

2/13/96

MEMORANDUM

Subject: PP# 3F4268/5H5720 - 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 the July 27, Sept. 22 and 26, 1995, Amendments. (MRID # 438041-01)[CBTS #s 16400, 16401, and 16402]{DP Barcode D220215, D220216, and D220217}

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and

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Thru: E. Zager, Acting Chief
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INTRODUCTION

E.I. duPont de Nemours and Company, Agricultural Products, submitted this amendment consisting of cover letters dated July 27, September 22 and 26, 1995, signed by Marie M. Chubb, a revised Section B (new label for use on sugar beets), a supplementary Section D (a revised frozen storage stability study), and an amended Section F (revised expression and numerical tolerances). This amendment is submitted in response to deficiencies outlined and summarized in our March 30, 1995, review by F. Griffith, Jr. (qv). Our conclusions and recommendations follow.

EXECUTIVE SUMMARY OF RESIDUE CHEMISTRY DEFICIENCIES

- COMPLETE TMV
- REVISE FAT FOR SUGARBEET MOLASSES
- ADDITIONAL SUGARBEET AND BEAN FIELD TRIALS

CONCLUSIONS

1. CBTS Conclusions on Directions for Use/Labeling

a. For sugarbeets the petitioner proposed a 7-day repeat application interval. The rest of the Assure® II label for sugarbeets is unchanged. The 60-day plantback interval has been deleted and the approved 120-day plantback remains on the rotational crop supplemental label. Deficiencies 2b and 2c are resolved.

b. 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, snap and dried beans, and now on sugarbeets.

2. CBTS Conclusion on the Residue Analytical Method

The petitioner needs to respond to ACB concerns with a revised method before we can get the TMV back on track in the near future. We reiterate that the results of the TMV are not a bar/delay for a favorable recommendation for the time-limited tolerance.

3. CBTS Conclusion on Storage Stability

The petitioner has provided supplemental 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 up to 3 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.

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

a. CBTS reiterates that the petitioner needs to present the following additional quizalofop-p ethyl ester magnitude of the residue crop field trial data for sugarbeets: 3 trials from Region V, 1 trial from Region VIII, and 1 trial from Region X. 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. The deficiency is not resolved.

b. CBTS reiterates that 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 I, 1 trial from Region II, and 1 trial from Region III. The following additional crop field trial residue data on dried beans need to be generated: 1 trial from Region I, 1 or 2 trials from Region V, 2 trials from Region VII, and 1 trial from Region VIII. The 3 trials, 1 each from Regions IV, IX, and XI for succulent beans and forage; and the 2 trials on

dried beans, one each from Region IV and Region XII, become supporting supplementary data. None of these data will be discarded. The deficiency is not resolved and continues outstanding.

c. The petitioner has presented the revised tolerance expression for quizalofop-p ethyl ester as requested that is identical to the expression in 40 CFR §180.441(c). Deficiency 8h is resolved.

5. CBTS Conclusion on Magnitude of the Residue - Processed Food/Feed

The petitioner submitted a revised Section F proposing a feed additive tolerance (FAT) for total quizalofop-p and its metabolites in molasses at 0.5 ppm. However, for the time limited tolerance the petitioner needs to submit a revised Section F for sugarbeet molasses at 0.2 ppm (0.05 ppm LOQ X 4X conc. factor = 0.2 ppm). Deficiency 9a is not resolved at this time.

RECOMMENDATION

CBTS cannot recommend at this time for the requested permanent tolerances for the combined residues of the herbicide quizalofop-p ethyl ester, its acid metabolite quizalofop-p, 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 0.25 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, cottonseed at 0.1 ppm, and a FAT for sugarbeet molasses at 0.5 ppm for the reasons cited above in our Executive Summary and further described in conclusions 2, 4a and b, and 5.

