9-8-87

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

SEP 8 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA MIRD 401992-01. [RCB # 2387, 2388,2425]
PP6E3443/FAP6H5507: Iprodione in or on Rice, Rice Straw and Rice Hulls. Letter of 5/12/87.

TO: L. Rossi, PM 21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

THRU: R. S. Quick, Section Head, RSQ
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

FROM: R. W. Cook, Chemist RWCook
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Conclusions:

Deficiencies #4, 5, 6, and 9 have been resolved.

Deficiencies #1, 2, 3, 7, and 8 have not been resolved.

Recommendations:

We recommend against the proposed tolerances for the reasons disucussed below under deficiencies 1, 2, 3, 7 and 8.

Discussion:

The petitioner, Agrochemical Divison, Rhone-Poulenc, Inc., has responded to our comments in our previous review (R. W. Cook, 3/17/87). We shall repeat the deficiency, provide the petitioner's response, and finally make comments or conclusions on the petitoner's response.

Deficiency #1:

Additional residue data reflecting label instructions for aerial application are needed. Major rice production areas

1/6

must be represented: Arkansas, Louisiana, Mississippi, Texas, and California.

Petitioner's Response:

The petitioner replies that he believes the residue data are adequate to establish tolerances. Aerial applications were made in Arkansas, Louisiana, Mississippi, and Texas. Residue values in these four aerial trials were comparable to residue levels from ground trial. The highest residues in grain and straw are found by ground application. Other residue trials for stone fruits and bean hay show similar results, with higher residues from ground application than from aerial application. The petitioner notes that the same concentration was employed in both aerial and ground application (10 gallons per acre).

RCB comments and conclusions:

We are not convinced that aerial application to rice is equivalent to aerial application to stonefruit tree crops or even bean hay. We further note that the label instructions for rice provide direction to "Apply Rovral® as a broadcast spray using aerial equipment." yet only 1/3 of the field residue trials employ aerial application. We conclude this deficiency is not resolved.

Deficiency #2

Additional information on the manner and method of sampling should be provided. We question whether representative samples of rice grain and straw can be gathered from combine or hopper after combining plots as small as 4 x 20 feet. Further, we do not believe a single sample analysis is adequate representation for each location. Replicate samples should be obtained and duplicate analysis conducted.

Petitioner's Response:

The petitioner replies that the smaller plots had enough replicates totaling a minimum of 400 square feet. A description and photograph of a small scale combine for rice is provided. The grain hopper was large enough to allow random aliquoted grain samples. The petitioner is surprised that a single analysis for each location is not adequate and claims the EPA guidelines do not dictate duplicate samples.

RCB comments and conclusions:

The discussion of the field design and harvesting practices has alleviated our concerns about the manner and method of sampling and about the combine used to harvest the rice grain. We do not consider the small number of trials adequate to reflect major rice growing areas. Furthermore, the residue data reflect a single sample analysis per residue component per field trial. Additional residue studies reflecting the proposed use (which is aerial) are

needed as stated previously. We suggest the petitioner collect replicate samples in his residue trials and run duplicate analyses.

Deficiency #3

> The label prohibition against use on California rice is not practical. Additional residue data reflecting aerial application on California rice are needed. Alternately, a persuasive argument that the label prohibition is practical may be submitted.

Petitioner's Response:

The target pest, sheath blight (Rhizoctonia solani), has not been found in California and the effectiveness of Rovral® against other Rhizoctonia species in California has not been established. For these reasons, the label included a prohibition against use in California. However, residue data were collected in California and submitted under separate cover.

RCB comments and conclusions:

In regard to the label restriction against use in California, RCB has no objection to retaining the prohibition, as long as the prohibition is not based on the absence of adequate residue data. Since the petitioner has submitted California residue data, we can deliberate the adequacy of the residue data rather than the practicality of the label restriction. The residue date are discussed below.

Deficiency #4

> The petitioner should advise us of the crop stage at each application, since label directions indicate aplication at joint movement-booting and again, no later than heading. The submitted residue data are reported at intervals after planting. This information should help in determining whether the residue data reflect the proposed use.

Petitioner's Response:

The petitioner has supplied information on the crop stage. Further, the label will be modified to direct the second application no later than 75% heading. With last application at 75% heading, the PHI will be 35 days, i.e., the time between 75% heading and grain maturity.

RCB comments and conclusions:

This deficiency is resolved.

Deficiency #5

The petitioner should clarify whether study TX-434285-105

reflects two or three applications.

