pm 84/ISB
0828

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

JUN 6 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#6E3361 - Benomyl on Potatoes (For South Florida, Only) - Evaluation of Analytical Methods and Residue Data - Accession No. 261143, RCB No. 584

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

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

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

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

Interregional Research Project No. 4 (IR-4) and the Agricultural Experiment Station of Florida request the establishment of a tolerance for residues of the fungicide benomyl (methyl-1-(butylcarbamoyl)-2-benzimidazolecarbamate) and its metabolites containing the benzimidazole moiety (calculated as benomyl) in or on the raw agricultural commodity (RAC) potatoes at 0.2 part per million (ppm).

Benomyl tolerances are established for several RAC's (40 CFR 180.294) ranging from 0.1 ppm in meat, milk, poultry, and eggs to 50.0 ppm in "bean vine forage." Other root crop tolerances have been established at 0.2 ppm for sugar beets and turnips. A Residue Chemistry Data Chapter (September 25, 1984, updated October 9, 1985) of the Benomyl Registration Standard has been prepared. A letter of authorization (December 11, 1985 - Marie M. Hodge of DuPont to H. Jamerson of EPA) has been submitted with the petition.

1

Conclusion:

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

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.

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.

4a. Since white mold (Sclerotinia sclerotium) 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: ID, OR/WA, ND, MN, WI, ME, CA, and CO (see also RCB's December 8, 1983 memorandum on IR-4 Crop Grouping Comments).

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.

5. An International Residue Limits Status sheet is attached. No benomyl tolerances on potatoes are established outside the United States.

Recommendations:

We recommend against the proposed tolerance of 0.2 ppm in the RAC, potatoes, because of reasons given in Conclusions 1, 2, 3, 4a, and 4b above.

Detailed Considerations

Formulation:

The formulation to be used on potatoes is Benlate® 50% WP, which is a 50 percent wettable powder formulation of benomyl,

technical grade (> 95% benomyl). All inerts in the formulation are cleared under section 180.1001. Other details, i.e., manufacturing process are discussed in our review of PP#4F1466 and also in the Registration Standard dated October 1, 1985.

Proposed Use:

Benomyl is to be applied at a rate of 0.5 to 0.75 lb ai/A as two foliar spray applications for control of Sclerotinia (white mold). Applications are made at 4 to 7 weeks after planting, or when disease is noted, followed by a second application 10 to 14 days later. Do not apply within 23 days of harvest.

The proposed use is to be limited to the subtropical area of Florida only. This area is defined as south of Orlando, Florida.

A restriction of use to the designated area of south Florida has been deemed practicable by the Benefits and Use Division (BUD) and Dr. Ray Webb, USDA potato specialist as indicated by the following March 24, 1986 memorandum of BUD (B.C. Smale):

> According to IR-4 surveys of Florida, California and Colorado, white mold of potatoes caused by Sclerotinia sclerotium is a serious disease only in Florida. I have confirmed these findings with Dr. Ray Webb, USDA potato specialist, and agree that white mold is unlikely to become a serious problem outside of Florida. White mold is favored by the Florida conditions of low temperature and high humidity experienced during growing season and causes 10 to 30 percent yield losses if untreated. Benomyl is the only effective product and has been used successfully for several years in Florida under the Section 18's specific exemptions.

While the IR-4 surveys of Florida, California, and Colorado provided useful information they are of limited value, because no consideration was given as to whether other States particularly the major potato producing areas were having any problems with white mold (Sclerotinia sclerotium). A May 6, 1986 telephone call to Dr. Jim Dwyer (Area Crop Specialist, University of Maine) of the Maine Agricultural Extension Service discovered that white mold is a serious problem in central Maine; this pest seems to have started about 2 years

ago. A May 7, 1986 telephone call to Dr. Gary Kleinschmidt (Ext. Prof. Potato Specialist, University of Idaho) discovered that white mold has been a problem in Idaho since the early 70's; the worst problem seem to be south of Burley, Idaho. Also, it was learned that some research on white mold has been done in the State of Oregon.

