3-30-95

3/30/95

MEMORANDUM

Subject: **PP# 3F4268 - QUIZALOFOP-P ETHYL ESTER (ASSURE® II) ON THE LEGUME VEGETABLES (SUCCULENT OR DRIED) AND FOLIAGE OF LEGUME VEGETABLES CROP GROUPS, SUGARBEET TOPS, ROOTS, MOLASSES, AND COTTONSEED.** Review of Magnitude of the Residue Data and Residue Analytical Method and the February 22, 1995, Amendment. (MRID #s 428275-01 thru -09, 433140-01, and 424391-01)[CBTS #s 12699, 12700, 14060, 14061, 14148, 14149, and 15196-98]{DP Barcode D196041, D196043, D205430, D205432, D206201, D206200, and D212620-22}

From: Francis D. Griffith, Jr., Chemist
Chemistry Branch I - Tolerance Support
Health Effects Division (7509C)

To: Robert J. Taylor PM-25
Herbicide-Fungicide Branch
Registration Division (7505C)

and

Jane Smith
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

Thru: E. Zager, Acting Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (7509C)

INTRODUCTION

E.I. duPont de Nemours and Company, Agricultural Products, proposes tolerances for the combined residues of the herbicide quizalofop-p ethyl ester, trade named Assure® II (ethyl(R)-2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxy] propionate), and the S enantiomers of the ester and the acid, all expressed as quizalofop-p ethyl ester in or on the following raw agricultural commodities (racs): legume vegetables (succulent or dried) crop group at 0.3 ppm, the forage of legume vegetables (except soybean and bean hay) crop group at 0.7 ppm, sugarbeet tops at 0.5 ppm, and sugarbeet roots at 0.1 ppm. The petitioner is also proposing a revised tolerance on cottonseed at 0.1 ppm. A feed additive tolerance (FAT) is proposed for sugarbeet molasses at 0.2 ppm. A feed additive petition does not appear to have been filed.

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EXECUTIVE SUMMARY OF RESIDUE CHEMISTRY DEFICIENCIES

- REVISE LABEL
- COMPLETE TMV
- ADDITIONAL SUGARBEET AND BEAN FIELD TRIALS
- REVISE TOLERANCE EXPRESSION AND SUGARBEET MOLASSES TOLERANCE

CONCLUSIONS

1. CBTS Conclusion on Product Chemistry/Chemical Identity

CBTS concludes that after reviewing the CSF for the TGAI the impurities present in the TGAI quizalofop-p ethyl ester are not expected to present a residue problem in the subject crops when formulated into Assure® II and used as directed.

2. CBTS Conclusions on Directions for Use/Labeling

a. The petitioner has proposed an adequate set of directions for use of quizalofop-p methyl ester, formulated as Assure® II, in conjunction with an approved oil concentrate or a non-ionic surfactant on succulent and dried peas, cotton, and on snap and dried beans.

b. For sugarbeets the petitioner needs to propose a repeat application interval for the 4-8 applications per crop growing season.

c. For rotational crops the petitioner will need to revise the label to have the approved 120 plant back interval, not the proposed 30-60 days plant back intervals as residues above 0.01 ppm were detected at 62 days.

3. CBTS Conclusion on the Nature of the Residue - Plants

CBTS reiterates that the nature of the quizalofop-p ethyl ester residue in cottonseed, potatoes, soybeans, tomatoes and sugarbeets is adequately understood. The residues of concern are quizalofop-p ethyl ester and its acid metabolite, quizalofop-p, and the S enantiomers of both the ester and the acid, all expressed as quizalofop-p ethyl ester.

4. CBTS Conclusion on the Nature of the Residue - Livestock

The nature of the quizalofop ethyl ester residue in livestock is adequately understood. The residues of concern are quizalofop ethyl, quizalofop methyl, and quizalofop, all expressed as quizalofop ethyl.

5. CBTS Conclusion on **Confined Accumulation Studies on Rotational Crops**

The petitioner has characterized and identified over 50% of the residue in each of the rotational crops from the labeled quizalofop ethyl soil treatment and has confirmed the pathways. The nature of the residue in rotational crops is adequately understood and is the same as identified above for tomatoes, cottonseed, soybeans, and sugar beets. The residues of concern are quizalofop ethyl and its acid metabolite.

6. CBTS Conclusions on the **Residue Analytical Method**

a. The petitioner has presented adequate recovery data to show that the extracting solvent recovers the bound radioactive residues, copies of the control test methods for the enzymes used in the enforcement method, as well as a revised (shorter) method with adequate supporting chromatographic data and sample calculations. Comments 1, 2, and 3 from our March 4, 1994, review for PP# 1F3951 have been adequately addressed.

b. The petitioner has generated adequate ILV data to show that the revised methods, LAN-1 and LAN-3 are suitable to gather the magnitude of the quizalofop-p ethyl ester and its metabolites residue crop field trial data. Since there are significantly higher numerical tolerances being proposed for the commodities in this petition and these commodities are quite different from those commodities with established quizalofop ethyl ester tolerances, the revised residue analytical methods will need a Tolerance Method Validation (TMV) in EPA laboratories. The TMV will be initiated shortly. However, the results of the TMV will not be a delay for a time limited tolerance.

7. CBTS Conclusion on **Storage Stability**

The petitioner has provided frozen storage stability data for quizalofop acid, phenols 2, 3, and 4 in cottonseeds and cotton processed commodities, snap bean pods and "straw," peas and pea forage, sugarbeet roots, and canola which show residues are stable for at least 2 years. The data are sufficient to support the magnitude of the residue crop field trial data submitted in this petition where samples were stored under like conditions and for a shorter time.

8. CBTS Conclusions on **Magnitude of the Residue - Crop Field Trials**

a. The petitioner needs to present the following additional quizalofop-p ethyl ester magnitude of the residue crop field trial data for sugarbeets: 3 trials form Region 5, 1 trial from Region 8, and 1 trial from Region 10. Once the petitioner decides on the appropriate repeat application interval, then the 5 new field trials should be conducted using the proposed maximum 1X application rate of Assure® II/season.

b. CBTS notes that there has been insufficient time since the imposition of the additional data requirement for specific geographical representation on sugarbeet and bean field trials to generate the necessary residue data. Thus, we can recommend for tolerances with an expiration date for total quizalofop residues on sugarbeet tops and roots, legume vegetables (succulent and dried), and foliage of legume vegetables crop groups to allow the company time to complete the trials, analyze the samples, and present a final report. While the granting of a registration and a tolerance is the prerogative of the Registration Division, CBTS suggests quizalofop-p tolerances with a 3 year expiration date are acceptable considering we are too far into the 1995 growing season for the company to adequately plan for these additional field trials. This should allow sufficient time to complete the trials even with crop failure, analyze the samples, and present a final report.

c. At this time we conclude that quizalofop and its metabolites all expressed as quizalofop-p ethyl ester are not expected to exceed the proposed 0.1 ppm tolerance on sugarbeet roots and 0.5 ppm tolerance on sugarbeet forage when Assure® II plus the surfactant are used as directed. This conclusion is drawn for a time limited tolerance.

d. The petitioner has presented an adequate amount of varietal and geographically representative pea crop field trial residue data to show that residues of quizalofop and quizalofop-p ethyl ester are not expected to exceed the proposed legume vegetables (succulent and dried) crop group tolerance of 0.3 ppm and not to exceed the proposed foliage of legume vegetables (except soybeans and bean hay) crop group tolerance of 0.7 ppm when Assure® II plus the surfactant are used as directed.

e. The petitioner needs to present the following additional quizalofop-p ethyl ester magnitude of the residue crop field trial data for succulent beans and forage: 1 trial from Region 1, 1 trial from Region 2, and 1 trial from Region 3. The following additional crop field trial residues data on dried beans needs to be generated: 1 trial from Region 1, 1 or 2 trials from Region 5, 2 trials from Region 7, and 1 trial from Region 8. The 3 trials 1 each from Regions 4, 9, and 11 for succulent beans and forage; and the 2 trials on dried beans one each from Region 4 and Region 12 become supporting supplementary data. None of these data will be discarded.

f. At this time we conclude that residues of quizalofop and its metabolites all expressed as quizalofop-p ethyl ester are not expected to exceed the proposed legume vegetables (succulent and dried) crop group tolerance of 0.3 ppm and not to exceed the proposed foliage of legume vegetables (except soybeans and bean hay) crop group tolerance of 0.7 ppm when Assure® II plus the surfactant are used as directed. This conclusion is drawn for a timed limited tolerance.

g. CBTS has no objection to the proposed increased quizalofop tolerance of 0.1 ppm on cottonseeds to reflect a use of 2X LD tolerance method. The petitioner has presented an adequate amount of geographically representative crop field trial residue data to show that total quizalofop residues are not expected to exceed the proposed 0.1 ppm tolerance when Assure® II is used as directed.

h. The tolerance expression should be revised in Section F to reflect the established tolerance expression as stated in 40 CFR §180.441(c).

