

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

UEC I 1986 OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT:

(RCB #1400) Iprodione on Dry, Snap, and PP #4F3150.

Amendment of 7/30/86. Accession No. Lima Beans.

264053.

FROM:

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Hazard Evaluation Division

THRU:

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Hazard Evaluation Division (TS-769)

TO:

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Registration Division

and

Toxicology Branch

Hazard Evaluation Division (TS-769)

Background

Rhone-Poulenc proposed the establishment of permanent tolerances for combined residues of the fungicide iprodione [3-(3,5-dichloro-pheny1)-N-(1-methylethyl)-2,4-dioxo-l-imidazolidinecarboxamide],its isomer, 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (also designated RP-30228), and its des-isopropyl metabolite, 3-(3,5-dichlorophenyl)-2,4-dioxo-l-imidazolidinecarboxamide (also designated RP-32490) in/on the following raw agricultural commodities:

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

In the amendment of 4/22/85, the petitioner submitted the following revised Section F:

Snap Beans 2.0 ppm
Dry Beans 2.0 ppm
Snap Bean Forage 30 ppm
Dry Bean Hay 90 ppm

The amendment of 4/22/85 still left a number of deficiencies unresolved and was rejected (see memo of C. Deyrup, 7/2/85).

Present Consideration

The present consideration consists of a revised Section B/label, additional residue data on dry beans from MI and lima and snap beans from CA, an interference study, and a revised Section F.

The deficiencies or pertinent Comments/Conclusions from previous reviews will be cited, followed by the Petitioner's Response, and RCB's Comments/Conclusions.

RCB's Comments/Conclusions (Amendment of 4/22/85) on Petitioner's Response to Deficiency 1b

"... Limiting iprodione application to snap beans eliminates the need for residue data on succulent beans other than snap beans, but the requirement for residue data from CA on snap beans and forage remains. Before RCB can conclude whether the residue data support a 14 day treatment to foraging interval, residue data on bean forage from CA need to be submitted for our review. Residues on snapbean forage ranging up to 25 ppm were reported in a NY field trial (PHI, 18 days). However, according to the petitioner, the CA cultural practice of furrow irrigation led to the markedly higher residues of iprodione observed in dry bean hay grown in CA (85.4 ppm in CA hay vs. 7.1 ppm in NY hay). Since the treatment to grazing interval for snap bean forage is about 2 weeks (compared to a 45 day PHI for dry bean hay), it is of the utmost importance to obtain residue data on forage from CA.

Since the revised label merely states, "Do not allow foraging for 14 days after application," under certain conditions, cattle might forage either snap bean plants or bean plants which were originally intended to produce dry beans. The petitioner should submit a revised Section F proposing a tolerance for residues of iprodione and metabolites on bean forage (instead of snap bean forage) so that Section F is in agreement with his revised label. Deficiency 1b is not yet resolved."

Petitioner's Response, re: Deficiency 1b

The petitioner has submitted residue data generated from 3 lima bean field trials and 6 snap bean field trials conducted in CA. The beans received two applications of 1.0 lb. a.i./A per application. The first application was made at early bloom, and the second treatment was made during late bloom, 7-14 days later. PHI's of 14 days were observed in all the CA trials.

This treatment of the beans represents the maximum proposed application rate. Snap beans and lima beans, treated at full bloom (in accordance with the proposed use), may be ready for harvest in two weeks. Lima beans were subjected to treatment with either aerial or ground equipment. The plots in the CA lima and snap bean field trials were watered by furrow irrigation.

Samples were delivered to the analytical laboratory on the day of harvest, stored frozen up to 6 months, processed, and then stored up to one month before analysis. Recovery studies on spiked samples treated the same way (i.e., processed and then stored) validate this procedure. Method No. 151 (described in the C. Deyrup memo of 2/15/85) was used to generate residue data. A Coulsen Nitrogen Cell detector was used instead of a $^{63}{\rm Ni}$ electron capture detector. However, in order to quantitate minor levels of RP-30228 (an isomer and metabolite of iprodione) in the presence of high levels of parent (RP-26019), it was necessary to use another GC column and the electron capture detector.