In view of this additional information, RCB concludes that white mold is a pest that is not unique only in the southern portion of Florida. Since white mold is a pest of national concern, RCB recommends that proper consideration be given to establishing a pesticidal tolerance on potatoes wherein all areas of the country are included. 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, DCN#OPP36114, I(B), "(1) Likelihood of expanded use. The petitioner must provide information that would allow the Agency to conclude that there is little likelihood of use of the pesticide outside of the geographically limited area. This would be the case when the range of the pest would be required to show that the pest is not known to occur outside of the proposed use area. Alternatively, the pest may be widely distributed but not of economic importance (i.e., not requiring pesticide control) to the production of the crop outside of the geographically limited area. Documentation of this would require information regarding where the crop is grown nationally, the range of the pest, and where the pest is of economic importance in the production of the crop. In all cases, the burden of proof is with the petitioner to provide information that would allow the Agency to conclude that there is little likelihood of use of the pesticide outside of the geographically limited area."

Nature of the Residue:

The metabolism and degradation of benomyl in beans, cotton, apples, oranges, and cucumbers, by foliar uptake, were discussed and concluded previously to be adequately defined in the review of PP#0G0936, February 20, 1970 by RCB (W.J. Boodee). These studies indicated that benomyl resulted in residues of methyl-2-benzimidazole carbamate (MBC) and 2-aminobenzimidazole (2-AB).

For some recent petition submissions involving the establishment of tolerances on minor crops, RCB has concluded that the nature of the residue was adequate. However, for the use of benomyl on major crops with high dietary exposure such as potatoes, RCB must consider the following issues (stated below in part) raised in the Agency's Residue Chemistry Data Chapter (September 25, 1984, updated October 9, 1985) of the Benomyl Registration Standard:

"NATURE OF THE RESIDUE IN PLANTS

The metabolism of benomyl in plants has not been adequately described. The following additional data are required:

- Data reflecting the distribution and metabolism of benzene ring-labeled [^{14}C]benomyl in (i) mature soybeans harvested 35 days after the last of two foliar applications at 0.5 lb ai/A (applied 14 days apart); (ii) mature rice (grain and straw) harvested 21 days after the last of two foliar applications at 1 lb ai/A (at booting and heading); (iii) peaches (fruit) harvested immediately after the last of two foliar applications (<3 weeks apart) at 1 lb ai/A; and (iv) sugar beets harvested 21 days after the last of 5 foliar applications at .25 lb a.i./A. In some instances it may be necessary to apply exaggerated rates to obtain sufficient metabolite residues for identification. Analyses should include hydrolysis and reextraction of plant residues and aqueous extracts to determine conjugated ^{14}C-residues of benomyl. If metabolism data differ significantly between these three crops, then metabolism data must be submitted for a representative crop in each crop group for which registered uses of benomyl exist.

Note: ^{14}C labeled treated crops should be analyzed by enforcement methodology to determine which benzimidazole containing moieties are determined by the method.

The available plant metabolism data for benomyl, though extensive, are not adequate for the following reasons: (i) representation of the metabolism of benomyl in the major raw agricultural commodities having tolerances for benomyl residues was poor; (ii) the major means of application (foliar spray) was poorly represented; and (iii) characterization of conjugated residues present in aqueous extracts and extracted plant residues was inadequate (refer to Discussion of the Data for details); and (iv) the available data submitted by the registrant are 10-20 years old and do not reflect state of the art methodology . . . ."

"NATURE OF THE RESIDUE IN ANIMALS

Conclusions:

Presently, the metabolism of benomyl [methyl 1(butylcarbamoyl)-2-benzimidazolecarbamate] (I) in animals is not adequately understood. Residues have not been characterized in the kidney, muscle or fat of ruminants, or in the eggs, liver, kidney, muscle or fat of poultry; thus the residues of toxi-

cological concern in these food items have not been determined. As a result, the adequacy of the established tolerance definition and the residue analytical methods for data collection and enforcement of tolerances for residues in these food items cannot be determined . . . ."