9. CBTS Conclusions on **Magnitude of the Residue - Processed Food/ Feed**

a. The petitioner has conducted an adequate sugarbeet processing study using sugarbeets bearing detectable residues following an individual 5X exaggerated application with a 45 days PHI. Total quizalofop residues were show to concentrate only in molasses; thus a FAT is required. In a revised Section F the petitioner will need to propose a total quizalofop FAT on molasses at 0.5 ppm.

b. The petitioner has conducted an adequate snap bean processing study using snap beans bearing detectable residues following an individual 5X exaggerated application rate with a 15 days PHI. Total quizalofop residues did not show concentration in either the central portions or the ends (cannery waste); thus no FAT is required.

10. CBTS Conclusions on **Magnitude of the Residue - Meat/Milk/ Poultry/Eggs**

a. The results of the quizalofop ethyl ester bovine feeding study show that finite residues will actually occur in milk and livestock tissues from the feeding of quizalofop ethyl ester treated racs or their processed feed items when Assure® II is used as directed. The established quizalofop and quizalofop ethyl ester tolerances in milk, and in fat, meat, and meat by-products of cattle, goats, hogs, horses, and sheep are adequate and need not be increased from these additional uses.

b. The results of the quizalofop ethyl ester poultry feeding study show that while it is not possible to establish with certainty whether finite residues will actually occur in eggs and tissues from the feeding of quizalofop ethyl ester treated racs or their processed feed items when Assure® II is used as directed, there is a reasonable expectation for such residues to occur. The established quizalofop and quizalofop ethyl ester tolerances in eggs, and in fat, meat, and meat by-products of poultry are adequate and need not be changed from these additional uses.

11. CBTS Conclusion on Harmonization of Tolerances

Since there are no Canadian, Mexican, Codex MRLs/ tolerances, compatibility is not a problem at this time.

RECOMMENDATION

CBTS cannot recommend at this time for the requested tolerances for the combined residues of the herbicide quizalofop-p ethyl ester and the S enantiomers of the ester and the acid, all expressed as quizalofop-p ethyl ester in or on the legume vegetables (succulent or dried) crop group at 0.3 ppm, the forage of legume vegetables (except soybean and bean hay) crop group at 0.7 ppm, sugarbeet tops at 0.5 ppm, sugarbeet roots at 0.1 ppm, on cottonseed at 0.1 ppm, and a FAT for sugarbeet molasses at 0.2 ppm for the reasons cited above in our Executive Summary and further described in the conclusions 2b and 2c, 6b, 8a, 8e, 8h, and 9a.

However, if the petitioner revises the quizalofop ethyl tolerance expression and the molasses tolerance, and proposes a repeat application interval for sugarbeets; then CBTS could recommend for tolerances with expiration dates for total quizalofop to allow the company time to plan and conduct the additional crop field trials, analyze the samples and prepare a final report. CBTS acknowledges that insufficient time has elapsed since the imposition of the additional data requirements for specific number of trials and the geographical location of these trials. While the granting of registrations and the issuing of tolerances is the prerogative of the Registration Division, CBTS suggests quizalofop tolerances with a 3 year expiration dates are acceptable.

No Feed Additive Tolerance appears to have been filed for the proposed molasses tolerance. A Feed Additive Petition needs to be filed.

DETAILED CONSIDERATIONS

BACKGROUND

CBTS has recommended for the established tolerance of the combined residues of the racemic mixture of quizalofop ethyl and its acid metabolite quizalofop, all expressed as quizalofop ethyl on soybeans at 0.05 ppm (see 40 CFR §180.441[a]). A food additive tolerance (FAT) has been established for the combined residues of the racemic mixture of quizalofop ethyl on soybean flour at 0.5 ppm (see 40 CFR §185.5250) and feed additive tolerances have been established for combined residues of the racemic mixture on soybean hulls at 0.2 ppm, on soybean meal at 0.5 ppm, and on soybean soapstock at 1 ppm (see 40 CFR §186.5250). CBTS has also recommended for the established tolerance of combined residues of the R enantiomer quizalofop-p ethyl ester and its acid metabolite, quizalofop-p, and the S enantiomers of both the ester and the acid, all expressed as quizalofop-p ethyl ester on cottonseed at 0.05 ppm (see 40 CFR §180.441[c]).

CBTS notes that the petitioner's proposed tolerance expression differs from that expressed in 40 CFR §180.441[c]. CBTS suggests that the tolerance expression in this CFR subsection accurately reflects the crop field trial residue data presented in this petition and that the petitioner needs to submit a revised Section F to have the tolerance expression compatible with the current CFR.

In addition, CBTS has recommended for two Emergency Exemptions (Section 18) for use of quizalofop-p ethyl ester on mint (see memoranda by M. Peters dated February 25, 1993, for 93WA0008 and 93MT0004). Quizalofop-p ethyl ester and its metabolite residues are not expected to exceed 5 ppm on mint hay and 0.05 ppm in mint oil.

PRODUCT CHEMISTRY/CHEMICAL IDENTITY

The product chemistry data for the R enantiomer were submitted as an amended registration to PP# 3F3252/6H5479.

CBTS concludes that after reviewing the results of the preliminary analysis of the TGAI (contains 98% active ingredient) as presented on the Confidential Statement of Formula (CSF) the impurities present in the TGAI quizalofop-p ethyl ester are not expected to present a residue problem in the subject crops in this petition when formulated into Assure® II and used as directed.

DIRECTIONS FOR USE/LABELING

Quizalofop-p ethyl ester is proposed for use as a herbicide to provide selective post-emergence control of annual grasses; eg, wild oats, foxtails, barnyardgrass, etc., and perennial grasses; eg, quackgrass, johnsongrass, etc.

The formulation to be used on the crops is Assure® II Herbicide (EPA Reg. No. 352-541) containing quizalofop-p ethyl ester at 10.3%, or 0.88 lb a.i. per gallon. In ground applications apply with standard fan or hollow cone nozzles, not with flood type nozzles. Also, in ground applications apply in a minimum of 10 gallons to 20 gallons per acre, and use either an EPA approved oil concentrate at a rate of 4 qts per 100 gallons (1%), or a non-ionic surfactant at a rate of 1 qt per 100 gallon (0.25%).

To control annual and perennial grasses in snap and dry beans, and in succulent and dry peas apply 6 to 12 ozs of Assure® II (1.2 ozs ai quizalofop-p ethyl ester per 3/4 pt) per acre per application once or twice per crop growing season when the grasses are actively growing, usually in the 3 leaf to pre-boot stage. The maximum application in a crop growing season to snap beans is 14 ozs Assure® II (1.5 ozs ai) with a 15 day PHI and to dry beans is 28 ozs Assure II (3 ozs ai quizalofop-p ethyl ester) with a 30 day PHI. The maximum application in a crop growing season to succulent and dry peas is 14 ozs of Assure® II (1.5 ozs ai) with a 30 day PHI for succulent peas and a 60 day PHI for dry peas.

To control annual and perennial grasses in sugar beets apply 5 to 12 oz (1.2 oz ai quizalofop-p ethyl ester per 3/4 pt) Assure® II per acre when the grasses are in the 3 leaf to tillering stage. The maximum application rate to sugarbeet is 50 ozs Assure® II with a 45 day PHI for the sugarbeet roots and a 60 day PHI for the sugarbeet tops. The petitioner needs to revise the directions for use on sugarbeets to have a repeat application interval for the 4-8 applications for the maximum application of Assure® II.

