US EPA ARCHIVE DOCUMENT

PMSD/ISB

1779

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

26 AUG 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#6E3361 (RCB No. 2153) - Benomyl on Potatoes (For South Florida Only) - Amendment Dated December 9, 1986 - Accession Nos. 400867-00 and 400867-01

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

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

TO: Hoyt Jamerson, Minor Use Officer
Registration Support and Emergency Response Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

The petitioner, IR-4, has now submitted an amendment to PP#6E3361. This amendment consists of a letter dated December 9, 1986, an amended Section D containing a potato processing study, and an amended Section G intended to support the petitioner's view that use of benomyl on potatoes will be economical only in southern Florida. This amendment was submitted in response to RCB's review of PP#6E3361 dated June 6, 1986 (F. Boyd).

Summary of Deficiencies Remaining to be Resolved

Note: All deficiencies are fully discussed in the Detailed Considerations Section that follows in this review.

1. Deficiency #1 concerning regional registration remains outstanding. The information available at this time does not satisfy the criterion regarding expanded use as stated in EPA's Policy Statement on Minor Uses of Pesticides, FRN #OPP36114, I(B), "(1) Likelihood of expanded use."

2. Deficiency #2 concerning plant and animal metabolism remains outstanding.

3. Deficiency #3 concerning the adequacy of the analytical method for benomyl remains outstanding since issues relating to the plant and animal metabolism studies have to be resolved.

4a. Deficiency #4a concerning the need for residue data reflecting all growing areas of the United States remains outstanding.

4b. Deficiency #4b pertaining to the requirement of an adequate potato processing study needs to be fulfilled.

Recommendations

RCB recommends against establishment of the proposed tolerance of 0.2 ppm for benomyl and its metabolites containing the benzimidazole moiety on potatoes because of Deficiencies #'s 1, 2, 3, 4a, and 4b stated above.

Detailed Considerations

The deficiencies listed in the June 6, 1986 review are outlined below, followed by the petitioner's responses and RCB's discussions/conclusions:

RCB's Deficiency #1

RCB concludes that consideration for the establishment of a benomyl tolerance should not be limited to southern Florida since the pest white mold (Sclerotinia sclerotiorum) has been observed in other areas of the United States.

Petitioner's Response to Deficiency #1

The petitioner has submitted reports from Washington and Oregon which indicate that no loss of yield of potatoes occurred in 1980 and 1977, respectively, as a result of Sclerotinia sclerotiorum. These reports are "A Review of the Epidemiology of Sclerotinia and Attempts to Control it in Potato," Gene Easton and Michael Nagle, Annu. Wash. State Potato Conference, Washington, and "Sclerotinia Stalk Rot of Potatoes," Dr. J.C. Zalewski, Oregon State University, November 17, 1977.

The petitioner indicates that potato extension specialists in Maine and Idaho indicated in phone conversations that there are no data from Maine and Idaho that indicate whether white mold causes decreases in yield.

The petitioner refers to the original Section G of PP#6E3361 as indicating that white mold is not a significant problem in California and Colorado. In a "Minor Use Pesticide Clearance Request Form" contained in the original Section G, Colorado makes the following statement dated September 1, 1985: "We have not detected serious problems with the disease yet,

but are concerned about its potential threat." California indicated in a July 23, 1985 memorandum that white mold is not and is not likely to be a problem in California.

The petitioner also submitted data which indicate that Florida has a white mold problem.

RCB's Discussion #1

RCB has previously discussed white mold with Dr. Jim Dwyer, Area Crop Specialist, University of Maine, who indicated in a phone conversation on May 6, 1986 that white mold has recently become a serious problem in central Maine. Dr. Gary Kleinschmidt indicated in a phone conversation on May 7, 1986 that white mold has been a problem in Idaho since the early 1970's.

RCB discussed white mold with Dr. F.E. Manzer, Professor, Plant Pathology, Potatoes, University of Maine and Dr. David Thompson, Extension Crop Specialist, Maine on August 7, 1987. They both indicated that white mold is a serious problem in a limited area. In 1984 and 1985, some farmers had losses up to 50 percent because of white mold although loss from white mold for Maine as a whole was low. White mold is spreading. Botran is not very effective. Rovral has been used. Dr. Thompson suggested that EPA call back in the fall when he will have data from studies now in progress.

RCB also discussed white mold with Dr. D.A. Johnson, Extension Plant Pathologist, Washington State University. In Washington state, Rovral is being used on white mold. Botran is not effective. Growers believe that spraying increases yields. Levels of white mold increased in Washington about 5 years ago.

Note: When considering geographically limited residue data, EPA's Policy Statement on Minor Uses of Pesticides (see Federal Register, Vol. 51, No. 63, April 2, 1986) specifies the following criteria:

1. likelihood of expanded use
2. quality of the available residue
3. availability of data on similar crops
4. variability of the residue data base
5. toxicity of the pesticide.

