry for an additional 6 to 10 days (below 10% moisture) to simulate meal. The maximum residue found was 6.1 ppm. According to the new Table II (11/3/95) residue data on alfalfa meal are not needed.

As can be seen from Tables I and II the maximum residues in alfalfa forage and hay were 5.7 ppm and 9.2 ppm respectively. The petitioner is proposing a 10 ppm tolerance for alfalfa forage and 15 ppm for alfalfa hay. Based on the residue data above, PIRAT considers a 6 ppm tolerance on alfalfa forage and 10 ppm tolerance on alfalfa hay to be more appropriate. The petitioner needs to submit a revised Section F proposing tolerances for residues of clethodim [(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, expressed as clethodim, in or on the following raw agricultural commodities at the indicated levels:

Alfalfa, forage	6.0 ppm
Alfalfa, Hay	10 ppm

Peanuts

Residue data reflecting the application of clethodim to peanuts appear in the following report:

> "Magnitude of Clethodim Residues in Peanuts Raw Agricultural Commodities and Processed Parts"; J. C. Lai; 8/30/94; Laboratory Project ID No. V1028; Performing Laboratory was Valent, U.S.A. Corporation, Dublin, CA (MRID# 434717-03).

Eight field trials on peanuts were conducted, five in 1989 and three in 1992. The 1989 field trials were conducted in AL (1), GA (2), NC (1), and TX (1). The 1992 field trials were conducted in GA (1), TX (1), and FL (1). The formulation used for the 1989 trials was Select® 2 EC herbicide; for the 1990 trials the formulation used was Select® 0.94 EC. In all trials, two applications at 14 day intervals, were made at the rate of 0.25 lbs. ai/A using ground equipment. The PHI was 40 days. After drying, hay samples were collected and frozen. Peanut samples were shelled and after shelling, the nutmeats and hulls were frozen. Duplicate samples of treated peanut commodities were collected for each trial. Upon collection, all samples were frozen until shipped to the Valent Dublin Laboratory.

A freezer storage stability study was conducted using frozen (-20°C) peanut nutmeat and hay macerates. Samples were fortified with 0.50 ppm clethodim and clethodim standard solutions. Reanalysis of peanut nutmeat and hay samples at intervals ranging from 0 to 13 months resulted in clethodim recoveries (as total residue of DME and DME-OH) which ranged from 97% to 117% for peanut nutmeat. For peanut hay, reanalysis of the samples at intervals ranging from 0 to 13 months resulted in clethodim recoveries (as total residue of DME and DME-OH) which ranged from 86% to 102%. Peanut samples were analyzed for total clethodim residues up to 14 months after sampling. Maximum interval between extraction and analyses was 5 days.

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Recovery data were obtained from untreated samples of peanut nutmeat and hay, analyzed concurrently with the field trial samples, fortified with clethodim and clethodim sulfoxide at the level of 0.05 ppm to 1.0 ppm. Overall recoveries of 64% to 134% were obtained for peanut nutmeat. Recovery data for 5-OH clethodim sulfone at fortification levels of 0.05 ppm to 1.0 ppm ranged from 84% to 122%. Recovery data for hay samples, analyzed concurrently with the field trial samples, fortified with clethodim and clethodim sulfoxide at the levels of 0.05 ppm to 1.0 ppm ranged from 63% to 96%. Recovery data for 5-OH clethodim sulfone at fortification levels of 0.05 ppm to 1.0 ppm ranged from 79% to 102%.

Residue data were sent for peanut hulls, and vines. According to the new Table II (11/3/95) residue data on these commodities are not needed; therefore, it would not be discussed in this review.

Table III summarizes the amount of residues on peanut nutmeat resulting from 2 applications of clethodim at the rate of 0.25 lbs. ai/A.

Table III. Clethodim Residues on Peanut Nutmeat

Field Trial Location	Formulation	PHI[1]	Total Clethodim Equivalents (ppm)
NC	2 EC	40+11	0.47, 1.3
GA	2 EC	40+8	0.15, 2.7
TX	2 EC	35+3	<0.05, <0.05
AL	2 EC	40+7	0.35, 1.7
GA	2 EC	40+3	1.7, 1.8
GA	0.94 EC	41+7	0.33, 0.35
TX	0.94 EC	40+9	0.52, 0.60
FL	0.94 EC	40+4	0.76, 0.82

1. Drying time is included.

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Table IV summarizes the amount of residues on peanut hay resulting from 2 applications of clethodim at the rate of 0.25 lbs. ai/A.