In view of the above, RCB must render an unfavorable conclusion on the nature of the residue for benomyl in potato and animal commodities until the registrant (E.I. du Pont de Nemours & Company) has addressed those issues of concern.

Analytical Methods:

The method used to collect residue data for this petition is that of Kirkland et al., J. Agric. and Food Chem. 21, 368 (1973). This method has undergone a successful method trial (PP#2F1192). Benomyl residues are converted to MBC and total benomyl/MBC residues are determined as MBC by HPLC. 2-AB can be quantitated on the same chromatogram, separately.

This method afforded a detectability of 0.1 ppm for MBC and 0.06 ppm for 2-AB. Recoveries at 0.1 and 0.5 ppm were 80 to 100 percent for MBC, 102 to 140 percent for benomyl and 32 to 40 percent for 2-AB.

At this time RCB must 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.

Residue Data:

Residue data are presented from four Florida, trials. Three of the trials were in the Homestead area with samples taken at 51, 61, and 64 days following the second of two applications at a rate of 0.5 lb ai/A. There were no residues of benomyl. The results are not really pertinent to the proposed use of 0.75 lb ai/A (maximum rate) and a PHI of 23 days.

The fourth Florida trial in Naples, Florida presents data following two applications of benomyl at each of two rates, 0.75 and 1.5 lb ai/A, with samples taken for analysis 23 days after the second application. These data show no total detectable residues (< 0.07 ppm) of parent plus MBC (< 0.01 ppm) or 2-AB (0.06 ppm) at either the 1X rate of 0.75 lb ai/A or the 2X rate of 1.5 lb ai/A. These data indicate that a residue level of 0.2 ppm for benomyl residues would not be exceeded by the proposed use in the areas of Florida where tests were done.

However, since white mold (Sclerotinia sclerotium) is not a pest that is limited to southern Florida (see the Proposed Use section of this review) the petitioner will need to submit appropriate residue data from the following States: ID, OR/WA, ND, MN, WI, ME, CA, and CO (see RCB's December 8, 1983 memorandum on IR-4 Crop Grouping Comments).

No processing data are presented in this petition for dehydrated potatoes, chips, or granules. This is a requirement that also needs to be fulfilled.

Meat and Milk, Poultry and Eggs:

The use of cull potatoes as a feed for poultry and livestock limits intake to 30 percent for cattle, 20 percent for poultry, and 50 percent for swine. At this time, RCB will reserve its conclusion on the adequacy of the established meat, milk, poultry, and eggs tolerances until more residue data have been submitted on potatoes and a potato fractionation study has been conducted.

Other Considerations:

An International Residue Limit Status sheet is attached. No Codex tolerance has been established for benomyl on potatoes. Thus, there is not a compatibility problem.

Attachments

cc: R.F., Circ., Boyd, TOX, EAB, EEB, PP#6E3361, FDA, PMSD/ISB, BUD-W. Phillips
RDI:JHOnley:5/21/86:RDSchmitt:5/21/86
TS-769:CM#2:RM810:FVBoyd:edited by:wh:6/4/86
87912:Boyd:C.Disk:KENCO:5/29/85:EK:VO

F. Ives
5/1/86

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Benomyl

PETITION NO. 6E3361
F. Boyd 5/1/86

CCPR NO. 69

Codex Status

/ / No Codex Proposal
Step 6 or above

Proposed U.S. Tolerances

Benomyl and its benzimidazole containing metabolites.

Residue (if Step 9):

carbendazim

Residue: Benomyl, MCB, and 2-AB

Crop(s)	Limit (mg/kg)
potatoes	3 4

Crop(s)	Tol. (ppm)
POTATOES	0.2

CANADIAN LIMIT

Residue: on other commodities: benomyl, carbendazim and thiophanate-methyl, expressed as carbendazim.

Crop	Limit (ppm)
none	(on potatoes)

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm
none (on potatoes	

NOTES:

4 Based on carbendazim uses and applies to "in product washed before analysis". Currently on step 3, provided for information.

8