7-2-85

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUL 2 1985

MEMORANDUM

SUBJECT: PP #4F3150. (RCB # 995) Iprodione on Dry, Snap, and Lima Beans. Amendment of 4/22/85. Accession No. 073523.

FROM: Cynthia Deyrup, Ph.D., Chemist
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Hazard Evaluation Division (TS-769)

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

TO: H.M. Jacoby, Product Manager No. 21
Registration Division (TS-767)

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-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-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-1-imidazolidinecarboxamide (also designated RP-32490) in/on the following raw agricultural commodities:

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

A temporary petition for iprodione on dry and succulent beans,

1/10

PP #3G2856, had been previously submitted and reviewed (PP #3G2856, memo of A. Rathman, 6/8/83).

Present Consideration

The present amendment consists of a cover letter addressing the deficiencies cited in RCB's reviews of PP #4F3150 (memos of C. Deyrup, 2/15/85 and 3/18/85), a revised Section B/label, and a revised Section F. For the sake of clarity, the remaining deficiencies cited in RCB's 3/18/85 review will be restated using the numbering of the original review, followed by the petitioner's response, and RCB's comments/conclusions.

Deficiency 1a

Residue data on succulent beans and bean forage reflect PHI's ranging from 3-21 days; therefore, the residue data on succulent beans and forage are relative to the proposed use. The residue data for bean hay reflect a 45 day PHI only. Although this PHI is reflective of dry bean hay, a PHI of 2 weeks is more reflective for snap bean hay. Because the proposed use implies PHI's ranging from 2-6 weeks, the petitioner will need to submit residue data on bean hay reflecting a PHI of about 14 days (see also the Proposed Use and Residue Data sections of this review).

Petitioner's Response to Deficiency 1a

The petitioner has submitted a revised Section B/label limiting application to snap beans and dry beans. The revised label contains a restriction against feeding snap bean hay to livestock and imposes a 45 day PHI for dry bean hay. The petitioner has also submitted a revised Section F which proposes a 2 ppm tolerance for residues of iprodione/metabolites on snap beans instead of on succulent beans, the commodity in the originally submitted Section F.

Revised Section F

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

RCB's Comments/Conclusions on Petitioner's Response to Deficiency 1a

Deficiency 1a regarding the need for residue data on succulent bean hay is resolved. RCB also accepts the 45 day PHI imposed upon dry bean hay.

Deficiency 1b

Since the forage residue data reflect PHI's of 3-21 days, the petitioner should restrict foraging to 3 days after treatment with iprodione in a revised Section B/label. The present label would permit foraging directly after application, and no data were submitted to reflect a 0 day PHI.

Petitioner's Response to Deficiency 1b

The petitioner has submitted a revised Section B/label which imposes a 14 day treatment to foraging interval. The revised Section F proposes a tolerance of 30 ppm for residues of iprodione/metabolites on snap bean forage.

RCB's Comments/Conclusions on Petitioner's Response to Deficiency 1b

RCB pointed out that no residue data on snap beans (beans or forage) have been submitted from CA, nor have dry bean forage residue data been submitted from CA (PP #4F3150, memo of C. Deyrup, 3/18/85). At that time, RCB requested residue data from CA on succulent beans other than snap beans to address 2 deficiencies:

1). The paucity of residue data on succulent beans other than snap beans, and

2). The total lack of residue data on succulent beans, including snap beans and forage, from CA.

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.

Deficiency 3b

Sample chromatograms were submitted of iprodione and RP-30228 standards, snap bean check samples and snap beans fortified with iprodione and RP-30228. The petitioner should also submit the corresponding chromatograms for lima beans, dry beans, bean forage, and bean hay. In addition, the petitioner will need to furnish representative chromatograms reflecting check samples and samples fortified with RP-32490 for succulent beans, dry beans, bean forage, and bean hay for RCB's evaluation. RCB can't judge the adequacy of the methodology used to generate the submitted residue data until representative chromatograms have been submitted.

The petitioner should submit more than one check sample chromatogram per commodity.

Petitioner's Response to Deficiency 3b

The petitioner has submitted the requested chromatograms of check and fortified samples.

RCB's Comments/Conclusions on Petitioner's Response to Deficiency 3b

Iprodione residue levels ranged from 0.00-0.13 ppm in check samples of snap beans (proposed tolerance, 2.0 ppm), from 0.00-0.66 ppm in check samples of forage (proposed tolerance, 30 ppm), from 0.00-0.10 ppm in check samples of dry beans (proposed tolerance, 2.0 ppm), and from 0.00-0.68 ppm in check samples of dry bean hay (proposed tolerance, 90 ppm). Residues of RP-30228 were generally undetectable in check samples, although one hay sample exhibited a residue level of 0.05 ppm RP-30228. Residues of RP-32490 were also generally undetectable in check samples, though one check forage sample exhibited a residue level of 0.05 ppm RP-32490. The petitioner claims a limit of detection of 0.05 ppm for the analyses of iprodione, RP-30228, and RP-32490. The reported residue levels in check samples are low relative to the proposed tolerances; therefore RCB concludes that adequate analytical methodology is available for enforcement purposes. Deficiency 3b is resolved.