Table IV. Clethodim Residues on Peanut Hay

Field Trial Location	Formulation	PHI[1]	Total Clethodim Equivalents (ppm)
NC	2 EC	40+9	2.5, 2.6
GA	2 EC	40+8	0.36, 0.43
TX	2 EC	35+3	1.7, 1.9
AL	2 EC	40+6	0.36, 0.38
GA	2 EC	40+3	1.9, 2.2
GA	0.94 EC	41+7	0.22, 0.23
TX	0.94 EC	40+5	0.58, 0.71
FL	0.94 EC	40+4	0.42, 0.43

1. Drying time is included.

For the processing studies, peanut nutmeat were treated with two applications of Select® 2 EC at the rate of 1.25 lbs. ai/A (5X). Samples were collected 40+3 days after the last application. The procedure used to calculate the concentration factors reflects the revised CBTS policy for determining the need for Section 409 Tolerances and 701 MRLs (memo dated 7/17/95). Briefly, instead of using the Section 408 tolerance for calculating the residue level in processed commodities (in other words, the concentration factor multiplied by the rac tolerance), the highest average field trial ("HAFT") value will be used. This "HAFT" value will be multiplied by the concentration factor or average concentration factor (if there is more than one processing study) to obtain the residue level in the processed commodity.

Results are shown in Table V.

Table V. Clethodim Residues in Peanut Processed Commodities

Commodity	Total Clethodim Found (ppm)	Concentration Factor
Peanut Nutmeat	3.5	--
Peanut Meal	9.6	3X
Peanut Crude Oil	1.7	0.5X
Peanut Refined Oil	0.32	0.1X
Soapstock	10	3X

Peanut meal is considered a not-ready to eat commodity. Therefore, in order to determine whether a 701 MRL or a 409 tolerance will be needed, the following procedure was used:

a) Determination of the HAFT: the field trial with the highest residue value was used. Inspection of Table III above shows the following values: 1.7 ppm, 1.8 ppm, The HAFT is determined by averaging these values. The HAFT value is 1.75 ppm.

b) The average concentration factor is multiplied by the HAFT. For peanut meal:

1.75 ppm x 3.0 = 5.25 ppm

c) Since the residue in paste and puree exceed the rac tolerance of 1 ppm, these will be divided by a dilution factor to determine the residue level in the ready-to eat food:

for peanut meal: 5.25/3 = 1.75 ppm

The dilution factor was obtained from the text: Feeds and Nutrition, 1978. Basically, the protein content in peanut meal was compared with the amount of protein generally found in finished feed.

d) Since the residues in the ready-to eat foods do not appreciably exceed the rac tolerance of 3.0 ppm, Section 701 MRL will be needed for peanut meal.

PIRAT cannot draw any conclusion on the adequacy of the proposed tolerances on peanut hay and nutmeat at this time. Based on the 6/2/94 Field Trial Document, a total of 12 field trial sites are required for the registration of a chemical in/on peanuts. The document indicates that of the 12 field trials, 8 should be conducted in region 2. Based on the fact that only 4 studies conducted in this region were submitted by the petitioner, that the highest residue values found were in these field trials, and that substantial translocation of residues occurred in peanut nutmeat, PIRAT cannot recommend for a permanent tolerance at this time.

Also, as can be seen from Tables III and IV the maximum residues in peanut nutmeat and hay were 2.7 ppm (highest single sample) and 2.6 ppm respectively. As can be seen from Table V, the concentration factor for peanut meal was 3X. The HAFT for peanut nutmeat is 1.75 ppm and the dilution factor is for peanut meal as a not ready-to-eat feed item is 3. The petitioner is proposing a 3 ppm tolerance for peanut nutmeat, a 5 ppm tolerance for peanut hay, and a 10 ppm tolerance on peanut meal. Based on the residue data above, PIRAT considers a 3 ppm tolerance on peanut hay and a Section 701 MRL of 5 ppm on peanut meal to be more appropriate. The petitioner needs to submit a revised Section F proposing tolerances for residues of clethodim [(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, expressed as clethodim, in or on the following raw agricultural commodities at the indicated levels:

Peanut, Hay	3 ppm
Peanut, Meal	5 ppm (Section 701 MRL)

Also, the proposed tolerance for peanut hulls should be deleted from the revised Section F as they are no longer considered a significant livestock feed item.