The petitioner cautions that the cereal grains are "highly sensitive" to Assure II, thus care should be taken to avoid application when drift is likely. Assure II should not be applied through any irrigation system. The petitioner has a feeding restriction for bean vines and hay to livestock. Since the residue crop field trial data were generated prior to the publication of Table II (June 1994) the feeding restrictions for bean straw/hay are accepted.

The application of Assure II to cotton fields is the essentially the same as previously proposed and accepted in PP# 1F3951; ie, up to 10 oz Assure II/application and 80 days PHI. Minor changes are to reduce total annual application to 18 ozs Assure II and to have aerial applications in a minimum of 3-5 gal/acre.

The petitioner has proposed an adequate set of directions for use of quizalofop-p methyl ester, formulated as Assure® II, in conjunction with an approved oil concentrate or a non-ionic surfactant on succulent and dried peas, cotton, and on snap and dried beans.

NATURE OF THE RESIDUE - PLANTS

COTTON AND SOYBEANS

The registrant has provided plant metabolism studies for soybeans, cotton, potatoes, and sugarbeets. These studies have been previously reviewed in PP#s 5F3252 and 1F3951.

In summary, quizalofop-p ethyl ester is metabolized by cleavage at three sites as follows:

1) Primary pathway is hydrolysis of the ethyl ester to form the quizalofop-p acid, then

2) Cleavage of the enol ether linkage in the acid between the phenyl and quinoxalinyl rings to form phenol 2 (6-chloroquinoxalin-2-ol) and phenol 4 (2-[4-hydroxyphenoxy]propanoic acid). Cleavage of the enol ether linkage in the intact quizalofop-p ethyl ester is a minor pathway that produces phenol 2 and phenol 3 (ethyl[2-(4-hydroxyphen-oxy)oxy] propanoate) which is the ester of phenol 4.

a. Phenols 2, 3, and 4 readily form plant glucose conjugates.

b. Some of the phenol 2 is hydroxylated to form hydroxyphenol 2, a minor metabolite.

c. Some phenol 3 is hydroxylated to phenol 4.

3) Cleavage of the ether linkage between the isopropanic group and the phenyl ring to form phenol 1 (4-[6-chloroquinoxalin-2-yl oxy] phenol).

a. Phenol 1 forms plant conjugates and/or

b. is cleaved at the enol ether linkage between the quinoxalinyl and phenyl rings to form phenol 2 (then some hydroxyphenol 2).

The plant metabolism data show that quizalofop-p ethyl ester does not translocate, but is rapidly hydrolyzed to the corresponding acid. Metabolism studies in soybeans using the racemic mixture quizalofop ethyl ester and the resolved D+ isomer show nearly identical pathways.

CBTS reiterates that the nature of the quizalofop-p ethyl ester residue in cottonseed, potatoes, soybeans, and sugarbeets is adequately understood. The residues of concern are quizalofop-p ethyl ester and its acid metabolite, quizalofop-p, and the S enantiomers of both the ester and the acid, all expressed as quizalofop-p ethyl ester.

TOMATOES (MRID # 429275-03)

The petitioner presented the results of a quizalofop-p ethyl ester on tomatoes metabolism study in a document titled "Metabolism of [Phenyl(U)-^{14}C] DPX-79376 and [Quinoxaline-phenyl(U)-^{14}C] DPX-79376 in Tomatoes" by I.E. Stevenson dated September 3, 1991, and coded DuPont report number AMR-1502-89.

The petitioner sprayed [phenyl (U)-^{14}C]quizalofop-p ethyl ester or [quinoxaline-phenyl(U)-^{14}C]quizalofop-p ethyl ester one time on greenhouse tomatoes (Sunny variety) at a rate of 6.4 oz a.i./acre (3.2X) and 0.5% (v/v) aqueous Ortho X-77. Tomato foliage samples were gathered immediately after spraying, then again on days 7, 14, 21, and 48. Tomatoes were harvested on day 7 (immature green), 14, 21, 30, and day 48 (mature green to overripe). The foliage and tomato fruit samples were analyzed by acceptable analytical techniques to determine the total ^{14}C-quizalofop-p and to characterize and identify the components of the total radioactive residue (TRR).

Total quizalofop-p residues in the unextracted tomatoes from the phenyl label were 0.346 ppm at 7 days PHI, 0.159 ppm at 14 days, 0.046 ppm at 21 days, 0.019 ppm at 30 days, and 0.008 ppm at 48 days. Slightly lower total quizalofop-p residues from the quinoxaline label were detected at 0.188 ppm 7 days after application, 0.049 ppm at 14 days, 0.036 ppm at 21 days, and 0.017 ppm at 30 days PHI.

Total quizalofop-p residues in the unextracted foliage from the phenyl label ranged from 4.87 ppm on the day of application declining to 2.24 ppm at 14 days and 0.085 ppm at 48 days. The total quizalofop-p residues on the foliage from the quinoxaline label ranged from 3.86 ppm on the day of application declining to 1.59 ppm after 14 days and were 0.79 ppm at 48 days PHI.

Identification of components on the tomato fruit in the 14 day residues from the phenyl application showed 0.014 ppm of the parent ethyl ester, 0.010 ppm of the free acid metabolite, 0.004 ppm of phenol 1, and 0.008 ppm of phenol 3 with no phenol 4 being detected. Using the quinoxaline label identification of residues on day 14 showed no parent residues were detected, 0.003 ppm of the free acid metabolite, <0.001 ppm of phenol 1, 0.004 ppm of phenol 2, and <0.001 ppm of the hydroxyphenol 2.

With a larger amount of ^{14}C material available on foliage identification of components in the 14 day residue from the phenyl label application showed 0.546 ppm parent, 0.245 ppm of the free acid metabolite, 0.026 ppm of phenol 1 and phenol 4, and 0.161 of phenol 3. At 14 days after application identification of the components from the quinoxaline label were 0.292 ppm of the parent, 0.151 ppm, of the free acid metabolite, 0.019 ppm of phenol 1, 0.105 ppm of phenol 2, and 0.037 ppm of hydroxyphenol 2.

The metabolic pathway of quizalofop-p in tomatoes is essentially the same as identified above for cottonseed, potatoes, soybeans, and sugarbeets. The nature of the quizalofop-p ethyl ester residue in tomatoes is adequately understood. The residues of concern are quizalofop-p ethyl ester and its acid metabolite, quizalofop-p, and the S enantiomers of both the ester and the acid, all expressed as quizalofop-p ethyl ester.

SUGARBEETS (MRID # 429275-04)

The petitioner presented the results of a quizalofop-p ethyl ester in/on sugarbeets metabolism study in a document titled "Metabolism of [Quinoxaline-Phenyl(U)-^{14}C] DPX-79376 and [Phenyl(U)-^{14}C] DPX-79376 in Sugar Beet" by I.E. Stevenson dated January 30, 1991, and coded DuPont report number AMR-1533-89.

The petitioner sprayed [phenyl (U)-^{14}C]quizalofop-p ethyl ester or [quinoxaline-phenyl(U)-^{14}C]quizalofop-p ethyl ester one time on 17 week old greenhouse sugarbeets (USH-11 variety) at a rate of 4 ozs a.i./acre (2X) and 0.25% (v/v) aqueous Ortho X-77. The plants were harvested immediately after the spray solution had dried, and again on day 31, 60, and 92 after application. The roots were separated from the foliage with the soil being superficially cleaned from the roots. The foliage and sugarbeet root samples were analyzed by acceptable analytical techniques to determine the total ^{14}C-quizalofop-p and to characterize and identify the components of the total radioactive residue (TRR).

Total quizalofop-p residues in the unextracted sugarbeet roots from the phenyl label were 0.176 ppm on the day of application, 0.091 ppm at 31 days PHI, 0.045 ppm at 60 days, and 0.033 ppm at 92 days. Slightly lower total quizalofop-p residues from the quinoxaline label were detected at 0.064 ppm immediately after application, 0.081 ppm at 30 days, 0.032 ppm at 60 days, and 0.018 ppm at 92 days PHI.