The available information provided by the petitioner to date clearly does not satisfy the criterion regarding expanded use.

RCB's Conclusion #1

Deficiency #1 remains outstanding. White mold is a pest in areas of the country other than southern Florida. It is increasing as a problem in several areas. The permanent tolerance proposal for benomyl should not be limited to southern Florida. The use of benomyl, Rovral, or any other compound to combat white mold on an important crop grown nationally such as potatoes should receive a just appraisal in all affected areas. If any compound proves to be effective against white mold, then all areas should benefit from that compound. Until residue data have been generated for benomyl on potatoes in the major potato-growing areas, it seems that a section 18 for controlling white mold in the southern portion of Florida would be more appropriate than a permanent tolerance.

RCB's Deficiency #2

Since the potato crop can present a high dietary exposure and there are certain plant and animal metabolism issues that the registrant for benomyl needs to resolve, RCB must render an unfavorable conclusion on the nature of the residue in potatoes and animal commodities at this time.

Petitioner's Response to Deficiency #2

IR-4 understands that DuPont has already submitted most of the plant and animal data needed to resolve the metabolism issues discussed in the Benomyl Registration Standard.

RCB's Discussion/Conclusion #2

Two cow metabolism studies [one on ^{14}C-benomyl and one on ^{14}C-carbendazim (i.e., MBC)] have been reviewed (K. Arne review dated January 30, 1986) since issuance of the Agency's Residue Chemistry Chapter (September 25, 1984 updated October 9, 1985) of the Benomyl Registration Standard. These studies contain some metabolism information on milk, liver, and kidney. If additional plant or animal metabolism studies have been submitted for review, the petitioner should reference them. At this time, it appears that the issues of plant and animal metabolism as detailed in the Residue Chemistry Chapter of the Benomyl Registration Standard have not been addressed completely.

Deficiency #2 remains outstanding.

RCB's Deficiency #3

RCB will reserve its conclusions on the adequacy of the analytical method for benomyl until the plant and animal metabolism issues discussed in the Benomyl Registration Standard have been resolved.

Petitioner's Response to Deficiency #3

The petitioner states that the analytical method is adequate for analyses of benomyl residues in plant tissues.

RCB's Conclusion #3

Deficiency #3 remains outstanding since deficiency #2, which deals with certain plant and animal metabolism issues, has not been resolved.

RCB's Deficiency #4a

Since white mold (Sclerotinia sclerotiorum) is not a pest that is limited to southern Florida (see the Proposed Use and Residue Data sections of this review), the petitioner will need to submit appropriate residue data from the following states: Idaho, Oregon/Washington, North Dakota, Minnesota, Wisconsin, Maine, California, and Colorado (see also RCB's December 8, 1983 memorandum on IR-4 Crop Grouping Comments).

Petitioner's Response to Deficiency #4a

The petitioner has submitted an amended Section G intended to support the idea that white mold is not a pest to areas other than southern Florida. (This submission is discussed under RCB's Deficiency #1 above.)

RCB's Conclusion #4a

As discussed under Deficiency #1 above, RCB does not consider white mold to be limited as a pest to southern Florida. Therefore, the residue data requested in Deficiency #4a are needed. Deficiency #4a remains outstanding.

RCB's Deficiency #4b

There are no data presented for benomyl residues in processed potatoes. Residue data on processed potatoes will be necessary in order to evaluate the need for a Food Additive Tolerance.

Petitioner's Response to Deficiency #4b

The petitioner has now submitted a potato processing study that was conducted in 1985-1986. Potatoes in a field in Florida were treated three times with benomyl (50 WP formulation) at the rate of 0.75 lb ai/A. Applications were made with ground equipment. Intervals between applications were 25 and 17 days. Potatoes were harvested 25 days after the last treatment. Residues were determined in fresh potatoes ("wet") and in potatoes that had been chopped and freeze-dried for approximately 2 days to remove water content ("dry"). (The weight of the freeze-dried potatoes was 20% of the weight of the fresh potatoes.) The analytical method that was used was Kirkland et al., J. Agricultural and Food Chemistry 21: 368 (1973) with modifications. The petitioner indicates that the sensitivities of the method for both wet and dry potatoes were 0.1 ppm for MBC (methyl-2-benzimidazolecarbamate) and 0.3 ppm for 2-AB (2-aminobenzimidazole). (Benomyl residues are converted to MBC and determined as MBC. 2-AB can be quantitated also.) Samples of potatoes were stored frozen and analyzed 8 months after sampling. Residues in wet and dry potatoes were all < 0.1 ppm MBC and < 0.3 ppm 2-AB. Recoveries from dry potato tubers at fortification levels of 0.1 and 0.5 ppm for each compound were 50 to 52% benomyl (as MBC), 80 to 84% MBC, and 60% 2-AB. Recoveries from wet potato tubers fortified with 0.1 and 0.5 ppm for each compound were 118 to 120% benomyl, 108 to 120% MBC, and 57 to 59% 2-AB.