However, pending submission of 4 field trials in region 2, conducted at the maximum use rate and proposed PHI, and a revised Section F, PIRAT can recommend for the establishment of Time Limited Tolerances for residues of clethodim in/on peanut nutmeat at 3 ppm, peanut hay at 3 ppm, and peanut meal at 5 ppm (Section 701 MRL).

Dry Beans

Residue data reflecting the application of clethodim to dry beans appear in the following report:

> "Magnitude of Clethodim Residues in Dry Beans Agricultural Commodities and Processed Parts"; J. C. Lai; 9/30/94; Laboratory Project ID No. V10270; Performing Laboratory was Valent, U.S.A. Corporation, Dublin, CA (MRID# 434717-02).

Nine field trials on dry beans were conducted, five in 1992 and four in 1993. The 1992 field trials were conducted in CA (1), CO (2), MI (1), NE (1) and ND (1). The 1993 field trials were conducted in CA (1), ID (1), MI (1) and ND (1). The formulation used for the 1992 trials was Select® 0.94 EC herbicide; for the 1993 trials the formulation used was Select® 2 EC. In all trials, two applications at 15 day intervals, were made at the rate of 0.25 lbs. ai/A using ground equipment. The PHI was 30 days. Dry bean plants were cut, mowed or pulled at 30 days after the last application and allowed to dry before threshing. After threshing, seed samples were collected and frozen. Duplicate samples of treated bean seeds were collected for each trial. Upon collection, all samples were frozen until shipped to the Valent Dublin Laboratory.

A freezer storage stability study was conducted using frozen (-20°C) dry bean seed macerates. No information was provided for the fortification levels used. Reanalysis of these samples at intervals ranging from 0 to 21 months resulted in clethodim recoveries (as total residue of DME and DME-OH) which ranged from 81% to 119%. Dry bean samples were analyzed for total clethodim residues up to 3 months after sampling. Maximum interval between extraction and analyses was 5 days.

PIRAT cannot make any conclusion on the storage stability of total clethodim residues in frozen dry bean seed macerates until the petitioner submits information on the fortification levels used in the submitted storage stability studies.

Recovery data were obtained from untreated samples of dry bean seeds, analyzed concurrently with the field trial samples, fortified with clethodim and clethodim sulfoxide at the level of 0.10 ppm to 1.0 ppm. Overall recoveries of 65% to 108% were obtained. Recovery data for 5-OH clethodim sulfone at fortification levels of 0.20 ppm to 1.0 ppm ranged from 80% to 110%.

Table VI summarizes the amount of residues on dry bean seeds resulting from 2 applications of clethodim at the rate of 0.25 lbs. ai/A.

Table VI. Clethodim Residues on Dry Bean Seeds

Field Trial Location	Formulation	PHI[1]	Total Clethodim Equivalents (ppm)
MI	2 EC	30+5	0.94, 0.98
ND	2 EC	30+1	0.80, 0.81
CA	2 EC	30+7	<0.10
ID	2 EC	30+15	0.64
MI	0.94 EC	30+1	0.58, 0.79
ND	0.94 EC	30+4	1.6
CO	0.94 EC	30+9	0.72, 1.1
CA	0.94 EC	30+7	1.2, 1.4
NE	0.94 EC	30+2	1.0, 1.1

1. Drying time is included.

Residue data were sent for dry bean forage and dry bean hay/straw. According to the new Table II (11/3/95) residue data on these commodities are not needed; therefore, it would not be discussed in this review.

PIRAT cannot draw any conclusion on the adequacy of the proposed tolerance on dry bean seeds at this time. Based on the 6/2/94 Field Trial Document, a total of 12 field trial sites are required for the registration of a chemical in/on dry beans. The document indicates that of the 12 field trials, 5 should be conducted in region 5. Based on the fact that only 2 studies conducted in this region were submitted by the petitioner, and that significant residue values found were in the submitted field trials, PIRAT cannot recommend for a permanent tolerance at this time. Also, dry bean hay/straw and dry bean vines are no longer considered significant livestock feed items. Therefore, the PHI for dry bean hay/straw and dry bean

vines should be deleted from the label. A revised Section B should be submitted reflecting this deletion. A revised Section F proposing tolerances for dry bean seeds only should be submitted by the petitioner. The tolerances for dry bean forage and straw/hay should be deleted from the Section F.

However, pending submission of 3 field trials in region 5, conducted at the maximum use rate and proposed PHI, a revised Section B and Section F, PIRAT can recommend for the establishment of Time Limited Tolerances for residues of clethodim in/on dry bean seeds at 2 ppm.