Total quizalofop-p residues in the unextracted foliage from the phenyl label ranged from 2.58 ppm on the day of application declining

to 0.773 ppm at 60 days and 0.403 ppm at 92 days. The total quizalofop-p residues on the foliage from the quinoxaline label ranged from 2.70 ppm on the day of application declining to 1.13 ppm after 30 days and were 0.892 ppm at 60 days PHI.

Identification of components in the sugarbeet roots in the 31 day residues from the phenyl application showed 0.003 ppm of the parent ethyl ester, 0.025 ppm of the free acid metabolite, 0.004 ppm of phenol 1 with no phenol 4 or phenol 3 being detected. Using the quinoxaline label identification of residues on day 31 showed 0.004 ppm of the parent were detected, 0.020 ppm of the free acid metabolite, 0.003 ppm of phenol 1 with on phenol 2 and hydroxyphenol 2 detected.

With a larger amount of ^{14}C material available from foliage identification of components in the 60 day residue from the phenyl label application showed 0.145 ppm parent, 0.034 ppm of the free acid metabolite, no phenol 1 and phenol 4, and 0.017 of phenol 3. At 60 days after application identification of the components in/on foliage from the quinoxaline label were 0.182 ppm of the parent, 0.044 ppm of the free acid metabolite, no phenol 1, 0.013 ppm of phenol 2, and 0.014 ppm of hydroxyphenol 2.

The metabolic pathway of quizalofop-p in sugarbeet foliage and roots is essentially the same as identified above from the application of the racemic mixture to cottonseed, potatoes, soybeans, and sugarbeets. The nature of the quizalofop-p ethyl ester residue in sugarbeet roots and foliage is adequately understood. The residues of concern are quizalofop-p ethyl ester and its acid metabolite, quizalofop-p, and the S enantiomers of both the ester and the acid, all expressed as quizalofop-p ethyl ester.

NATURE OF THE RESIDUE - LIVESTOCK

^{14}C-phenyl and ^{14}C-quinoxaline quizalofop ethyl ester caprine and poultry metabolism studies have been submitted and reviewed.

In summary, the primary pathway in ruminants is hydrolysis of the ethyl ester to form the quizalofop-p acid, then methyl esterification to form the quizalofop methyl ester. Since neither phenol 1 or phenol 2 were detected cleavage of the enol ether linkage in the acid between the phenyl and quinoxalinyl rings and cleavage of the ether linkage between the isopropanic group and the phenyl ring are not ruminant metabolic pathways.

In poultry the primary metabolic pathway is also the hydrolysis of the ethyl ester to form the quizalofop-p acid, then methyl esterification to form the quizalofop methyl ester becomes a minor pathway. Poultry apparently recognize the free acid metabolite as a fatty acid and utilize it in fatty acid chain elongation to from the quizalofop-pentanoic acid metabolite through a series of reactions involving acetyl Co-A, NAD/NADPH, and catalyzed by beta-hydroxyaryl dehydrogenase and enoyl reductase. Since neither phenol 1 or phenol 2 were detected cleavage of the enol ether linkage in the acid between the phenyl and quinoxalinyl rings and cleavage of the ether linkage

between the isopropanic group and the phenyl ring are not poultry metabolic pathways.

The nature of the quizalofop ethyl ester residue in livestock is adequately understood. The residues of concern are quizalofop ethyl, quizalofop methyl, and quizalofop, all expressed as quizalofop ethyl.

CONFINED ACCUMULATION STUDIES ON ROTATIONAL CROPS (MRID # 424390-01)

The petitioner provided a supplement to the original study to up-grade it with additional data as requested in the initial review. The title of the document is "Supplement No. 1 to: [Phenyl(U)-^{14}C] and [Quinoxaline-Phenyl(U)-^{14}C]DPX-Y6202 on Rotational Crops (Beets, Cotton, Lettuce, Peanuts, and Wheat) and Greenhouse Soil Degradation of [Phenyl(U)-14C DPX-Y6202 on Sassafras" by T. Priester dated July 15, 1992, and coded DuPont report number AMR 1265-88 Supp. 1.

[Phenyl-^{14}C] and [quinoxaline-^{14}C] quizalofop ethyl treated soils were aged 30 and 62 days before planting with the rotational crops red beets, lettuce, wheat, peanuts, and cotton. The petitioner has characterized and identified over 50% of the residue in each of the rotational crops from the phenyl and quinoxaline labeled quizalofop ethyl soil treatment and has confirmed the hydrolysis of the ethyl ester, and the cleavage of the enol and ether linkages metabolic pathways. At the 30 day plant back total quizalofop residues ranged from 0.032 ppm in lettuce to 0.104 ppm in beets. For the 62 day plant back total quizalofop residues were 0.071 ppm in lettuce, 0.053 ppm in beets, 0.058 ppm in wheat, 0.054 ppm in cotton, and 0.045 ppm in peanuts. These data will not support the shorter rotational crop plant back intervals of 30-60 days, thus the petitioner will need to present a revised label with the approved 120 day plant back interval.

The nature of the residue in rotational crops is adequately understood and is the same as identified above for tomatoes, cottonseed, soybeans, and sugar beets. The residues of concern are quizalofop ethyl and its acid metabolite.

RESIDUE ANALYTICAL METHOD

The petitioner presented enzyme control assay procedures and recovery data for the cold method using cottonseeds treated with radiolabeled quizalofop ethyl ester in a document titled "Determination of DPX-79376, DPX-79376 Acid and Conjugates as DPX-79376 Acid in Cottonseed and Fractions treated with Assure II Herbicide" by J. Amoo dated June 27, 1994, and coded DuPont Report Number AMR 1853-90 and **MRID # 433140-01.**

The petitioner presented Independent Laboratory Validation (ILV) data along with extensive supporting chromatographic data for the revised; ie, shorter proposed enforcement method in a study titled "Validation of Quizalofop P-Ethyl (DPX-79376), Quizalofop Acid (YE-945), Phenol 2 (IN-A6208), Phenol 3 (IN-G7057), and Phenol 4 (IN-H8515) in Cottonseed, Beans, Peas, Canola, and Sugarbeets" by T.

Mester dated August 26, 1994, and coded DuPont Study Number AMR 1854-90 and **MRID # 429275-09.**

Recovery of radiolabeled quizalofop residues using the ACN/1% HOAc (3/3, v/v) extracting solvent mixture ranged from 71 to 99%, averaging 81%. The petitioner has presented adequate data to show recovery of bound residues by the proposed enforcement method. Comment 3 of our March 4, 1992, review for PP# 1F3951 has been adequately addressed.

The petitioner presented a copy of Sigma Chemical's colorimetric method control test method for beta-glucosidase from almonds, a copy of the spectrophotometric stop rate method for cellulase, and a copy of the titrimetric method for esterase. These methods are adequate to confirm the strength of the enzymes used in the enforcement method. They will be attached to enforcement method when it is published in PAM-II. Comment 2 of our March 4, 1992, review for PP# 1F3951 has been adequately addressed.

The petitioner has presented adequate recovery data to show that the enzyme hydrolysis step can be shortened from 24 hours (overnight) to 2 hours. The petitioner has presented an adequate number of copies of supporting chromatograms for the control and treated samples as well as a detailed explanation (with examples) of the calculations used. The revised method for cottonseed differs from the version for succulent and dried beans and peas and their forage in that there is the added partition step to remove the oils and the extracts are chilled for 30 minutes in the freezer prior to the final filtering step for HPLC analysis. Comment 1 of our March 4, 1992, review for PP# 1F3951 has been addressed.

The petitioner presented ILV data generated by Enviro-Test Laboratories, 9936-67 Avenue, Edmonton, Alberta T6E OP5. The method used to generate ILV data for quizalofop ethyl ester and its acid metabolite was titled "Analytical Method for the Quantification of Quizalofop (YE-945) and Quizalofop-ethyl (DPX-79376) in Raw and Processed Agricultural Commodities." It is referred to as LAN-1.

