

6/14/96

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 May 23, 1996, Amendment.
Chemical No. 128711
(No MRID #){DP Barcode D226691}

From: Francis D. Griffith, Jr., Chemist
Chemistry Branch I - Tolerance Support

To: D. McCall, Acting Section Head
Risk Characterization and Analysis Branch

Thru: E. Zager, Acting Chief
Chemistry Branch I - Tolerance Support

INTRODUCTION

E.I. duPont de Nemours and Company, Agricultural Products, submitted this amendment consisting of cover letter dated May 23, 1996, signed by T.E. Catika and a revised Section F (revised expression and numerical tolerances). This amendment is submitted in response to deficiencies outlined and summarized in our 13 Feb 96 review by F. Griffith, Jr. (qv). Our conclusions and recommendations follow.

EXECUTIVE SUMMARY OF RESIDUE CHEMISTRY DEFICIENCIES

- NONE -

CONCLUSIONS**1. CBTS Conclusion on Directions for Use/Labeling**

The petitioner has proposed an adequate set of directions for use of quizalofop-p ethyl 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

CBTS reiterates that 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 tolerances as there is an adequate residue analytical method in PAM-II.

3. 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 for permanent tolerance; however it is not a bar to a time limited tolerance.

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 data. None of these data will be discarded. The deficiency is not resolved for a permanent; however it is not a bar to a time limited tolerance.

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

The petitioner submitted a revised Section F proposing a food additive tolerance (FAT) for total quizalofop-p and its metabolites in molasses at 0.2 ppm. Deficiency 5 is resolved.

RECOMMENDATION

CBTS recommends 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 cottonseed at 0.1 ppm.

CBTS recommends for a 3 year time limited tolerances 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 3 ppm, sugarbeet tops at 0.5 ppm, sugarbeet roots at 0.1 ppm, and a FAT for sugarbeet molasses at 0.2 ppm. This allows DuPont time to

plan and conduct the additional crop field trials, analyze the samples and prepare a final report.

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, sugarbeet molasses at 0.2 ppm, and on cottonseed at 0.1 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

DIRECTIONS FOR USE/LABELING

The petitioner has proposed an adequate set of directions for use of quizalofop-p ethyl 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

CBTS has responded to the Analytical Chemistry Branch (ACB) review of July 21, 1995, on October 7, 1995. CBTS reiterates that 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 tolerances as there is an adequate residue analytical method in PAM-II.

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

The petitioner has not had time to respond.

CBTS COMMENTS

CBTS reiterates that 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.

MAGNITUDE OF THE RESIDUE - PROCESSED FOOD/FEED

DEFICIENCY

5. The petitioner submitted a revised Section F proposing a feed additive tolerance (FAT) for total quinalofop-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.

PETITIONER'S RESPONSE

The petitioner submitted a revised Section F proposing a FAT for total quinalofop-p and its metabolites in molasses at 0.2 ppm.

CBTS COMMENTS

Deficiency 5 is resolved.

cc:R.F.Taylor[PM-25,HFB/RD],R.F.,Circu,Reviewer(FDG),PP#3F4268.
7509C:CBTS:Reviewer(FDG):CM#2:Rm804Q:305-5826:FDG:6//96:edit:fdg:6/14/96.
RDI:TPT-1:6/13/96:BrSrSci:RALoranger:6/13/96:ActBrCh:EZager:6/14/96.