If the petitioner proposes a revised Section F for sugarbeet molasses at 0.2 ppm, then CBTS can recommend for tolerances with expiration dates for total quizalofop to allow DuPont time to plan and conduct the additional crop field trials, analyze the samples and prepare a final report. While the granting of registrations and the issuing of tolerances is the prerogative of the Registration Division, CBTS suggests quizalofop tolerances be set at the levels proposed in the most recent Section F.

A DRES analysis may now be initiated using the proposed legume vegetables crop group tolerance of 0.25 ppm, and the proposed tolerances on sugarbeets roots at 0.1 ppm, and on sugarbeet molasses at 0.2 ppm. The DRES Section should refer to the CBTS memorandum of Oct. 6, 1995, by F. Griffith for guidance on what values to use for soybeans and the soybean processed commodities.

DETAILED CONSIDERATIONS

BACKGROUND

The petitioner has filed a Feed Additive Petition, 5H5720. This deficiency is resolved.

DIRECTIONS FOR USE/LABELING

DEFICIENCIES

2b. For sugarbeets the petitioner needs to propose a repeat application interval for the 4-8 applications per crop growing season.

2c. 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.

PETITIONER'S RESPONSES

The petitioner has presented a revised label for sugarbeets and the rotational plantback interval has been revised.

CBTS COMMENTS

For sugarbeets the petitioner proposed a 7-day repeat application interval. The rest of the Assure® II label for sugarbeets is unchanged. Deficiency 2b is resolved.

The 60-day plantback interval has been deleted and the approved 120-day plantback remains on the rotational crop supplemental label. Deficiency 2c is resolved.

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, snap and dried beans, and now on sugarbeets.

RESIDUE ANALYTICAL METHOD

DEFICIENCY

6b. 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. The results of the TMV will not be a delay for a time limited tolerance.

CBTS COMMENTS

CBTS has responded to the Analytical chemistry Branch review of July 21, 1995, on October 7, 1995. The petitioner needs to respond to ACB concerns with a revised method before we can get the TMV back

on track in the near future. We reiterate that the results of the TMV are not a bar/delay for a favorable recommendation for the time-limited tolerance.

STORAGE STABILITY

(MRID # 438041-01)

The petitioner submitted new frozen storage stability data for quizalofop ethyl ester as revision 1 to the 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 W. Harnish dated September 13, 1995, and coded DuPont Study Number AMR 1880-90, Revision 1.

The submission is a continuation of the initial frozen storage stability data report reviewed on March 30, 1995. It provides the additional recovery data for 24, 27, and 36 months of frozen storage.

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 cottonseeds, cottonseed oil and meal were removed for analysis at 1, 36, 95, 184-189, 372, 570, 670, and 841 days after fortification. Quizalofop recoveries from the cotton commodities ranged from 66 to 129%, all averaging above 70%.

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 to 218 days until analysis with quizalofop recoveries ranging from 72 to 118%. Recovery of quizalofop from canola seed stored 30, 92, 185, 367, 545, and 841 days ranged from 61 to 124%.

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, about 12 months, 21, 24, and 27 months after fortification with phenol 2 recoveries ranging from 70 to 121% and phenol 4 recoveries ranging from 63 to 130%.

Sugarbeet roots and canola seed were fortified with 0.23 ppm quizalofop phenol 2, phenol 3 at 0.22 ppm into sugarbeet roots, and 0.24 ppm into canola seed. Then the sugarbeet roots were stored frozen for 2 years and the canola seeds were stored frozen for 3-years. Analysis of stored samples showed quizalofop phenol 2 recoveries averaging 78-87%, quizalofop phenol 4 recoveries averaging 75%, and quizalofop phenol 3 recoveries averaging 107%.

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 up to 3 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 similar conditions and for a shorter time.

MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALS

DEFICIENCIES

8a. The petitioner needs to present the following additional quizalofop-p ethyl ester magnitude of the residue crop field trial data for sugarbeets: 3 trials from Region V, 1 trial from Region VIII, and 1 trial from Region X. 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.