In summary, 10 grams of sample were extracted 2 X 75 mls with ACN/1% HOAc (3/1, v/v), centrifuged and combined. The ACN was removed by rotary evaporation at 40°C and the aqueous extract was adjusted to pH 5 with either KOH or H_3PO_4, and cellulase and beta-glucosidase were added. The sample was incubated for 2 hours at 37°C, then the pH was adjusted to 8 with KOH and the sample was hydrolyzed an additional 2 hours after addition of esterase. The sample was cooled, pH adjusted to 3, then partitioned with 2 X 60 mls ACN/CH_2Cl_2 (2/1, v/v). The extracts were combined, concentrated by rotary evaporation, transferred into ACN, then partitioned 2 X 5 mls hexane (discard the hexane). 40 mls of KH_2PO_4 buffer were added and after mixing the sample was centrifuged and filtered. The sample was cleaned up on a prep or cleanup HPLC column; ie, Zorbax® Phenyl 4 x 80 mm, 5 mu, reliance cartridge with a "heart cut" collected which contained quizalofop and reanalyzed by HPLC using a Zorbax® R_x, 5 mu 4.6 X 250 mm column with the mobile phase of 22% ACN/K_2HPO_4 at 1.5

ml/min flow rate and detection by UV at 254 nm. Quantitation was by peak height. Acceptable linearity curves were presented.

The limit of quantitation is 0.05 ppm with a set of 12 samples being analyzed in 3 working days.

Control samples of cottonseeds, cottonseed hulls and crude oil; snap pods, forage, dry seed, and straw/hay; peas, dried peas, pea forage, and straw/hay; canola seed; and sugarbeet foliage and roots were fortified with quizalofop at 0.047, 0.2, and 0.47 ppm. Overall quizalofop recoveries ranged from 70 to 120%, averaging 98 ± 14% from snap and dry beans, 90 ± 12% from peas, and 101 ± 10% from sugarbeets.

Concurrent quizalofop and quizalofop-p recoveries from sugarbeet roots and forage spiked at 0.045 to 0.47 ppm ranged from 68 to 107%, averaging 90 ± 12%, n = 31. Concurrent quizalofop and quizalofop ethyl recoveries from edible peas, dried peas, pea forage and pea "straw" spiked at 0.047, 0.2, and 0.47 ppm ranged from 72 to 120% averaging 98 ± 12%, n = 57.

The petitioner presented additional ILV data also generated by Enviro-Test Laboratories. The method used to generate ILV data for the quizalofop phenol 2 and phenol 4 metabolites was titled "Analytical Method for the Quantification of Assure Metabolites, Phenol 2 (IN-A6208) and Phenol 4 (IN-H8515) in Raw and Processed Agricultural Commodities." It is referred to as LAN-3.

In summary, 5 grams of samples was extracted 2 X 100 mls with aqueous ACN (3/2, v/v), centrifuged, and filtered. The combined extracts were acidified with 10 mls of 10% HCl and partitioned with 100 mls of CH_2Cl_2 to remove the unconjugated phenols. The aqueous layer was adjusted to pH 5, then incubated with beta-glucosidase and cellulase. After incubation the aqueous layer was adjusted further to pH 2 and partitioned again with 100 mls of CH_2Cl_2. The CH_2Cl_2 extracts were combined and rotary evaporated at 35°C to just dryness. 50 mls of ACN were used to dissolve the sample before it was partitioned 3 X 50 mls hexane (discard hexane). The sample was blown dry at room temperature under a gentle stream of N_2. The sample was derivatized with diazomethane for an hour at 65°C then cleaned-up through a 7 gram 5% deactivated florisil column. The methyl esters of phenol 2 and phenol 4 were eluted off the column with 50 mls of acetone/hexane (1/9, v/v). Determination was by capillary GC-MSD using a HP 5890 GC containing a J & W DB 1701, 25 m X 0.25 mm column connected to a HP 5971 MSD. Ions 165 or 124 were used for identification and quantitation of phenol 2 and ions 210 or 123 were used for identification and quantification of phenol 4.

The LOQ is 0.05 ppm for both phenols and a set of 12 samples can be analyzed within 2 days.

Control samples of cottonseeds, snap forage, peas, and canola seed were fortified with quizalofop phenol 2 and 4 at levels around 0.045, 0.22, and 0.46 ppm. Overall quizalofop phenol 2 and 4 recoveries ranged from 70 to 124%.

Control sugarbeets were fortified with quizalofop phenol 2 and 3 with recoveries ranging from 82 to 109% averaging 94 ± 11%. Concurrent recoveries from sugarbeet forage and roots for phenol 2 ranged from 70 to 130%, averaging 99 ± 15%, n = 22; and for phenol 3 ranged from 71 to 129%, averaging 93 ± 14%. Concurrent recoveries from edible peas, dried peas, pea forage, and "straw" spiked at 0.043-0.047, 0.22-0.24, and 0.45-0.47 ppm ranged from 69 to 127% averaging 94 ± 18%, n = 48, for phenol 2; and from 68 to 129% averaging 99 ± 18% for phenol 4.

The petitioner has generated adequate ILV data to show that the revised methods, LAN-1 and LAN-3 are suitable to gather the magnitude of the quizalofop-p ethyl ester and its metabolites residue crop field trial data. Since there are significantly higher numerical tolerances being proposed for the commodities in this petition and these commodities are quite different from those commodities with established quizalofop ethyl ester tolerances, the revised residue analytical methods will need a Tolerance Method Validation (TMV) in EPA laboratories. The TMV will be initiated shortly; however, completion of the TMV is not a prerequisite for establishing time limited tolerances.

STORAGE STABILITY (MRID # 429275-08)

Storage stability data have been previously submitted for soybeans and cottonseed (high oil content commodities) which show that quizalofop ethyl ester, the free acid, and phenols 1, 2, and 4 metabolites are stable in frozen storage for at least 5 1/2 months.

The petitioner submitted new frozen storage stability data for quizalofop ethyl ester in a study titled "Freezer Storage Study of Quizalofop P-Ethyl (DPX-79376), Quizalofop Acid (YE-945), Phenol 2 (IN-A6208), Phenol 3 (IN-G7057), and Phenol 4 (IN-H8515) in Cottonseed, Beans, peas, Sugarbeets, and Canola" by T. Mester dated August 26, 1993, and coded DuPont Study Number AMR 1880-90.

Samples of cottonseed, cottonseed oil, cottonseed meal, snap bean pods and "straw," peas and pea forage, sugarbeet roots, and canola seed were fortified with quizalofop; ie, the acid metabolite, at levels of 0.093 ppm and 0.47-0.49 ppm, and placed into frozen storage under the same conditions as the magnitude of the residue samples. Aliquots of the frozen cottonseed were removed for analysis at 1, 36, 95, 189. and 372 days after fortification with all recoveries of quizalofop above 70%. Aliquots of the frozen cottonseed meal and oil were removed at 0, 42, 92, and 570 days after fortification with quizalofop recoveries ranging from 66 to 129%. Samples of snap bean pods, bean "straw", peas, and pea forage were removed for analysis at 0, 1, 3, 6, 12, and 24 months after fortification with quizalofop recoveries all above 66%. The spiked samples of sugarbeet roots and foliage were stored 1, 43, 93, and 184 days until analysis with quizalofop recoveries ranging from 72 to 118%.

Cottonseeds, snap bean pods, and peas were fortified with 0.23 ppm quizalofop phenol 2 and 0.24 ppm phenol 4 and placed into frozen storage under the same conditions as the magnitude of the residue

samples. Aliquots were taken at 0 day, 1, 3, 6, and about 12 months after fortification with phenol 2 recoveries ranging from 87 to 121% and phenol 4 recoveries ranging from 75 to 117%. Sugarbeets were fortified with 0.22 ppm quizalofop phenol 2 and phenol 3 at 0.23 ppm then stored frozen for 1 year. Analysis of stored samples showed quizalofop phenol 2 recoveries averaging 107% and quizalofop phenol 3 recoveries averaging 98%.