RCB's Discussion/Conclusion #4b

Processed commodities of potatoes are granules, potato chips, wet peel, and dry peel. Feeds are cull potatoes and processed potato waste. Potato waste is wet or dried potato pulp, wet or dry potato peel, or a mixture of these commodities. (Refer to Dr. Charles Trichilo's memorandum dated February 20, 1987, which is attached.)

RCB concludes that the submitted potato processing study is not adequate. Residue data on granules, potato chips, wet peel, dry peel, cull potatoes, and processed potato waste are needed. Although not required, RCB suggests that the petitioner submit a potato processing protocol before undertaking a study. RCB refers the petitioner to the Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, which includes the following paragraph under Section 171-4(c)(2)(iv), processed food/feed studies:

"Processing studies must simulate commercial practices as closely as possible. RAC samples used in processing studies must contain field-treated detectable residues, preferably at or near the proposed tolerance level, so that concentration

factors for the various byproducts can be determined. This may require field treatment at exaggerated application rates to obtain sufficient residue levels for processing studies. Processing studies utilizing spiked samples are not acceptable, unless it can be demonstrated that the RAC residue consists entirely of a surface residue."

"If the processing studies indicate that residues concentrate on processing, then a Food Additive Petition, including a Food Additive Regulations proposal, is required. If the processing of the RAC may result in alteration of the residue, then a radiolabeled processing study to determine the nature of the residue in food/feed as consumed may be needed. If significant alteration of the residue occurs, and the additional residue components are of toxicological concern, then the Food Additive Regulation must include the additional residue components."

Deficiency #4b is not resolved.

Other Considerations

An International Residue Limits (IRL) Status sheet was attached to RCB's review of PP#6E3361 dated June 6, 1986. No benomyl tolerances on potatoes are established outside the United States. Therefore, no compatibility problems exist with respect to Codex.

Attachment 1: RCB memorandum of February 20, 1987 on Potato Waste

cc: RF, Circu, Reviewer-N.Dodd, TOX, PP#6E3361, PM#43, BUD-W. Phillips, PMSD/ISB-Eldredge, F.Boyd-RCB
RDI:J.H.Onley:8/17/87:R.D.Schmitt:8/17/87
TS-769:RCB:CM#2:RM800D:X1681:N.Dodd:Kendrick & Co.:8/19/87

7

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

FEB 20 1987

MEMORANDUM

SUBJECT: Potato Waste as a Livestock Feed Item.

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

TO: RCB Staff

The use of potato processing waste as an animal feed is discussed in a recent memo by Sami Malak and Philip Errico (December 22, 1986, entitled "Potato Waste as a Livestock Feed. Documentation for Requiring Residue Data for Potato Processing Waste"). In this memo, it was apparent that the Processed Commodities of potato should include wet and dried peel, and the Feeds should include processing potato waste. Furthermore, the memo recommends that in calculating the dietary intake of livestock, the percentages cited in the Harris Guide should be used.

After careful evaluation of the Malak/Errico's memo, I have concluded that potato waste is a significant feed item of livestock and that the Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, dated October, 1982, should be amended from the following version:

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	SOWS & BOARS	FINISHING
Potato	Tuber	Granules Chips Dried	Cull potatoes	30	30	7	20	50	50

8

To the following version:

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY BROILERS	& LAYING HENS	SOWS BOARS	& FINISHING
Potato Tuber		Granules Chips Wet peel	Cull potatoes Processed potato	30	30	7	20	50	50
		Dry peel	waste	50	25	NU	10	50	50

Potato waste is defined as wet or dried potato pulp, wet or dry potato peel, or a mixture of these commodities. Tolerances for pesticide residues should be established in/on processed potato waste using the maximum reported level in/on cull potatoes, granules, wet peel or dry peel.

This policy on potato waste is effective immediately for all uses on potatoes. For actions reviewed between now and December 31, 1987, the RCB recommendation should state that a favorable recommendation is contingent on submission of data on potato waste within one year. After December 31, 1987, the reviews of actions on potatoes should include consideration of potato waste as an animal feed. All temporary tolerance petition reviews which include a proposed use on potatoes should now include a requirement for data on potato waste in the list of data necessary for a permanent tolerance.

The subdivision O guidelines are being revised to reflect this change.

Attachment: Malak/Errico's memo, dated 12/22/86 (8 pages).

cc: Circu, RF, SF (potatoes), Cultural Practices File (potatoes), S. Malak, P. Errico, R. D. Schmitt, John Melone/HED, Anne Barton/HED, and E. Tinsworth/RD.
RDI: P. V. Errico: 2/11/87: R. D. Schmitt: 2/10/87
TS-769:RCB/HED:RM814A:S.Malak:X-557-4379:2/11/87