Petitioner's Response:

The petitioner states that the residue data obtained in TX-434285-105 reflect two applications. The other treatments were not sampled for residue purposes.

RCB comments and conclusions:

This deficiency is resolved.

Deficiency #6

The petitioner should comment upon the differing results of study TX-434285-113 and the ^{14}C study. In the first case, the data indicate a concentration factor of 5X is appropriate for rice hulls, while the ^{14}C study shows less that 1X in certain processed fractions. The petitioner should resolve this conflict.

Petitioner's Response:

Several differences are mentioned. The ^{14}C study used laboratory scale equipment and samples in the gram range, while TX-434285-113 used pilot scale equipment and pound size samples. The ^{14}C rice samples were not combined, while the TX samples were combined. The petitioner does not consider the samples equal. The cold study included analysis for RP-26019, RP-30228, and RP-32490, while the ^{14}C study included total ^{14}C residues of RP-26019, RP-30228, RP-32490, trace metabolites, aqueous fractions, and bound residues.

RCB comments and conclusions:

The petitioner's response adequately resolves the above deficiency.

Deficiency #7

The petitioner should propose an appropriate feed additive tolerance for rice bran.

Petitioner's Response:

The petitioner has proposed a feed additive tolerance at 30 ppm in rice bran, based upon a concentration factor of 3X from rough rice to rice bran.

RCB comments and conclusions:

We are unable to draw conclusions on proposed feed additive tolerances until final conclusions can be drawn regarding residue levels in the raw agricultural commodity rice grain.

Deficiency #8

The petitioner should be advised to add the following: Do not apply in areas where catfish and crawfish are commercially cultivated.

Petitioner's Response:

The petitioner reports that acute toxicity studies for crayfish and catfish have already been submitted and there is no need for the restriction.

RCB comments and conclusions:

The petitioner should be aware that the restriction is not based upon toxicity to aquatic organisms. The petitioner failed to note that the restriction is applicable to commercial fish production areas. The restriction is intended to preclude residues in crayfish resulting from pesticide applications to rice. The alternative to the label restriction is the submission of appropriate and adequate residue data for catfish and crawfish tissues. This deficency is not resolved.

Deficiency #9

We note the statement on page 4, Book 2, Section D, that the petition is confidential and trade secret, except for the method. The analytical method is inserted about 100 pages later and bears the claim "Confidential". The method submission is not adequate. For publication in PAM, we require a "clean" copy without any claim of confidentiality; the ambiguous statement mentioned above will not substitute.

Petitioner's Response:

A non-confidential copy of the analytical method is included in the submission of the California rice residue data.

RCB comments and conclusions:

This deficiency has been resolved.

DETAILED CONSIDERATIONS:

Residue Data - CA Rice. MIRD 401992-01.

The petitioner submits additional residue data for two trials in CA; neither trial involved aerial application and neither trial had replicate plots. Trial 0640486-156 (5' x 50') was conducted in Richvale, CA, and trial 0640486163 (5' x 30') was conducted in Robbins CA. Both trials included two applications (8/12/86 booting stage and 8/26/86 heading stage) at 0.5 lb. a.i./A in 20 gallons of spray per acre by backpack sprayer at 1.8 mph. Grain and straw samples were obtained 32 days after last application. A portable

grain thrasher was used to separate rice grain from straw.

Rhone-Poulenc Method No. 162 was used to analyze the rice samples. The method is reproted to be sensitive to 0.05 ppm each of RP-26019, RP-30228, and RP-32490. Recovery values are reported at >95%.

Residues in CA field trials described above:

		RP-26019	RP-30228	RP-32490	Total
Richvale, CA					
Rice grain	2 x 0.51b	7.26	1.05	0.14	8.45
Rice straw	2 x 0.51b	25.38	6.63	0.09	32.10
Robbins, CA					
Rice grain	2 x 0.51b	4.22	0.21	0.10	4.53
Rice straw	2 x 0.51b	28.68	7.55	0.09	36.32

While this residue data is useful in our consideration, it does not resolve the deficiency regarding aerial application residue data. We are not able to draw final conclusions regarding the exepcted level of residues in rice grain or rice straw from the use as proposed.

cc: R.F., Circu, R. W. Cook, PP6E3443/FAP6H5507, TOX, PMSD/ISB.
TS-769:RCB:Reviewer:RWCook:Date:8/20/87:CM#2:RM:810:557-7324
RDI:Section Head:RSQuick:Date:9/4/87:RDSchmitt:Date:9/4/87