8e. 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 I, 1 trial from Region II, and 1 trial from Region III. The following additional crop field trial residue data on dried beans need to be generated: 1 trial from Region I, 1 or 2 trials from Region V, 2 trials from Region VII, and 1 trial from Region VIII. The 3 trials, 1 each from Regions IV, IX, and XI for succulent beans and forage; and the 2 trials on dried beans, one each from Region IV and Region XII, become supporting supplementary data. None of these data will be discarded.

8h. The tolerance expression should be revised in Section F to reflect the established tolerance expression as stated in 40 CFR §180.441(c).

PETITIONER'S RESPONSES

In the July 27, 1995 letter the petitioner agreed to generate the requested additional quizalofop-p sugarbeet crop field trial data as requested in deficiency 8a above. The petitioner also agreed to generate the additional quizalofop-p succulent beans, bean forage, and dried beans crop field trial residue data as requested in 8e above.

In the July and September letters the petitioner presented a revised quizalofop-p tolerances expression that is identical to that in 40 CFR §180.441(c).

CBTS COMMENTS

While the agreement to conduct the additional field trial does not resolve these deficiencies, it shows significant movement to their resolution. At this time they are reiterated and remain outstanding.

The petitioner has presented the revised tolerance expression for quizalofop-p ethyl ester as requested that is identical to the

expression in 40 CFR §180.441(c). The tolerance expression now accurately reflects the crop field trial residue data presented in this petition. Deficiency 8h is resolved.

MAGNITUDE OF THE RESIDUE - PROCESSED FOOD/FEED

DEFICIENCY

9a. The petitioner has conducted an adequate sugarbeet processing study using sugarbeets bearing detectable residues following an individual 5X exaggerated application with a 45-day 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 feed additive tolerance (FAT) on molasses at 0.5 ppm.

PETITIONER'S RESPONSE

The petitioner submitted a revised Section F proposing a FAT for total quizalofop-p and its metabolites in molasses at 0.5 ppm.

CBTS COMMENTS

During the time the petitioner was preparing these amendments CBTS/CBRS revised the procedures for review of processing studies and determination of the need for Section 409 tolerances. There is no highest "average" field trial (HAFT) residue value above the method's LOQ for quizalofop on sugarbeets per se. From the limited data presented we know there are no residues on the rac from the crop field trials above the LOQ of 0.05 ppm; thus, the LOQ will become our HAFT for quizalofop on sugarbeets. There was only one quizalofop sugarbeet processing study. The results from a 5X exaggerated application are 0.03-0.04 ppm (X = 0.035 ppm) on the rac sugarbeets and 0.12-0.16 ppm (X = 0.14 ppm) for a concentration factor of 4X. For the time limited tolerance the petitioner needs to submit a revised Section F for sugarbeet molasses at 0.2 ppm (0.05 ppm LOQ X 4X conc. factor = 0.2 ppm).

SUGARBEET MOLASSES IS CONSIDERED TO BE A READY-TO-EAT (RTE) FEED-STUFF. THEREFORE, A 701 MRL (MAXIMUM RESIDUE LIMIT) IS NOT APPROPRIATE IN THIS INSTANCE.

When the petitioner completes the additional 5 or 6 quizalofop sugarbeet field trials at least two independent samples should be analyzed at each site per the June 1994 guidance document on crop field trials. The two samples at each site will be used to determine the HAFT values. We also suggest that all supporting chromatographic data be presented so that we can determine if there are detectable quizalofop residues below the LOQ. These data will impact our final decision on the need for a 409 tolerance, or no permanent feed additive tolerance on sugarbeet molasses. Deficiency 9a is not resolved at this time.

cc:R.F., Circu, Reviewer (FDG), PP#3F4268.

7509C:CBTS:Reviewer (FDG):CM#2:Rm804Q:305-5826:FDG:1/14/96:edit:fdg:2/13/96.