Deficiency 4a

The petitioner needs to provide residue data for iprodione residues on lima beans grown in CA. RCB needs residue data from CA, not only because CA is a leading producer of lima beans, but also because residue levels on lima beans from CA may differ from residue levels observed in other areas because of California agricultural practices, such as irrigation.

Petitioner's Response to Deficiency 4a

The petitioner has submitted a revised Section B/label restricting

iprodione application to snap beans. A revised Section F was also submitted in which a tolerance of 2.0 ppm was proposed for residues of iprodione/metabolites in/on snap beans instead of the originally proposed succulent beans.

RCB's Comments/Conclusions 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. Residue levels of iprodione ranged up to 1.16 ppm in dry beans grown in CA, whereas residue levels were reported as <0.05 ppm in NY, NE, and ID. According to the petitioner, the higher residues resulted from the CA cultural practice of furrow irrigation. The proposed use imposes a PHI of 45 days or more on dry beans, but the PHI for snap beans would be about 2 weeks. Therefore, RCB can reach no conclusion on the adequacy of the proposed tolerance on snap beans until residue data on snap beans from CA reflecting furrow irrigation and the maximum proposed application rate have been submitted and reviewed. Deficiency 4a is not yet resolved.

Deficiency 4b

The petitioner will need to submit additional residue data from MI and CA on dry beans in order to achieve adequate geographic representation.

Petitioner's Response to Deficiency 4b

The petitioner contends that the major bean growing areas of MI and NY are representative of each other. They are at approximately the same latitude and have similar rainfall and air temperature patterns during the growing season (June-October), according to the Climatic Atlas of the US (cited by the petitioner).

RCB's Comments/Conclusions on Petitioner's Response to Deficiency 4b

Dry beans are a crop of major importance. The requirement for residue data on dry beans from CA has been resolved, since the residue data from CA did reflect irrigation. 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.

Deficiency 4c

RCB still needs representative chromatograms reflecting analyses

for iprodione on treated hay, chromatograms reflecting analyses for RP-30228 on treated hay, and chromatograms reflecting analyses for RP-32490 on treated snap beans and dry beans in order to complete the analytical profile on the involved samples. Deficiency 4c is not yet resolved.

Petitioner's Response to Deficiency 4c

The petitioner has submitted the requested chromatograms.

RCB's Comments/Conclusions on Petitioner's Response to Deficiency 4c

Deficiency 4c is now resolved.

Deficiency 4d

Both bean hay field trials reflect a PHI of 45 days. Although this PHI is relative to the proposed use for dry bean hay, about 2 weeks would be a more relative PHI for snap bean hay. The petitioner will need to submit residue data for bean hay reflecting about a 14 day PHI. (See Residue Data section of this review).

Petitioner's Response to Deficiency 4d

The petitioner has submitted a revised Section B/label restricting iprodione application to snap beans and prohibiting the feeding of hay from treated snap beans to livestock. A revised Section F was also submitted in which a tolerance for residues of iprodione/metabolites on dry bean hay only is proposed.

RCB's Comments/Conclusions on Petitioner's Response to Deficiency 4d

Deficiency 4d is now resolved.

Deficiency 4e

Although the maximum level of combined residues of iprodione/metabolites observed in bean forage was 13.3 ppm after a 9 day PHI, and the maximum level of combined residues of iprodione/metabolites observed in bean hay was 19.1 ppm after a 45 day PHI, the petitioner has proposed iprodione tolerance levels of 30 ppm on bean forage and 90 ppm on bean hay. The petitioner needs to explain why he feels that tolerances of 30 ppm and 90 ppm are necessary for residues of iprodione/metabolites on bean forage and bean hay respectively.

Petitioner's Response to Deficiency 4e

The petitioner has submitted a revised Section B/label containing a feeding restriction for iprodione-treated snap bean hay.

RCB's Comments/Conclusions on Petitioner's Response to Deficiency 4e

In RCB's 3/18/85 review of PP #4F3150 (memo of C. Deyrup), it was pointed out that no residue data on dry bean forage in CA were submitted, and no residue data on snap bean hay from NY were submitted. Residue data data on snap bean hay are no longer required, but residue data on forage from CA reflecting furrow irrigation and a 14 day treatment to grazing interval should be submitted. Presently RCB has no residue data on bean forage from CA. According to the petitioner, higher iprodione residues in dry beans and dry bean hay resulted from the CA cultural practice of furrow irrigation. At this time, RCB can draw no conclusions on the adequacy of the proposed iprodione/ metabolites tolerance level on bean forage until residue data on bean forage from CA reflecting furrow irrigation, maximum proposed application rates, and a 14 day treatment to grazing interval have been submitted. Since the feed item foraged will be primarily snap bean forage, residue data on snap bean forage should be submitted.