The petitioner has provided frozen storage stability data for quizalofop acid, phenols 2, 3, and 4 in cottonseeds and cotton processed commodities, snap bean pods and "straw," peas and pea forage, sugarbeet roots, and canola which show residues are stable for at least 2 years. The data are sufficient to support the magnitude of the residue crop field trial data submitted in this petition where samples were stored under like conditions and for a shorter time.

MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALS

SUGARBEET TOPS AND ROOTS (MRID # 429275-05)

The petitioner presented quizalofop residue data on sugarbeets and tops in a study titled "Magnitude of Residues of Assure® II Herbicide Applied in Sugarbeet Roots and Foliage" by T. Mester dated June 28, 1993, and coded Dupont Report Number AMR 1614-90.

The petitioner presented total quizalofop-p magnitude of the residue data on sugarbeet tops and roots from 8 crop field trials in 7 states: Ohio, North Dakota, New Mexico, Colorado, Wyoming, California, and Idaho all for the 1990 crop year on 7 varieties. Crop field trial data from these states represent a production from 670,200 acres out of a national sugarbeet harvest from 1,377,500 acres [48.6%] (see Agr. Stat., USDA, 1991). When the number of crop field trials presented are reviewed against the data requirements for number of trials as described in the "EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances", June 1994, the petitioner needs to present the following additional quizalofop-p ethyl ester magnitude of the residue crop field trial data for sugarbeets: 3 trials form Region 5, 1 trial from Region 8, and 1 trial from Region 10. Once the petitioner decides on the appropriate repeat application interval, then the 6 new field trials should be conducted using the proposed maximum 1X application rate of 50 ozs of Assure® II/season.

Each trial had a control plot and 2 test plots. One sugarbeet test plot received 3 broadcast ground sprays at 1.2 oz ai (approx. 1X)/acre/application along with the surfactant in each application for a total of 3.6 ozs ai/season. The applications were pre-emergence, 3-5 leaf stage, and the third application varied from the 10-16 inch height to 24-32 inch height with roots 1 1/2 to 3 inches. The other sugarbeet test plot received 3 broadcast ground sprays at a rate of 2.4 oz ai (2X)/acre/application for a total of 7.2 ozs ai/season. Both the 1X and 2X applications were done at the same time.

12 mature sugarbeet plants with roots were harvested at 45 and 60 days PHI. Samples were promptly frozen and remained frozen until preparation and analysis. Samples were analyzed by the residue analytical methods reviewed above which have adequate validation and concurrent recovery data for quizalofop ethyl ester and the phenol metabolites.

Residues of quizalofop and phenols 2 and 3 were not detected to the LD of 0.02 ppm in any of the control sugarbeet tops and roots.

One root sample at the 45 day PHI from the 1X application showed detectable quizalofop residues, but was less then the LOQ of 0.05 ppm. At 45 days PHI from the 2X application 2 root samples were positive for quizalofop with residues ranging from 0.02 to 0.091 ppm. No quizalofop residues were detected from either the 1X or the 2X application at 60 days PHI in the sugarbeet roots.

No phenol 2 or phenol 3 residues were detected in the root samples from the 1X and 2X applications at either 45 day or 60 day PHI.

From the 1X application quizalofop residues on sugarbeet forage ranged from 0.053 to 0.25 ppm averaging 0.1 $\pm$ 0.075 ppm at the 45 day PHI and ranged from 0.07 to 0.52 ppm averaging 0.146 $\pm$ 0.17 ppm at the 60 day PHI. Following an exaggerated 2X application quizalofop residues on forage ranged 0.081 ppm to 0.37 ppm averaging 0.105 $\pm$ 0.09 ppm at 45 days PHI and from 0.053 to 0.10 ppm averaging 0.066 $\pm$ 0.019 ppm at the 60 day PHI.

Phenol 3 residues were not detected in forage from either application or PHI. No phenol 2 residues were detected in the forage at the 60 day PHI following either the 1X or 2X applications. At 45 days PHI following the proposed use application phenol 2 residues were detected on only 2 samples of forage ranging from <0.05 to 0.076 ppm averaging 0.069 $\pm$ 0.01 ppm for the positive samples and from the 2X application only 1 sample had phenol 2 residues at 0.21 ppm.

CBTS notes that there has been insufficient time since the imposition of the additional data requirement for specific geographical representation on sugarbeet field trials to generate the necessary residue data. Thus, we can recommend for a tolerance with an expiration date for total quizalofop residues on sugarbeet tops and roots to allow the company time to complete the trials, analyze the samples, and present a final report. While the granting of a registration and a tolerance is the prerogative of the Registration Division, CBTS suggests a quizalofop on sugarbeet tops and roots tolerance with a 3 year expiration date is acceptable considering we are too far into the 1995 growing season for the company to adequately plan for these additional field trials. This should allow sufficient time to complete the trials even with crop failure, analyze the samples, and present a final report.

At this time we conclude that quizalofop and its metabolites all expressed as quizalofop-p ethyl ester are not expected to exceed the proposed 0.1 ppm tolerance on sugarbeet roots and 0.5 ppm tolerance

on sugarbeet forage when Assure® II is used as directed. This conclusion is drawn for a time limited tolerance.

SUCCULENT AND DRIED PEAS (MRID # 429275-01)

The petitioner presented quizalofop residue data on edible and dried peas and pea forage and "straw" in a study titled "Magnitude of Residues of D+ Isomer of Assure® Herbicide When Applied to English Peas" by T. Mester dated April 21, 1993, and coded Dupont Report Number AMR 1381-89.

The petitioner presented total quizalofop-p magnitude of the residue data on edible peas, dried peas, pea forage, and "straw" from 15 crop field trials in 10 states: Maryland, New Jersey, Delaware, Pennsylvania, Minnesota, Wisconsin, Washington, California, Oregon, and Idaho all for the 1989 crop year on 10 varieties. Crop field trial data from these states represent a production from 332,700 acres out of a national pea harvest from 341,100 acres [97.5%] (see Agr. Stat., USDA, 1991). When the number of crop field trials presented are reviewed against the data requirements for number of trials as described in the "EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances", June 1994, the petitioner has presented an adequate number of geographically representative quizalofop-p peas crop field trials.

Each trial had a control plot and 2 test plots. One succulent pea plot received 1 broadcast ground spray when the plants were around 5-9 inches high at a rate of 1.5 oz ai (1.25 X)/acre along with the surfactant. The application was at approximately 30 days PHI for succulent peas and forage. The other pea test plot received broadcast ground spray at a rate of 3 oz ai (2.5X)/acre along with the surfactant approximately 60 days PHI for dried peas and "straw." Both the 1X and 2X applications were done at the same time.

From both treated test plots approximately 1 kg of succulent peas and forage were harvested at 30 days PHI and about 0.5 kg of dried peas and "straw" were harvested at 60 days PHI. Samples were promptly frozen and remained frozen until preparation and analysis. Samples were analyzed by the residue analytical methods reviewed above which have adequate validation and concurrent recovery data for quizalofop ethyl ester and the phenol metabolites.

Residues of quizalofop and phenols 2 and 4 were not detected to the LD of 0.02 ppm in any of the control succulent peas, forage, dried peas, and "straw."

No edible pea samples at the 30 days PHI from the 1X application showed detectable quizalofop residues greater then the LOQ of 0.05 ppm. From the 2X application 4 succulent pea samples were positive for quizalofop with residues ranging from 0.02 (3 samples) to 0.078 ppm. Quizalofop residues were detected from the 1X application at 30 days PHI in pea forage ranging from 0.061 to 0.28 ppm averaging 0.112 $\pm$ 0.071 ppm and from the 2X application ranging from 0.067 to 0.47 ppm averaging 0.16 $\pm$ 0.12 ppm.

No phenol 2 or phenol 4 residues were detected in the succulent peas, forage, dried peas, and "straw" samples from the 1X and 2X applications at either 30 day or 60 day PHI.

From the 1X application quizalofop residues on dried peas ranged from 0.02 to 0.063 ppm at the 60 day PHI, and ranged from 0.02 (4 samples) to 0.077 ppm averaging 0.055 ± 0.01 ppm following the exaggerated 2X application. On pea "straw" quizalofop residues ranged from 0.053 ppm to 0.22 ppm averaging 0.082 ± 0.044 ppm from the proposed use application and from 0.059 to 0.32 ppm averaging 0.126 ± 0.078 ppm from the 2X application.

