PMSD/TSB

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

NOV 20 1986

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#6F3316 and ID#8340-EG (RCB #'s 1579 and 1580). Fenoxaprop-ethyl (HOE 33171) on Soybeans and Rice. Amendment Dated October 29, 1986 (Accession No. 265853).

FROM: Nancy Dodd, Chemist
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Richard Mountfort, PM 23
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

Note: This review was expedited as requested in the memorandum of October 10, 1986 from James W. Akerman, Deputy Director, Registration Division.

The petitioner, American Hoechst Corporation, submits an amendment dated October 29, 1986 to PP#6F3316 for tolerances for residues of the herbicide fenoxaprop-ethyl [(±)-ethyl 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoate] and its metabolites 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoic acid and 6-chloro-2,3-dihydrobenzoxazol-2-one on soybeans, rice, and rice straw at 0.05 ppm. The amendment is submitted in response to RCB's review of August 21, 1986 (N. Dodd) and a meeting on September 11, 1986. The amendment consists of a revised label, a discussion of the residue data base for soybeans and rice, and bridging data for the original method #AL3/84 and the new method dated September 5, 1986.

The deficiencies listed in the August 21, 1986 review and discussed in the September 11, 1986 meeting are outlined below, followed by the petitioner's responses and RCB's discussions/ conclusions.

RCB's Deficiencies 5b and 5c

RCB will reserve its conclusion on the acceptance of the proposed analytical methodology for regulatory purposes pending receipt of a satisfactory method trial.

RCB's Discussion of Deficiencies 5b and 5c

Since RCB's August 21, 1986 review of the May 22, 1986 amendment to PP#6F3316 (N. Dodd), RCB has evaluated a method trial report for fenoxaprop-ethyl on soybeans (see PP#6F3316, N. Dodd, October 30, 1986). The following conclusions concerning the analytical method were made:

1. The petitioner needs to submit residue data on soybeans and rice which were obtained by using the new method dated September 5, 1986. If reserve samples are available, the petitioner could reanalyze the reserve samples using the new method dated September 5, 1986. Otherwise, additional field trials will be needed.

2. The method trial is not yet complete for the following reasons:

   a. RCB must receive an official "non-Draft" copy of the September 5, 1986 procedure along with chromatograms, etc., reflecting the use of both the packed and capillary columns. (The petitioner's chromatograms are missing.)

   b. BUD/COB/ECL needs to provide some testing of the subject procedure using the GLC capillary column.

   c. No residue data have been reported on any field samples using the new procedure dated September 5, 1986. These data are needed.

   Note: In the future (but not for tolerances on soybeans and rice) when fenoxaprop-ethyl tolerances are proposed, the petitioner will need to analyze residues of fenoxaprop-ethyl using the FDA multiresidue method protocols (read the Attachments).

Petitioner's Response to Deficiencies 5b and 5c

The petitioner submits a copy of the new improved method, "Determination of Fenoxaprop-ethyl [HOE-33171: Ethyl-2-(4-(6-chloro-2-benzoxazolyloxy)phenoxy)propanoate] and its metabolites [HOE-53022: 2-(4-(6-chloro-2-benzoxazolyloxy)phenoxy propanoic acid and HOE-54014: 6-chloro-2,3-dihydrobenzoxazol-2-one] in Various Matrices," Hoechst Analytical Method #AL48/86 and HRAV-1. This method was previously referred to as the new procedure dated September 5, 1986. This submission is an official "non-Draft" copy. This method uses either packed column chromatography or capillary column chromatography. Chromatograms are submitted for the packed column and capillary column.

The petitioner submits bridging data for rice grain and soybean seeds. The rice grain samples (Experiment #11-TX-83-005) were from the 1983 field residue trials. The rice grain samples were obtained from TX after one treatment at the rate of 0.40 lb ai/A and a 92-day PHI. The soybean seed samples were from the 1985 EUP trials. Soybean seed samples were obtained from the following trials:

Experiment No.	State	Treatment Rate (lb ai/A)	PHI (days)
21-85-414	AR	0.15 + 0.10	92
18-IL-85-29	IL	0.15	113
18-IN-85-301	IN	0.15	91
21-85-417	MS	0.15 + 0.10	103

Residues in the rice grain (Experiment #11-TX-83-005) were < 0.05 ppm as determined by both methods #AL3/84 and the new improved method. Residues in soybean seeds (Experiment #18-IL-85-29, 18-IN-85-301, 21-85-414, and 21-85-417) were < 0.05 ppm as determined by both methods #AL3/84 and the new improved method.

