3-7-85

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

MAR 7 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: PP #4F3150. (RCB #656) Iprodione on dry, snap, and lima beans. Amendment of 1/11/85. Accession No. 073242.

From: Cynthia Deyrup, Ph.D., Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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

To: Henry Jacoby, Product Manager No. 21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Background

In PP #4F3150, Rhone-Poulenc proposed previously the establishment of the following permanent tolerances for the combined residues of iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer, 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (designated RP-30228), and its des-isopropyl metabolite, 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (designated RP-32490) in/on the raw agricultural commodities listed below:

Beans, succulent	2 ppm
Beans, dry	2 ppm
Bean forage	30 ppm
Bean hay	90 ppm

Present Consideration

In this amendment (1/11/85), the petitioner has submitted additional residue data involving iprodione/metabolites residues on snap bean cannery waste. Also, the petitioner has provided a copy of his Rhone-Poulenc Method No. 151 and a radioactive validation study of his analytical methodology.

The deficiencies cited in RCB's review of PP #4F3150 (memo of C. Deyrup, 2/15/85) were not addressed in the present submittal and are still outstanding.

Analytical Methodology and Radioactive Validation Study

Rhone-Poulenc Method N0.151 was used to determine levels of iprodione, its isomer, RP-30228, and its des-isopropyl metabolite, RP-32490, in snap beans and snap bean cannery waste. This method, reviewed in PP #4F3150 (memo of C. Deyrup, 2/15/85), consists of acetone extraction, liquid-liquid partitioning, gel permeation chromatography, florisil column clean-up, and analysis with GLC using a ^{63}Ni electron capture detector.

Recoveries obtained from this method are listed below.

Commodity	Fortification level (ppm)	% Recoveries Iprodione	RP-30228	RP-32490
Snap beans	2.0	89	--	--
	0.5	83	94	93
	0.2	--	69	120
Cannery waste	30.0	85	--	--
	5.0	101	--	--
	1.0	--	105	107
	0.2	--	112	128

The limit of detection of the method is claimed to be 0.05 ppm.

Chromatograms of standards of iprodione, RP-30228, and RP-32490 were submitted. A chromatogram of one check sample of cannery waste reflecting chromatographic conditions for the analysis

of iprodione was submitted as well as chromatograms of check samples of snap bean pods reflecting chromatographic conditions for the analysis of RP-30228 and RP-32490. Chromatograms of cannery waste fortified at levels of 5 and 30 ppm iprodione and of snap beans fortified at 0.2 and 0.5 ppm RP-30228 and RP-32490 were also submitted.

A radioactive validation study comparing iprodione, RP-30228, and RP-32490 residue levels as determined by Rhone-Poulenc Method No. 151 with the levels determined by liquid scintillation counting was carried out with peaches.

RCB's Comments/Conclusions

Neither chromatograms of check samples of cannery waste reflecting analyses of RP-30228 and RP-32490 nor chromatograms of cannery waste fortified with RP-30228 and RP-32490 were submitted. If the establishment of a permanent tolerance for iprodione/metabolites on cannery waste were under consideration, RCB would also require these chromatograms so that the analytical methodology for the determination of RP-30228 and RP-32490 could be validated.

The radioactive validation study of Rhone-Poulenc Method No. 151 was discussed in RCB's review of PP #2F2596 (memo of R. Perfetti, 5/13/82). RCB concluded at that time that the subject method adequately extracts and determines the terminal residues of concern; that conclusion is reiterated here.

Residue Data

A 20 acre plot of snap beans in WI was treated aerially with a wettable powder formulation which was 50% iprodione. The first application (1.0 lb. a.i./A) was made at early bloom, and the second application (1.0 lb. a.i./A) was made at full bloom, about 5 days later. The beans were harvested 17 days after treatment. Thus the residue data reflect the maximum proposed application rate.

The snap beans were processed directly after harvesting. A representative sample of snap beans was reserved for analysis and for comparison purposes.

According to the petitioner, the cannery waste pile generally consists of snipped ends from the snap beans (48-60% of the waste) and leaves and stems (40-52% of the waste).

Cannery waste and snap beans were stored frozen for 2 months before analysis. Storage stability data submitted with

PP #8G2087 indicated that residues of iprodione and RP-30228 are stable under frozen conditions for periods of up to one year on stone fruit. In RCB's review or PP #4F3150, RCB concluded that storage stability data on stone fruit may be translated to beans (memo of C. Deyrup, 2/15/85); therefore appropriate storage stability data for beans and cannery waste have been submitted.

Residue levels of iprodione, RP-30228, and RP-32490 were below the limit of detection (<0.05 ppm) in all samples (snap beans and cannery waste) except for one check sample of snap beans, which exhibited an iprodione level of 0.05 ppm.

RCB's Comments/Conclusions

At the present time, RCB does not establish tolerances on cannery waste, although this policy may change; residues on cannery waste are presently covered by the forage tolerance.

Other Considerations

Codex has established a tolerance for residues of iprodione per se on dry beans at 0.2 ppm. Canada has established a tolerance for iprodione (presumably parent) residues at 0.1 ppm on white beans. If the proposed tolerances on dry and succulent beans are established, there will be a compatibility problem.

Recommendations

RCB continues to recommend against the proposed tolerances for iprodione/metabolites residues on dry and succulent beans, bean hay, and bean forage because of the still outstanding deficiencies cited in its review of 2/15/85 (PP #4F3150, memo of C. Deyrup).

cc:R.F., Circu, Reviewer, TOX, EEB, EAB, PP# 5F3150
FDA, Robert Thompson
RDI: JHO: 3/5/85: RDS: 3/5/85
TS-769:CD:cd:RM:810:CM#2:X-557-3043:3/6/85

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Iprodione

PETITION NO. 4F 3150

CCPR NO. 111

Reviewer: C. Deyrup

Codex Status

[ ] No Codex Proposal
Step 6 or above

Proposed U.S. Tolerances

Residue (if Step 9):

iprodione only

Residue: iprodione

3-(3-METHYLETHYL)-N-(3,5-DICHLOROPHENYL)-2,4-DIOXO-1-IMIDAZOLIDINECARBOXAMIDE

3-(3,5-DICHLOROPHENYL)-2,4-DIOXO-1-IMIDAZOLIDINECARBOXAMIDE

Crop(s)	Limit (mg/kg)
beans (dry)	0.2

Crop(s)	Tol. (ppm)
Beans, succulent	2.0
Beans, dry	2.0
Bean Forage	30
Bean Hay	90

CANADIAN LIMIT

Residue:

presumably parent [1]

Crop	Limit (ppm)
white beans	0.1 [2]

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm
none	

NOTES:

[1] Definition for other than "negligible residue" type tolerance include the metabolites.

[2] Negligible residue type tolerance.