Lima bean samples consisted of the pod and bean, in accordance with 40 CFR 180.1 (j)(8).

Recoveries of iprodione and its metabolites (RP-30228 and RP-32490) are given below.

Substrate	Spike level (ppm)	RP-26019	% Recovery RP-30228	RP - 32490
Lima beans	0.5	84	112	74
Lima bean forage	0.05-5.0	66	63-78	72
Snap beans	0.05-2.0	68-84	68-111	80-90
Snap bean forage	0.05-2.0	76-103	94-102	82-92

Representative chromatograms of check, fortified, and treated samples of lima and snap beans and lima and snap bean forage were submitted. Control samples of lima bean forage exhibited residue levels ranging up to 0.08 ppm iprodione; residue levels were <0.05 ppm for all residues in all other samples. Control samples of snap bean forage exhibited residue levels ranging up to 0.07 ppm iprodione; residue levels were <0.05 ppm for all residues in all other samples.

The residue levels of iprodione and its metabolites in lima and snap beans from the CA field trials are given below.

Substrate	PHI	Residue Level (ppm)		
	(days)	RP-26019	RP-30228	RP-32490
Lima Beans	14	1.28	<0.05	<0.05
Bean Foliage	14	26.8	0.49	0.33
Lima Beans (A)	14	1.20	<0.05	<0.05
Bean Foliage (A)	14	27.6	0.19	0.25
Snap Beans	14	0.58-0.82	<0.05	<0.05
Bean Foliage	14	48.4-72.4	0.30-0.68	0.21-0.38

(A) = Aerial application

The petitioner has submitted a revised Section F, which is given below.

Permanent tolerances are proposed for combined residues of iprodione, its isomer (RP-30228) and its metabolite (RP-32490) on the following raw agricultural commodities:

Beans, succulent	2.0	ppm
Beans, dry	2.0	ppm
Bean forage	90.0	ppm
Bean hav	90.0	ppm

RCB's Comments/Conclusions

The CA residue data on bean forage have borne out RCB's concerns that residues on bean forage from CA could exceed the originally proposed tolerance of 30 ppm, which was based on a field trial conducted in NY. Combined residues of iprodione, its isomer, and its metabolite ranged up to 73.5 ppm on snap bean forage, up to 0.82 ppm in snap beans, up to 28 ppm on lima bean forage, and up to 1.28 ppm in lima beans. RCB concludes that the proposed tolerance of 90 ppm on bean forage is adequate to cover residues of iprodione and its metabolites arising from the proposed use.

The petitioner has submitted a revised label in which application of iprodione to dry beans, snap beans, and lima beans is permitted. The revised Section F now lists the commodity succulent beans instead of snap beans. Residue data on green lima beans have been submitted from DE and CA, which together produce about 61% of the nation's beans. RCB concludes that the proposed tolerance of 2 ppm is adequate to cover residues of iprodione/metabolites expected to arise from the proposed use on succulent beans.

The revised Section F includes a proposed tolerance for bean forage, instead of snap bean forage. Therefore the Section F is now in agreement with the label, which allows foraging.

Since the revised label now permits application of iprodione to lima and snap beans, the petitioner needs to submit a revised label

which prohibits the feeding of <u>succulent</u> bean hay to livestock. This restriction is needed to prevent the feeding of lima bean hay after the harvest of green lima beans, because harvest of succulent lima beans may take place 14 days after treatment. RCB only has residue data which supports the proposed tolerance on bean hay 45 days after treatment. In addition, a revised Section F should be submitted; it should change the commodity "Bean Hay" to "Beans, dried, vine hay." Alternatively, the petitioner has the option of submitting additional residue data on succulent bean hay 14 days after treatment; then the commodity "Bean hay" may stay "as is."

Deficiency 1b is not yet resolved. The petitioner needs to submit a revised Section B/label which contains a restriction against feeding succulent bean hay to livestock (instead of the current restriction against the feeding of snap bean hay) and a revised Section F in which the commodity "Bean hay" is changed to "Beans, dried, vine hay" or additional residue data on succulent bean hay.