A comparison of recoveries of HOE 33171 from rice grain and soybean seeds using Method #AL3/84 vs. the improved method #AL48/86 is given below:

	Recoveries	
Rice Grain	AL3/84	AL48/86
0.02 ppm	70	78
0.05 ppm	49	84
0.10 ppm	77	78

Soybean Seed	Recoveries AL3/84	AL48/86
0.02 ppm	36	109
0.05 ppm	50, 52	74
0.10 ppm	45	87

RCB's Conclusion 5b and 5c

RCB concludes that deficiency 2a from RCB's review dated October 30, 1986 (see above) concerning submission of a non-draft copy of the analytical method and chromatograms is resolved.

RCB also concludes that deficiencies 1 and 2c from RCB's review dated October 30, 1986 (see above) are also resolved by submission of analyses of reserve samples of rice grain and soybean seeds.

However, RCB concludes that deficiencies 5b and 5c from RCB's August 21, 1986 review remain outstanding pending the following:

> BUD/COB/ECL needs to provide some testing of the subject procedure using the GLC capillary column. Alternatively, the petitioner could delete the GLC capillary column from the procedure and submit the revised analytical method.

The petitioner should also note the following:

> In the future (but not for tolerances on soybeans and rice) when fenoxaprop-ethyl tolerances are proposed, the petitioner will need to analyze residues of fenoxaprop-ethyl using the FDA multiresidue method protocols (read the Attachments to RCB's October 30, 1986 review).

RCB's Deficiency 7a

RCB reserves its conclusion on the adequacy of the proposed 0.05 ppm fenoxaprop-ethyl tolerance on soybeans and possibly soybean fractions. Pending a successful method trial, RCB's questions concerning metabolism, analytical methods, and storage stability are resolved for the proposed use on soybeans and rice only. However, additional residue data reflecting the proposed use and shorter PHI's are needed. Since the time from before bloom to maturity can be as short as 60 days, RCB

requires some residue data for PHI's of approximately 60 days for the proposed use (i.e., soybeans treated before bloom). The data base upon which to establish a 0.05 ppm tolerance on soybean and soybean fractions, especially for early maturing varieties, is too scant.

Petitioner's Response to Deficiency 7a

The petitioner has submitted a revised label with the following statement added:

> "Do not apply Whip 1EC Herbicide less than 60 days before harvesting soybeans."

The petitioner submits an additional metabolism study to support the idea that no detectable residues would be present in soybean seeds as a result of the proposed use. The study is "^{14}C-HOE-33171 Field Dissipation Study in Soybeans," Borriston Laboratories, Inc., Borriston Project Number 1901, March 3, 1982, Tab D-1. Soybeans were treated with HOE-33171 (labeled with ^{14}C in the benzoxazolyl ring) at the rate of 0.22 lb ai/A either at the first trifoliate leaf stage or at the first trifoliate leaf stage and 40 days later. ^{14}C levels in the whole plant after one or two treatments at a 0-day PHI were a maximum of 27.4 ppm. Radiocarbon levels from a single treatment declined in leaves to 0.020 to 0.023 ppm through the 120-day growing season. Residues in leaves from the split application decreased to 0.015 ppm at a 39-day PHI, increased to 5.84 ppm immediately after the second treatment (40 days), decreased to 0.847 ppm at day 60, and increased to 2.87 to 6.05 ppm by day 90 (probably due to dessication). Radioactivity in stems from one treatment was 0.241 ppm at a 14-day PHI, decreased to < 0.006 ppm at 60- and 90-day PHI's, and increased to 0.15 to 0.37 ppm at a 120-day PHI. Radioactivity in stems from two treatments were 0.559 ppm at 14 days after the first treatment, 0.794 ppm immediately after the second treatment (40 days), 0.117 to 0.137 ppm at 90 days, and 0.179 to 0.379 ppm at 120 days. Radioactivity in roots of soybeans over the 120-day study ranged from 0.030 to 0.427 ppm for one application and 0.027 to 0.562 ppm for two applications. Radioactivity in bean pod samples for one application was < 0.006 ppm (90-day PHI) and < 0.006 to 0.010 ppm (120-day PHI). Radioactivity in bean pods from two treatments was 0.174 to 0.227 ppm on day 90 and 0.152 to 0.267 ppm on day 120 of the study. Radioactivity in beans at 90 and 120 days after one application was < 0.006 ppm. Radioactivity in beans after two applications were 0.034 to 0.035 ppm on day 90 of the study and 0.025 to 0.043 ppm on day 120 of the study.

