1278-A

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

DEC 30 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#6F3316 and ID #8340-EG (RCB Nos. 1731 and 1732). Fenoxaprop-ethyl (HOE 33171) on Soybeans and Rice. Amendments Dated November 14, 1986 and December 8, 1986.

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

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

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

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

The petitioner, American Hoechst Corporation, submits amendments dated November 14, 1986 and December 8, 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 amendments are submitted in response to RCB's reviews of October 30, 1986 and November 20, 1986 and a meeting on December 3, 1986. The amendments consist of a revised label dated December 8, 1986, a revised analytical method dated November 12, 1986, and a letter dated November 14, 1986.

The deficiencies listed in the November 20, 1986 review and discussed in the December 3, 1986 meeting are outlined below, followed by the petitioner's responses and RCB's discussions/conclusions.

Deficiencies 5b and 5c

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).

Petitioner's Response to Deficiencies 5b and 5c

The petitioner has submitted a revised analytical method dated November 12, 1986 which deletes the GLC capillary column from the procedure.

RCB's Conclusion #5b and 5c

Deficiencies #5b and 5c are resolved by submission of the revised analytical method. If at any time the petitioner seeks to put the capillary column back into the analytical methodology, then a new method trial should be initiated.

Deficiency #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.

Petitioner's Response to Deficiency #7a

The petitioner submits a revised label dated December 8, 1986 which adds the following statement:

> "Do not apply Whip 1EC Herbicide less than 90 days before harvesting soybeans."

RCB's Conclusion #7a

Deficiency #7a is resolved by submission of the revised label.

Deficiency #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.

Petitioner's Response to Deficiency #8

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

> "Do not graze or feed rice straw to livestock."

> "Do not apply Whip 1EC Herbicide less than 90 days before harvesting rice."

"Do not make more than two applications of Whip 1EC Herbicide per growing season and do not apply more than 2.4 pints (0.30 pounds of active ingredient) per acre per growing season."

RCB's Conclusion #8

RCB agreed in the meeting on December 3 that the residue data support two applications with the maximum application of 0.30 lb ai/A/season.

Deficiency #8 is resolved by submission of the revised label.

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 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.

Petitioner's Response to Deficiencies #9a and 9b

The petitioner has resolved deficiencies 5b, 5c, 7a, and 8.

RCB's Conclusion #9a and 9b

RCB concludes that cattle and poultry feeding studies will not be required.

No detectable residues are expected to occur in meat, milk, poultry, and eggs as a result of the proposed use on rice and soybeans. Therefore, RCB concludes that this use falls in category 3 of section 180.6(a) with respect to residues in meat, milk, poultry, and eggs.

Deficiencies #9a and 9b are resolved by resolution of deficiencies 5b, 5c, 7a, and 8.

"Other Deficiencies" Listed in RCB's Review of November 20, 1986

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 1EC 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.

Petitioner's Response to "Other Deficiencies"

The petitioner has submitted a revised label with addition of the following statement for soybeans:

"Do not make more than two applications of Whip 1EC Herbicide per growing season and do not apply more than two pints (0.25 lbs of ai) per acre per growing season."

The revised label also adds a statement which limits application to rice to 0.30 lb ai/A/season (as RCB agreed in the meeting of December 3, 1986).

Concerning red rice, the petitioner has revised page 6 of the rice label to read as follows:

> "For suppression of red rice, apply Whip 1EC Herbicide at 1.2 pts/A when the red rice is in the 4-leaf stage of growth."

Note #3 on page 7 of the rice label is revised by replacing the term "rice development" with the term "rice crop development" to read as follows:

> "Do not apply Whip 1EC Herbicide after the late tillering stage of the rice crop development (but prior to panicle initiation)."

Since red rice (which has a red seed coat) is a weed, this statement more clearly applies to the crop of rice (which has a brown seed coat).

RCB's Conclusion for "Other Deficiencies"

The "Other Deficiencies" are resolved by submission of the revised label.

Other Considerations

An International Residue Limits (IRL) Status sheet is attached. There are no Codex, Canadian, and Mexican tolerances for fenoxaprop-ethyl on soybeans and rice. Therefore, no compatibility questions exist with respect to Codex.

Recommendation

TB and EAB considerations permitting, RCB recommends for the establishment of the proposed tolerance of 0.05 ppm for fenoxaprop-ethyl on soybeans and rice grain.

Attachment 1: International Residue Limit Status Sheet

cc: RF, Circu, Reviewer - N. Dodd, EAB, EEB, FDA, TB, PM #23, PP#6F3316, PMSD/ISB-Eldredge

RDI: J.H. Onley:12/17/1986:R.D. Schmitt:12/17/86
TS-769:RCB:CM #2:RM 810:557-1681:N. Dodd:Kendrick & Co.:12/23/86

INTERNATIONAL RESIDUE LIMIT STATUS

J. Jones 12/19/86

CHEMICAL Fenoxaprop-ethyl

CODEX NO. ____

CODEX STATUS:

☑ No Codex Proposal Step 6 or above

Residue(if Step 8): ____

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 6F3316

RCB Reviewer N. Gould

Residue: fenoxaprop-ethyl and its metabolites*

Crop(s)	Limit (mg/kg)
soybeans	0.05
rice	0.05

CANADIAN LIMITS:

☑ No Canadian limit

Residue: ____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

☑ No Mexican limit

Residue: ____

Crop(s)	Limit (mg/kg)

NOTES: *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

Form revised 1986