The petitioner has presented an adequate amount of varietal and geographically representative pea crop field trial residue data to show that residues of quizalofop and quizalofop-p ethyl ester are not expected to exceed the proposed legume vegetables (succulent and dried) crop group tolerance of 0.3 ppm and not to exceed the proposed foliage of legume vegetables (except soybeans and bean hay) crop group tolerance of 0.7 ppm when Assure® II plus the surfactant are used as directed.

SUCCULENT AND DRIED BEANS (MRID # 429275-02)

The petitioner presented quizalofop residue data on succulent (snap) and dried beans and bean forage and "straw" in a study titled "Magnitude of Residues of D+ Isomer of Assure® Herbicide When Applied to Snap and Dry Beans" by T. Mester dated February 19, 1993, and coded Dupont Report Number AMR 1428-89.

The petitioner presented total quizalofop-p magnitude of the residue data on edible and dried beans, bean forage, and "straw" from 8 crop field trials in 7 states: Michigan (2), Minnesota, Colorado, Mississippi, California, Oregon, and Idaho all for the 1989 crop year on 8 varieties. Crop field trial data on succulent beans from these states represent a production from 87,230 acres out of a national harvest from 245,930 acres [35.5%] and on dried beans represent a production on 876,000 acres out of a national harvest on 2,086,400 acres [42%] (see Agr. Stat., USDA, 1991). When the number of crop field trials presented are reviewed against the data requirements for number of trials as described in the "EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances", June 1994, the petitioner needs to present the following additional quizalofop-p ethyl ester magnitude of the residue crop field trial data for succulent beans and forage: 1 trial from Region 1, 1 trial from Region 2, and 1 trial from Region 3. The following additional crop field trial residues data on dried beans needs to be generated: 1 trial from Region 1, 1 or 2 trials from Region 5, 2 trials from Region 7, and 1 trial from Region 8. The 3 trials 1 each from Regions 4, 9, and 11 for succulent beans and forage; and the 2 trials on dried beans one each from Region 4 and Region 12 become supporting supplementary data. None of these data will be discarded.

Each trial had a control plot and 4 test plots. One test plot received broadcast foliar spray at a rate of 1.5 oz ai (1.25 X)/acre

along with the surfactant at approximately 30 days PHI for succulent beans and forage, then a second application of 1.5 oz ai/acre (3.0 oz ai total) for a 45 day PHI for dry beans and straw. The second test plot received a foliar broadcast spray at a rate of 1.5 ozs ai (1.25X)/acre along with the surfactant at approximately 15 days PHI for succulent beans and forage, then a second application of 1.5 ozs ai/acre (3.0 ozs ai) for a 30 PHI for dried beans and straw. The third bean test plot received a 2 foliar broadcast sprays at a rate of 1.5 ozs ai (1.25X)/acre along with the surfactant, then 15 days after second application succulent beans and forage were harvested, then at 70 days PHI dried beans and straw were harvested. The fourth bean test plot received a broadcast foliar spray at a rate of 3 oz ai (2.5X)/acre along with the surfactant approximately 15 days PHI for succulent beans and forage, then a second application at a rate of 3.0 ai/acre (6.0 ai total or 5X) for a 30 day PHI for dried beans and "straw."

From both treated test plots approximately 1 kg of succulent beans and forage were harvested at 15 and 30 days PHI and about 0.5 kg of dried beans and "straw" were harvested at the 30, 45, an 70 days PHI. Samples were promptly frozen and remained frozen until preparation and analysis. Samples were analyzed by the residue analytical methods reviewed above which have adequate validation and concurrent recovery data for quizalofop ethyl ester and the phenol metabolites.

Residues of quizalofop and phenols 2 and 4 were not detected to the LD of 0.02 ppm in any of the control succulent beans, forage, dried beans, and "straw."

No edible bean samples at the 30 days PHI from the 1.25X application showed detectable quizalofop residues greater then the LOQ of 0.05 ppm. From the 1.25X application at 15 days PHI 3 succulent bean samples were positive for quizalofop with residues ranging from 0.054 to 0.11 ppm averaging 0.06 $\pm$ 0.02 ppm. Quizalofop residues were detected from the two 1.25X applications at 15 days after the second application in succulent beans ranging from 0.02 to 0.05 ppm. And from the 2.5X application at 15 days PHI residues ranged from 0.02 to 0.11 ppm averaging 0.06 $\pm$ 0.02 ppm.

Two bean forage samples at the 30 days PHI from the 1.25X application showed detectable quizalofop residues less then the LOQ of 0.05 ppm. From the 1.25X application at 15 days PHI 3 bean forage samples were positive for quizalofop with residues ranging from 0.02 to 0.22 ppm averaging 0.13 $\pm$ 0.07 ppm. Quizalofop residues were detected from the two 1.25X applications at 15 days after the second application in bean forage ranged from < 0.05 to 0.10 ppm averaging 0.07 $\pm$ 0.02 ppm. And from the 2.5X application at 15 days PHI residues in bean forage ranged from 0.02 to 0.63 ppm averaging 0.19 $\pm$ 0.2 ppm.

No phenol 2 or phenol 4 residues at or above the LOQ of 0.05 ppm were detected in the succulent beans, bean forage, and dried beans samples from any of the four quizalofop treatments at various PHIs.

From the 2.5X application quizalofop residues on dried beans ranged from 0.02 to 0.11 ppm averaging 0.07 ± 0.03 ppm at the 45 day PHI. From the 2.5X application at 30 days PHI quizalofop residues ranged from 0.02 (5 samples) to 0.197 ppm averaging 0.07 ± 0.05 ppm. Applying two applications at a rate of 1.5 ozs ai/application, then harvest after 70 days quizalofop residues were all < 0.05 ppm. Quizalofop residues following the exaggerated 5X application at 30 days PHI ranged from 0.02 to 0.26 ppm averaging 0.11 ± 0.08 ppm.

On bean "straw" quizalofop residues following the 2.5X application with a 45 day PHI ranged from 0.02 to 0.19 ppm averaging 0.1 ± 0.05 ppm and from the 30 day PHI following the 2.5X application residues ranged from 0.02 to 0.67 ppm averaging 0.28 ± 0.23 ppm. Applying two applications at a rate of 1.5 ozs ai/application, then harvest after 70 days quizalofop residues ranged from 0.02 ppm to 0.11 ppm averaging 0.06 ± 0.02 ppm. Quizalofop residues on bean "straw" following the 5X application ranged from 0.051 to 2.5 ppm averaging 0.48 ± 0.83 ppm.

Comments made above on the need for the additional data required for specific geographical representation on sugarbeet field trials are germane to succulent and dried beans. At this time we conclude that quizalofop and its metabolites all expressed as quizalofop-p ethyl ester are not expected to exceed the proposed legume vegetables (succulent and dried) crop group tolerance of 0.3 ppm and not to exceed the proposed foliage of legume vegetables (except soybeans and bean hay) crop group tolerance of 0.7 ppm when Assure® II plus the surfactant are used as directed. This conclusion is drawn for a time limited tolerance.

COTTONSEED (MRID # 432805-01)

Crop field trial residue data on cottonseed from 13 trials in 12 states treated with quizalofop-p ethyl ester at 1X and 2X rates has been previously submitted and reviewed in March 4, 1992, memo for PP# 1F3951. At PHIs of 74 to 93 days with a proposed 80 day PHI quizalofop residues were all < 0.05 ppm from the 1X application.

In this submission residue data for the phenol 2 and phenol 4 metabolites were presented from these same trials. No residues of phenol 2 or 4 from either the 1X or 2X application were detected to < 0.05 ppm. Adequate concurrent validation data were presented.

CBTS has no objection to the proposed increased quizalofop tolerance of 0.1 ppm on cottonseeds to reflect a use of 2X LD tolerance method. The petitioner has presented an adequate amount of geographically representative crop field trial residue data to show that total quizalofop residues are not expected to exceed the proposed 0.1 ppm tolerance when Assure® II is used as directed.