RCB's Conclusion 7a

The petitioner must submit more residue data for the 60-day PHI for soybeans and processed commodities resulting from treatment prior to bloom. RCB continues to consider the present data base to be too scant to establish a 0.05 ppm tolerance on soybeans and soybean fractions, especially for early maturing varieties. The only available soybean processing studies are for soybeans treated at bloom.

Alternatively, a 90-day PHI could be proposed by the petitioner on a revised Section B/label (see also results of the soybean metabolism study above at a 90-day PHI) and accepted by RCB without additional residue data.

RCB's Deficiency 8

RCB reserves its conclusion on the adequacy of the proposed 0.05 ppm fenoxaprop-ethyl tolerance on rice grain and straw. Pending a successful method trial, RCB's questions concerning metabolism, analytical methods, and storage stability are tentatively resolved. However, additional residue data reflecting the proposed use and shorter PHI's (i.e., approximately 52 days) are needed for rice.

Petitioner's Response to Deficiency 8

The petitioner has submitted a revised label with the following statement added:

> "Do not apply Whip 1 EC Herbicide less than 75 days before harvesting rice."

The petitioner summarizes the data base on rice to argue that no detectable residues are expected on rice grain in typical use situations.

RCB's Conclusion 8

The petitioner must submit a revised Section B/label with a restriction against feeding or grazing rice straw (for which there is grower control). This is needed because some low residues were found in rice straw, such as radioactive residues of 1.1 ppm at a height of 0 to 10 cm 106 days after application of 0.1 lb ai/A.

The revised Section B/label should also contain a 90-day PHI for rice, since PHI's of residue data start at approximately 80 days but are primarily longer.

The revised Section B/label should also restrict the number of applications to one, since most of the residue data on rice are for one application.

Alternatively, additional residue data reflecting a 75-day PHI and two applications could be submitted along with the restriction on straw.

RCB's Deficiencies 9a and 9b

No cattle or poultry feeding studies have been submitted. Soybeans, soybean hulls, rice straw, and hulls may be fed to livestock.

For the proposed use on soybeans and rice, RCB has tentatively concluded that cattle and poultry feeding studies will not be required. However, if the proposed use on soybeans and rice is replaced or finite tolerances are proposed in the future, then the petitioner will need to submit these studies for review.

RCB must review the results from the method trial and additional residue data that are requested before making a final conclusion on the need for cattle and poultry feeding studies.

Petitioner's Response to Deficiencies 9a and 9b

Refer to Deficiencies 5b, 5c, 7a, and 8 above.

RCB's Conclusion 9a and 9b

RCB continues to await resolution of deficiencies 5b, 5c, 7a, and 8 above before making a final conclusion on the need for cattle and poultry feeding studies.

Other Deficiencies

The following page was submitted in the meeting between RCB and the petitioner on September 10, 1986:

WHIP® Herbicide - Soybeans

- Maximum single application - 0.20 lb ai/A
- Maximum split application - 0.15 lb ai/A + 0.10 lb ai/A

WHIP® Herbicide - Rice

Maximum label rate: 0.20 lb ai/A

Restricted to a total of 0.20 lb ai/A/season

This page should be incorporated in the label directions for soybeans and rice.(i.e. The split application for soybeans is not contained in the body of the label for soybeans. The maximum of 0.2 lb ai/A/season is not contained in the body of the label for rice). Also, the maximum lb ai/A/season should be specified for soybeans.

Note #3 on the rice label (page 7) states "Do not apply Whip 1 EC Herbicide after the late tillering stage of the rice development (but prior to panicle initiation)." However, a conflicting statement for red rice appears on page 6 of the label:

> "Apply when red rice is in the panicle initiation stage of growth."

These two conflicting statements must be resolved.

Other Considerations

An International Residue Limit (IRL) Status sheet was attached to RCB's review of February 4, 1986. There are no Codex, Canadian, and Mexican tolerances for fenoxaprop-ethyl on soybeans and rice. Therefore, no compatibility questions exist with respect to Codex.

Recommendations

RCB recommends against the establishment of the proposed tolerance of 0.05 ppm fenoxaprop-ethyl on soybeans, rice, and rice straw for reasons given in Conclusions 5b, 5c, 7a, 8, 9a, and 9b, and also under "Other Deficiencies" above.

cc: RF, Circu, Reviewer - N. Dodd, EAB, EEB, FDA, D. Marlow, TOX, PM #23, PP#6F3316, PMSD/ISB-Eldredge
RDI:J.H.Onley:11/12/86:R.D.Schmitt:11/12/86
TS-769:RCB:CM#2:RM810:557-1681:N.Dodd: Kendrick & Co:11/17/86

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