Deficiency 4a (Memo of 2/18/85)

"The petitioner needs to provide residue data for iprodione residues on lima beans grown in CA...."

RCB's Comments/Conclusions (Amendment of 4/22/85) on Petitioner's Response to Deficiency 4a

"RCB emphasized that no residue data on succulent beans grown in CA have been submitted (PP #4F3150, memo of C. Deyrup, 3/18/85). This includes the commodities snap beans and lima beans. Lima bean data were requested by RCB for estimation of residues on all succulent beans. Although limiting iprodione application to snap beans obviates the need for residue data from CA on lima beans, residue data from CA on snap beans are still required...."

Petitioner's Response, re: Deficiency 4a

The petitioner has submitted residue data on succulent lima beans and snap beans grown in CA (see Petitioner's Response, re: Deficiency 1b).

RCB's Comments/Conclusions

RCB concluded above (see RCB's response under Deficiency 1b) that the submitted residue data support the proposed tolerance of 2.0 ppm on succulent beans. However, the petitioner will need to submit either a revised Section B/label which specifies that succulent bean hay not be fed to livestock and a revised Section F which changes the commodity "Bean hay" to "Beans, dried, vine hay" or submit additional residue data on succulent bean hay. Deficiency 4a is not yet resolved.

RCB's Comments/Conclusions (Amendment of 4/22/85) on Petitioner's Response to Deficiency 4b

"Dry beans are a crop of major importance... However, since the MI production of dry beans is almost twelve times that of NY (Agricultural Statistics-1983), residue data on dry beans and dry bean hay from MI should be submitted. Deficiency 4b is not yet resolved.

Petitioner's Response, re: Deficiency 4b

The petitioner has submitted residue data from two MI field trials. The beans (variety, Cranberry Taylor) were treated twice at a rate of 0.75 lb. a.i./A per application. The first application was made at early bloom, and the second treatment was made during late bloom, 7 to 14 days later. PHI's of 49 days were observed. The maximum proposed use allows two applications of 1.0 lb. a.i./A. with the second application at peak bloom.

Residue samples were stored frozen for one month before processing, then stored two months before analysis. Check and fortified samples were treated in the same way as residue samples.

The dry beans and hay were analyzed by Method No. 162, which was described in RCB's memo of 2/15/85 (PP #4F3150, memo of C. Deyrup).

Recoveries of iprodione (RP-26019) and its metabolites (RP-30228 and RP-26019) are given below.

Substrate	Spike level (ppm)	RP-26019	% Recovery RP-30228	RP-32490
Dry Beans	0.05-0.2	54-100	57-109	79-102
Bean Hay		71-89	92-98	67-99

A residue level of 0.07 ppm parent was reported in one check sample of hay; all other samples were reported as <0.05 ppm for all residues.

The residue levels of iprodione and its metabolites in dry beans from the MI field trials are given below.

Substrate	PHI	Residue Level (ppm)		
34530.400	(days)	RP-26019	RP-30228	RP-32490
Dry Beans (A)(G)	49	<0.05	<0.05	<0.05
Bean Hay (G)	49	0.18	0.05	<0.05
Bean Hay (A)	49	0.76	0.22	0.30

(A) = Aerial application

(G) = Ground equipment application

RCB's Comments/Conclusions

Residue data on dry beans have been submitted from NY and CA (PP #3G2956), NE and ID (PP #4F3150), and, with this amendment, from MI, the leading producer of US dry beans. RCB can now conclude that the proposed tolerances of 2 ppm on dry beans and 90 ppm on dry bean hay are adequate, provided that the petitioner submits a revised Section B/label specifying that succulent bean hay may not be fed to livestock and a revised Section F which changes the commodity "Bean hay" to "Beans, dried, vine hay." Alternatively, the petitioner has the option of submitting additional residue data on succulent bean hay to support the proposed tolerance in the absence of this label restriction.

RCB's Comments/Conclusions (Amendment of 4/22/85) on Petitioner's Response to Deficiency 4e

The need for residue data on snap bean forage from CA, reflecting furrow irrigation, was restated. It was also pointed out that a revised Section F specifying the raw agricultural commodity as bean forage (instead of snap bean forage) was needed.

