

10-5-95

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MEMORANDUM

Subject: PP# 3F4268 - QUIZALOFOP-P ETHYL ESTER (ASSURE II) ON LEGUME VEGETABLE (SUCCULENT OR DRIED) AND FOLIAGE OF LEGUME VEGETABLES CROP GROUPS, SUGARBEET TOPS, ROOTS, MOLASSES, AND COTTONSEED.
Response to SAB on Adequacy of Existing Tolerances for a DRES Analysis.
(No MRID #)[CBTS # 16261]{DP Barcode D219638}

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To: Elizabeth Doyle, Ph.D., DRES Section
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and

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Thru: Michael S. Metzger, Chief
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INTRODUCTION/BACKGROUND

The August 23, 1995, cc:mail message from Elizabeth Haeberer to Gary Otakie presented the following question: is the 0.5 ppm FAT for quizalofop ethyl on soybean flour adequate in view of the proposed 0.3 ppm legume vegetables crop tolerance. There appears to be a 10X concentration factor based on the established raw and processed commodity tolerances.

E.I. duPont de Nemours and Company, Agricultural Products, recently proposed 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 and on the foliage of legume vegetables (except soybean and bean hay) crop group at 0.7 ppm. The trade name for the chemical is Assure® II. CBTS conditionally recommended for time limited tolerances/condi-

tional registration (see memorandum by F. Griffith dated March 30, 1995).

There are established tolerances for 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 the racemic mixture on soybean hulls at 0.2 ppm, on soybean meal at 0.5 ppm, and soybean soapstock at 1 ppm (see 40 CFR §186.5250).

Since CBTS had conditionally recommended for time limited tolerances a DRES analysis was initiated. The key question is whether the existing 0.5 ppm tolerance on soybean flour is adequate in view of the proposed 0.3 ppm legume vegetables (succulent or dried) crop group tolerance. A worst case 10X concentration factor from soybeans at 0.05 ppm to the 0.5 ppm in soybean flour was utilized in establishing the current 409 tolerances.

CONCLUSIONS/RECOMMENDATIONS

1. The 0.05 ppm tolerance on soybeans and 0.5 ppm tolerance on soybean flour and meal have not been changed. The existing FATs were established on a worst case scenario using a 10X concentration factor. In the absence of a proposal from the petitioner to revise the existing quizalofop ethyl soybean FAT tolerances in accordance with the current CBTS policies, the established FATs for soybean flour and meal based on a 10X concentration factor remain in effect. If a DRES analysis is necessary, then CBTS recommends a DRES analysis be run using the established quizalofop ethyl tolerances.
2. CBTS recommends against using the 0.3 ppm crop group tolerance in a DRES analysis as the petitioner plans to propose a revised the tolerance.
3. CBTS recommends against using the future proposed 0.25 ppm crop group tolerance (excluding soybeans) in a DRES analysis until the petitioner has submitted the necessary data and CBTS has completed its review of these data.
4. Discussions with the petitioner indicate they do not plan to propose changes to any of the established FATs for quizalofop ethyl on soybean processed commodities. However, depending upon the additional data to be submitted on legume vegetables, CBTS may recommend revisions to the FAT's.

DETAILED CONSIDERATIONS

Review of the CBTS files by G. Otakie revealed the following:
(see cc:Mail memo by G. Otakie dated 23 Aug 95 at 1616 hrs)

1. There were four quizalofop ethyl on soybean processing studies reported in PP# 3F3252. Application rates were 0.5X, 1X or 4 ozs ai/a/season, and 2X. The studies showed that the highest concentration factors were at least 4.3X/4.4X from soybeans to soybean meal and flour.
2. If we include concentration factors from the 0.5X application rate processing study (only study with non-detectable residues on the rac) and all calculations were made on the **assumption** that residues were present at the limit of detection, then the AVERAGE concentration factor becomes 1.63X for soybean hulls, 2.12X for soybean meal, and 3.17X for defatted flour.
3. The highest average field trial residue was 0.046 ppm which was rounded to 0.05 ppm and became the established quizalofop ethyl tolerance on the rac soybeans.
4. If we were to multiply the **highest average field trial X average concentration factor** in accordance with current branch policy, then values of 0.1 ppm for soybean meal and 0.2 ppm for defatted soybean flour would be more appropriate.

Contacts with the petitioner (telcons D. Griffith, EPA - R. Holt and M. Chubb, Dupont) brought out there are problems with the sample preparation step and that there is a lack of homogeneity in these samples. Duplicate analysis will confirm this, especially for the high soybean sample. The petitioner plans to submit a revised Section F to lower the legume vegetables crop group tolerance to 0.25 ppm and to exclude soybeans. The petitioner wants the existing 0.05 ppm tolerance to remain on soybeans.

CBTS feels it is prudent to wait for the formal submission and reevaluate the entire package using the revised Table II and new policy on the appropriate tolerances for processed commodities. CBTS needs time to review these data in view of the recent changes to Table II and the new policy on tolerances using the highest average field trial results to determine whether a 409 FAT or 701 MRL is appropriate. CBTS recommends no DRES analysis should be initiated for the 0.3 ppm crop group tolerance and judgement should be deferred on initiating a DRES analysis on the 0.25 ppm "proposed" tolerance.

CBTS also inquired if the petitioner had any additional processing studies for quizalofop on soybeans and if they were planning to revise any of the FATs in view of the recent guidance on calculating residues on processed commodities. The petitioner's response is there have been no new processing studies for quizalofop ethyl on soybeans. They noted that the original quizalofop ethyl soybean processing studies were run using the **racemic mixture**. DuPont plans no proposals to revise for the existing quizalofop ethyl FATs for processed soybean commodities. The petitioner is aware that using the existing tolerances give the appearance that there is a 10X concentration factor.

The existing FATs were established on a worst case scenario using the petitioner's 10X concentration factor. In the absence of a

proposal to revise the existing quizalofop ethyl soybean FAT tolerances in accordance with the current CBTS policies, the established FATs for soybean flour and meal based on the 10X concentration factor remains in effect. If a DRES analysis is necessary, then CBTS recommends a DRES analysis be run using the established quizalofop ethyl tolerances. However, depending upon the additional data to be submitted on legume vegetables, CBTS may recommend revisions to the soybean FAT's in the future.

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

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