MEAT, MILK, POULTRY AND EGGS

We expect no increase in the dietary burden of ruminants and poultry as a result of this use. Therefore, PIRAT anticipates that any secondary residues that might result in milk, eggs, and meat, fat, and mbyp of cattle, goats, hogs, horses, poultry, and sheep would be covered by the established tolerances on these commodities.

OTHER CONSIDERATIONS

According to the CBTS document "Trigger for Rotational Crop Studies" (5/21/96), alfalfa is usually grown for 3 to 4 years and then rotated to a cereal grain crop such as corn or wheat. Therefore, confined rotational crop studies are needed for alfalfa.

Confined rotational studies were submitted in the following:

"Confined Rotational Crop Study of [Ring-4,6-^{14}C]-Clethodim with Carrots, Lettuce and Wheat"; V. Gaddamidi; 12/28/88; Laboratory ID# MEF-0036; Performing Laboratory was Chevron Chemical Company, Richmond, CA (MRID# 410302-11).

Crops were planted in sandy loam that had been treated at 1 lb/A (2X) with [ring-4,6-^{14}C]-clethodim and then aged for fallow periods of 30, 120 and 365 days in the greenhouse. The crops were lettuce, carrot and wheat representing a leafy crop, a root crop, and a small grain crop. The soil treatment was twice the maximum label rate of two postemergence applications of 0.25 lbs. ai/A and was applied to bare soil rather than to a cover crop.

The total ^{14}C found in the harvested food crop parts is summarized in Table VII.

Table VII. Total ^{14}C-clethodim in Edible Crop Parts[1]

Fallow Period (Days) Before Planting	Total ppm ^{14}C Calculated as Clethodim		
	Carrot Root	Lettuce Leaf	Wheat Grain
30	0.010	0.025	0.013
120	0.016	0.022	0.006
365	0.002	0.008	0.011

1. These values have been corrected to reflect 1X application.

Of the edible food crop parts, only the lettuce leaf from the 30 day planting was extracted. It contained 0.0125 ppm total ^{14}C as three metabolites (imine sulfoxide, oxazole sulfoxide, and oxazole sulfone), which are currently regulated.

The total ^{14}C found in the harvested crop parts fed to animals is summarized in Table VIII.

Table VIII. Total ^{14}C-clethodim in Crop Parts Fed to Animals[1]

Fallow Period (Days) Before Planting	Total ppm ^{14}C Calculated as Clethodim	
	Wheat Straw	Wheat Hulls
30	0.24	0.15
120	0.33	0.29
365	0.21	0.18

1. These values have been corrected to reflect 1X application.

Straw and hulls from wheat planted at 30, 120, and 365 days after soil treatment had approximately 0.03, 0.03, and 0.015 ppm total ^{14}C as three metabolites (imine sulfoxide, oxazole sulfoxide, and oxazole sulfone), which are currently regulated. A substantial portion (40-70%) of the ^{14}C could not be extracted.

Due to the fact that the applications were made to bare soil in the submitted confined rotational crop study, and that this is a postemergence herbicide applied in part to weeds, PIRAT concludes that residues in rotated crops under actual use conditions are going to be lower than the ones in the confined study. Therefore, there is no need for limited crop field trials. However, due to the fact that there may be residues of concern close to or at the trigger value of 0.01 ppm, a rotational crop restriction of 1 month for crops rotated with alfalfa should be added to the label. A revised Section B is needed.

CODEX CONSIDERATIONS

An International Residue Limits (IRL) Status Sheet is attached (see attachment 2). There are no Canadian, or Mexican tolerances for clethodim on alfalfa, peanuts, and dry beans. A Codex tolerance of 0.1 ppm on dry beans exists. As shown above, the highest residue values found on dry bean seeds was 1.6 ppm. Therefore, a compatibility problem exists.

However, once the deficiencies associated with this petition are resolved, PIRAT recommends that the petitioner consider submitting the petition information which supports the tolerance to Codex once the United States tolerance is approved.

Attachments: 1. ACB review of 4/3/96.
2. International Residue Limit Status Sheet

cc with attachments: RF, Circu., José J. Morales, CHEM Branch I (5F4440/5H5713), F. Ives, RCAB
7509C: Reviewer (JJM): CM#2: Rm 804-Q: 305-5010: typist (JJM): 6/18/96
RDI: R. Loranger (6/20/96): M. Metzger (6/25/96)