RCB's Comments/Conclusions (Amendment of 4/22/85) on Petitioner's Response to Deficiency 4f

RCB repeated the need for additional residue data on dry beans and dry bean hay from MI and on snap beans and snap bean forage from CA.

Petitioner's Response, re: Deficiencies 4e and 4f

The petitioner has submitted the requested residue data (see the Petitioner's Response under Deficiencies 1b and 4b).

RCB's Comments/Conclusions

RCB concluded that the proposed tolerances on dry beans, dry bean hay, succulent beans, and bean forage were adequate, provided the petitioner submitted a revised Section B/label specifying that succulent bean hay may not be fed to livestock and a revised Section F which changes the commodity "Bean hay" to "Beans, dried, vine hay." If the petitioner elects to permit the feeding of succulent bean hay to livestock, additional residue data on succulent bean hay, reflecting a 14 day PHI, would be needed (see RCB's Comments/ Conclusions under Deficiencies 1b and 4b).

Other Considerations

The petitioner has submitted an interference study in which the possible interference of 11 pesticides with iprodione and its metabolites was investigated. The pesticides investigated are tabulated below:

Phosalone Malathion Sevin Parathion Kelthane Methoxychlor Guthion Benlate Captan Dichlone Dicloran

The only interference (with parent) was encountered with the methoxychlor standard. However, after methoxychlor was carried through the analytical methodology, it was reported that interference with iprodione was no longer a problem.

Codex has established a MRL (maximum residue limit) of 0.2 ppm iprodione per se on dry beans; this residue limit is not compatible with the proposed 2 ppm US tolerance. Canada has established a MRL of 0.1 ppm (presumably parent) on white beans. There is no Mexican tolerance for residues of iprodione on snap beans, dry beans, bean forage, or hay.

Recommendations

RCB recommends against establishing the proposed tolerances for the combined residues of iprodione and its metabolites on dry beans, succulent beans, bean forage, and bean hay until the petitioner submits a revised Section B/label specifying that succulent bean hay not be fed to livestock and a revised Section F which changes "Bean hay" to "Beans, dried, vine hay," or additional residue data on succulent bean hay 14 days after treatment.

Attachment-International Residue Limit Status cc:R.F., S.F., Circu, Reviewer, TOX, EEB, EAB, PP#4F3150, FDA, Robert Thompson, PMSD/ISB

RDI: JHOnley: 11/24/86: RDSchmitt: 11/25/85

TS-769:RCB:CM#2:RM810:X7484:CDeyrup:cd:11/25/85

INTERNA	ATTOMAL RESIDO	1 July 1 /24/	
CHEMICAL Iprodione		Jan	46
CODEX NO. 111	*	11/24/	
CODEX STATUS:		PROPOSED U.S. TOLERANC	
/ No Codex Proposal		Petition No. 194F	3150
Step 6 or above		RCB Reviewer Dexau	ρ
Residue(if Step 8):		Residue: invodime 3-	(1-methylethyl
iprodione		(3,5-dichtbropheng!)-2 imidaeolidinecaranam chloropheng!)-2,4-dione	ide, 3-(3,5-0
	Limit	crop(s)	Limit (mg/kg)
Crop(s)	(mg/kg)		2.0
Beans (dry)	0.2	Beans, succulent	2.0
	• • • • • • • • • • • • • • • • • • •	Beans, dry Bean Forage	90.0
		Bean Forage Bean hay	90.0
		0	
	*		
CANADIAN LIMITS:		MEXICAN LIMITS:	
/Two Canadian limit		No Mexican limit	· · · · · · · · · · · · · · · · · · ·
iprodion e and its	- Oli Ch (0) V (X (4)) 7.1	Residue:	
2,4 - dioxoima da zoline - 1 - carboxami 3-(3,5-dichlorophenyl)-2,4- dioxoima	de and		
3-(3,5-dichloppeny) - 257- alexeromas carhoxamide	Limit		Limit
Crop(s)	(mg/kg)	Crop(s)	(mg/kg)
Beans	0,3		

NOTES: * Negligible residue type limit (parent any).)

white beans

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