The label restricts foraging to 14 days after treatment. Therefore under certain conditions, cattle might forage either snap bean plants or bean plants which were originally intended to produce dry beans. The petitioner should also submit a revised Section F proposing a tolerance for bean forage (instead of snap bean forage) so that Section F is in agreement with his revised Section B, which permits foraging 14 days after treatment. Deficiency 4e is not yet resolved.

Deficiency 4f

At this time RCB can not judge the appropriateness of the proposed tolerances for the reasons summarized below:

i. Residue data on lima beans from CA are needed.

ii. Residue data on dry beans from CA and MI are needed.

iii. Pertinent representative chromatograms of check samples, fortified samples, and treated samples reflecting analyses for iprodione, RP-30228 and RP-32490 need to be submitted for dry and succulent beans, bean forage and bean hay.

iv. Residue data for bean hay reflecting about a 14 day PHI are needed.

v. Once the deficiencies involving the residue data have been resolved, the petitioner may find it

appropriate to repropose lower tolerance levels for iprodione/metabolites on bean forage and hay in a revised Section F.

Petitioner's Response to Deficiency 4f

The petitioner's responses have been described above.

RCB's Comments/Conclusions on Petitioner's Response to Deficiency 4f

RCB's Comments/Conclusions were discussed above. Briefly, lima bean residue data from CA and bean hay residue data reflecting a 14 day PHI are no longer required because of the amended proposed use. Residue data from MI on dry beans and dry bean hay are still required. Snap bean and snap bean forage residue data from CA reflecting about a 2 week PHI, furrow irrigation, and the maximum application rate should be submitted. The requested chromatograms have been submitted. Until the appropriate residue data have been submitted and reviewed, RCB can make no judgment on the appropriateness of the proposed tolerances. Deficiency 4f is not yet resolved.

Recommendations

RCB continues to recommend against establishing a tolerance for residue of iprodione/metabolites on snap beans, dry beans, snap bean forage, and dry bean hay because of our Comments/Conclusions detailed above under Deficiencies 1b, 4a, 4b, 4e, and 4f. The petitioner needs to submit residue data on dry beans and bean hay from MI, residue data on snap beans and snap bean forage from CA reflecting furrow irrigation and about a 14 day treatment to grazing interval, and a revised Section F proposing a tolerance on bean forage (instead of snap bean forage) so that his tolerance proposal agrees with his proposed use.

Other Considerations

Codex has established a MRL (maximum residue limit) of 0.2 ppm iprodione *per se* on dry beans. 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.

In conjunction with PP #4F3129, proposed tolerances are pending which would raise the level of residues allowed in meat, fat and meat by-products (excluding liver and kidney) of cattle, goats, hogs, horses and sheep to 0.6 ppm. The petitioner was advised by RCB (*see* R. Cook memo of 5/3/85 re: PP#4F3129) to revise the tolerance expression under 40 CFR 180.399(b) to read:

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-imidazolidine-

carboxamide and its metabolites 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and N-(3,5-dichloro-4-hydroxyphenyl)-ureidocarboxamide, all expressed as iprodione equivalents.

cc:R.F., S.F., Circu, Reviewer, TOX, EEB, EAB, PP#4F3150, FDA, Robert Thompson, PMSD/ISB
RDI:JHOnley:6/25/85:RDSchmitt:6/27/85
TS-769:RCB:CM#2:RM810:X7484:CDeyrup:cd:7/1/85

7/1/35

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL iprodione

PETITION NO. 4F 3158

CCPR NO. 111

Reviewer: C Deyrup

Codex Status

Proposed U.S. Tolerances

[/] No Codex Proposal Step 6 or above

Residue (if Step 9): ~~iprodione per se~~

Residue: Iprodione 3-(1-methylethyl)-N-(3,5-di Cl phenyl -2,4-dioxo-1-imidazolidine carboxamide 3-(3,5-di Cl phenyl)-2,4-dioxo-1-imidazolidine carboxamide

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

Crop(s)	Tol. (ppm)
Snapbeans	2.0
Beans, dry	2.0
Snapbean forage	30
Dry Bean Hay	90

CANADIAN LIMIT

Residue: iprodione + metabolites *

Crop	Limit (ppm)
beans	0.3 *
white beans	0.1 **

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm

NOTES:

* 3-isopropyl-N(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide. and 3-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide

** Parent compound only, negligible residue type limit.