MAGNITUDE OF THE RESIDUE - PROCESSED FOOD/FEED

SUGARBEETS (MRID # 429275-06)

The petitioner submitted the results of a quizalofop sugarbeet processing study in a document titled "Magnitude of the Residues of Assure® II Herbicide in Sugarbeets and their Processed Fractions" by T. Mester dated July 3, 1993, and coded DuPont study number AMR 1615-90.

The sugarbeet processing study was conducted using sugarbeets grown in 1990 in North Dakota treated once at a rate of 6 ozs ai/acre (5X for an individual application) broadcast ground spray with the surfactant at a rate of 0.25% (v/v) 45 days before harvest. Mature sugarbeets (rac) had no residues of quizalofop and phenols 2 and 3 < 0.05 ppm; however, residues of quizalofop were detected at 0.03-0.04 ppm. The sugarbeets were processed by the American Crystal Sugar Company using a small scale commercial process into cossettes, dried beet pulp, refined sugar, and molasses. No phenol 2 or 3 residues were detected in the rac, dried beet pulp, refined sugar, or molasses except phenol 3 residues may have been in the refined sugar < 0.05 ppm. Quizalofop was detected in dried beet pulp; however there was no concentration. Quizalofop residues in molasses were 0.12 and 0.16 ppm (5X conc. factor). The petitioner has conducted an adequate sugarbeet processing study using sugarbeets bearing detectable residues following an individual 5X exaggerated application with a 45 days PHI. Total quizalofop residues were shown to concentrate only in molasses; thus a FAT is required. In a revised Section F the petitioner will need to propose a total quizalofop FAT on molasses at 0.5 ppm [5 X conc. factor X 0.1 ppm tolerance on rac = 0.5 ppm].

SNAP BEANS (MRID # 429275-07)

The petitioner submitted the results of a quizalofop snap bean processing study in a document titled "Magnitude of the Residues of Assure® II Herbicide in Snap Beans - A Simulated Processing Study" by T. Mester dated January 25, 1993, and coded DuPont study number AMR 1616-90.

The snap bean processing study was conducted using snap beans (Tenderette variety) grown in 1990 in Illinois treated once at a rate of 6 ozs ai/acre (5X for an individual application) broadcast foliar spray with the surfactant at a rate of 0.25% (v/v) 15 days before harvest. Succulent mature whole snap beans (rac) had detectable residues of phenols 2 and 4 between 0.02 and < 0.05 ppm with residues of quizalofop at 0.17 ppm. The snap beans were processed by hand in the field to simulate commercial cannery processing into 1 inch center portions and ends. No phenol 2 or 4 residues were confirmed in the rac, center portions, and ends at 0.05 ppm and above. However, phenol 4 was detected at 0.034 ppm in the whole bean and at 0.015 ppm in the ends indicating no concentration. Quizalofop was detected in center portions of the beans at 0.056 ppm and in the ends at 0.069 ppm; both values indicate there was no concentration of residues. The petitioner has conducted an adequate snap bean processing study using snap beans bearing detectable residues following an individual 5X exaggerated application rate with a 15 days PHI. Total quizalofop residues did not show concentration in either the central portions or the ends (cannery waste); thus no FAT is required.

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

RUMINANTS

A ruminant feeding study has been submitted and reviewed. In summary, 3 group of 3 lactating dairy cows (plus a control group) were fed 0.1, 0.5, and 5.0 ppm quizalofop ethyl ester encapsulated for 28 consecutive days. Milk was collected daily and a sub-sample was divided into skim milk and cream. 2 cows were sacrificed after 28 days with samples of fat, skeletal muscle, liver, and kidney being collected and analyzed. The remaining cow in each test group was fed a regular diet without encapsulated quizalofop ethyl ester for 7 additional days before sacrifice. Whole milk, skim milk, and cream from the control, and the 0.1 and 0.5 ppm dose groups show no quizalofop to <0.02 ppm (0.05 ppm in cream). From the 5 ppm dose quizalofop residues ranged from 0.01 to 0.02 ppm in whole milk, and when these samples were separated into cream and skim milk the quizalofop partitioned into the cream with residues plateauing at 0.26 to 0.31 ppm. No quizalofop to < 0.02 ppm was detected in skeletal muscle, and to < 0.05 ppm was detected in any liver or fat sample from any of the 3 doses. Quizalofop was detected in one kidney sample at 0.05 ppm from the 5 ppm dose.

Bovine feed items in this petition include sugarbeet tops up to 20% in beef cattle diets and 10% in dairy cattle diets. Bean forage can be in dairy cattle diets up to 60% and up to 30% in beef cattle diets for potential dietary burdens of 0.6 and 1.2 ppm respectively. Bean hay/straw can be fed to beef and dairy cattle; however the petitioner has proposed a feeding restriction. Pea vines/forage can be included in beef cattle diets up to 35% and up to 50% of dairy cattle diets for potential dietary burdens of 0.98 and 1.4 ppm respectively. Pea hay [88% DM] can be up to 25% in beef cattle diets and up to 60% of dairy cattle diets. Molasses, dried bean and pea seeds, and undelinted cottonseed can be fed to beef and dairy cattle; however in this petition they contribute little to the dietary burden.

From the feed items in this petition all of the feed items in cattle diets can be treated with quizalofop ethyl ester. A theoretical beef cattle diet consisting of bean and pea forage, pea hay, and sugarbeet tops which none-the-less maximizes the potential quizalofop exposure of 2.1 ppm. A theoretical dairy cattle diet consisting of pea and bean forage would none-the-less maximize the potential quizalofop exposure at 2.4 ppm. Substitutions of other feed items and varying their percentages in the diets would give a lower dietary quizalofop burden.

The results of the quizalofop ethyl ester bovine feeding study show that finite residues will actually occur in milk and tissues from the feeding of quizalofop ethyl ester treated racs or their processed feed items when Assure® II is used as directed. The established quizalofop and quizalofop ethyl ester tolerance in milk, and in fat, meat, and meat by-products of cattle, goats, hogs, horse, and sheep are adequate and need not be increased from these additional uses.

POULTRY

A poultry feeding study has been submitted and reviewed. In summary, 3 groups of 20 hens (plus one control group) were dosed encapsulated at 0.1, 0.5, and 5 ppm of quizalofop ethyl ester daily for 28 consecutive days. Eggs were collected daily and after 28 days 3/4 of the hens in each test group were sacrificed and samples of fat, liver, kidney, breast and thigh muscles were collected and analyzed. Tissues from each test group were pooled prior to analysis. The remaining 5 hens were fed a regular poultry diet without quizalofop ethyl ester for an additional 7 days before sacrifice. No quizalofop residues were detected in the liver to <0.05 ppm, and in breast and thigh muscles to <0.02 ppm for any dose administered. From the 5 ppm dose one kidney sample showed 0.09 ppm quizalofop, 2 fat samples were 0.05 and 0.06 ppm quizalofop, and one egg sample has 0.02 ppm quizalofop.

Poultry feed items in this petition include dried bean seeds at 10% of the diet and dried pea seeds at 60% of the diet. The potential poultry dietary burden from the these feed items is 0.21 ppm.

The results of the quizalofop ethyl ester poultry feeding study show that while it is not possible to establish with certainty whether finite residues will actually occur in eggs and tissues from the feeding of quizalofop ethyl ester treated racs or their processed feed items when Assure® II is used as directed, there is a reasonable expectation for such residues to occur. The established quizalofop and quizalofop ethyl ester in eggs, and in fat, meat, and meat by-products of poultry are adequate and need not be changed from these additional uses.

HARMONIZATION OF TOLERANCES

An INTERNATIONAL RESIDUE LIMIT STATUS SHEET (IRL) is attached to this review. Since there are no Canadian, Mexican, Codex MRLs/ tolerances, compatibility is not a problem at this time.

cc:R.F.,Circu,Reviewer(FDG),PP#3F4268.
7509C:CBTS:Reviewer(FDG):CM#2:Rm804Q:305-5826:FDG:3/7/95:edit:3/30/95.
RDI:SecHd:RSQuick:3/29/95:ActBrSrSci:MTFlood:3/30/95:ActBrCh:EZager:3/30/95.