3-18-85

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAR 18 1985

MEMORANDUM

SUBJECT: PP #4F3150. (RCB # 723) Iprodione on Dry, Snap, and Lima Beans. To review again residue data submitted in PP #3G2856 and to correlate these data with those residue data submitted in PP #4F3150. No Accession No.

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THRU: Charles L. Trichilo, Ph.D., Chief
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TO: H.M. Jacoby, Product Manager No. 21
Registration Division (TS-767)

and

Toxicology Branch
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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,

1/12

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

Present Consideration

RCB has been asked by the Product Manager to review again data submitted for supporting temporary tolerances in PP #3G2856 in order to supplement the residue data submitted for supporting permanent tolerances proposed in PP #4F3150. For the sake of clarity, each deficiency will be restated (following the numbering in RCB's 2/15/85 review of PP #4F3150), followed by pertinent data presented in PP #3G2856, if any, and RCB's Comments/ Conclusions.

Deficiency 1a--stated in RCB's 2/15/85 review of PP #4F3150

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).

PP #3G2856

Residue data were generated from field trials of dry bean hay submitted from CA and NY. PHI's of 49-72 days were observed. No data on succulent bean hay were submitted.

RCB's Comments/Conclusions

RCB requires residue data for forage and hay from both succulent and dry beans. After consulting with several agricultural experts specializing in the production of beans (Dr. R. Ferry, USDA, Dr. J. Motes, Oklahoma State University, Dr. J. Wyatt, University of Tennessee Experimental Station), RCB has learned that it is not unusual for farmers to grow succulent beans for hay. Cowpeas are the most common succulent bean used for this purpose, although snap bean hay may also be produced. RCB was informed that the crop is harvested for hay before the pod has dried on the vine. Cowpeas, like snap beans, would be harvested for hay about 2 weeks after peak bloom. Therefore, the proposed use on succulent beans implies a PHI of about 2

weeks. Deficiency 1a is not yet resolved.

Deficiency 1b--stated in RCB's 2/15/85 review of PP #4F3150

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.

PP #3G2856

Residue data on snap bean forage submitted with PP #3G2856 reflect PHI's of 18-33 days.

RCB's Comments/Conclusions

Since no residue data reflecting PHI's of less than 3 days for snap bean forage were submitted in PP #3F2856 or PP #4F3150, Deficiency 1b is still outstanding in RCB's 2/15/85 review of PP 4F#3150.

Deficiency 2c--stated in RCB's 2/15/85 review of PP #4F3150

This deficiency will be discussed in the Other Considerations section near the end of this review.

Deficiency 3a--stated in RCB's 2/15/85 review of PP #4F3150

The petitioner should furnish recovery data for metabolites RP-30228 and RP-32490 from dry beans and bean hay.

PP #3G2856

Recoveries from dry beans fortified at levels of 0.2 ppm RP-30228 and RP-32490 were reported as 80 and 87% respectively. Recoveries of dry bean hay fortified at levels of 1-2 ppm RP-30228 were reported to range from 71-90%. Recoveries from dry bean hay fortified at levels of 1-5 ppm RP-32490 were reported to range from 63-118%.

RCB's Comments/Conclusions

Although there was a limited amount of recovery data generated on dry beans and bean hay submitted with PP #3G2856, RCB will not pursue Deficiency 3a any further in its review of any amendments to PP #4F3150.

Deficiency 3b--stated in RCB's 2/15/85 review of PP #4F3150

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.

PP #3G2856

Chromatograms reflecting analyses of iprodione were submitted for one check sample of snap beans and one sample each of a check sample of dry kidney beans and fortified kidney bean hay (fortification level, 100 ppm; requested tolerance, 90 ppm).

Chromatograms reflecting analyses of RP-30228 were submitted for one check sample of snap beans, one fortified sample of snap beans (fortification level, 1.0 ppm), and one check sample of bean hay.

Chromatograms reflecting analyses for RP-32490 were submitted for one check sample of bean hay and one fortified sample of bean hay (fortification level, 1.0 ppm).

RCB's Comments/Conclusions

RCB still needs chromatograms reflecting analyses of iprodione for check samples of bean hay and forage and fortified dry beans and bean forage. The petitioner should also submit

representative chromatograms reflecting analyses of RP-30228 for check samples of bean forage, dry beans, and fortified samples of forage, hay, and dry beans. RCB also needs chromatograms reflecting analyses of RP-32490 for check samples of succulent beans, dry beans, and forage, and for fortified samples of succulent beans, dry beans, and forage. Since residue data have been submitted for the concerned samples, the petitioner, without doubt, should have all the requested chromatograms in his files. Submission of these chromatograms will allow RCB to complete its analytical profile for treated and non-treated samples. Deficiency 3b is not yet resolved.

Deficiency 4a--stated in RCB's 2/15/85 review of PP #4F3150

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.

PP #3G2856

Residue data reflecting one field trial of dry lima beans from CA were submitted. No residue data on succulent beans grown in CA were submitted.

RCB's Comments/Conclusions

In PP #4F3150 and PP #3G2856, with the exception of one succulent lima bean field trial, all of the succulent bean residue data were generated from snap beans. Both petitions overlook the diversity of the succulent bean group as defined in 40 CFR 180.1 (soybeans, kidney beans, blackeyed peas, cowpeas, etc.). RCB had requested residue data on succulent lima beans grown in CA to address the paucity of residue data on succulent beans other than snap beans and because no residue data on succulent beans grown in CA had ever been submitted (PP #4F3150, memo of C. Deyrup, 2/15/85, p 14). RCB will need more iprodione/metabolites residue data on succulent beans other than snap beans. Because of the markedly higher residue levels of iprodione/ metabolites observed in dry beans and dry bean hay from CA field trials (PP #3G2856), succulent bean residue data from field trials conducted in this state are needed. Deficiency 4a is not yet resolved.

Deficiency 4b--stated in RCB's 2/15/85 review of PP #4F3150

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

PP #3G2856

Residue data on dry kidney beans, pinto beans, lima beans, and dry bean hay were generated in 5 field trials (2 in NY and 3 in CA). The residue data reflect 2 applications of 1 lb. a.i./A (the maximum proposed application rate) and PHI's of 49-72 days. There were no detectable residues of iprodione/ metabolites on the dry bean samples from NY. Combined residue levels of iprodione/ metabolites were reported to range from 0.24-1.16 ppm in the dry bean samples from CA. Levels of combined residues of iprodione/metabolites ranged from 4.8-7.2 ppm in dry bean hay from NY and from 13-86 ppm in dry bean hay from CA.

RCB's Comments/Conclusions

Residue data from dry beans were submitted from NE and ID in PP #4F3150 (memo of C. Deyrup, 2/15/85) and from NY and CA in PP #3G2856. In most cases, the residue data submitted to support temporary tolerances have to be extended in order to support the establishment of permanent tolerances. In RCB's previous review of PP #3G2856, residues (0.1-1.16 ppm) on dry beans grown in CA were very much higher than residues (0-0.1 ppm) on dry beans grown in other parts of the country; thus, RCB was interested in investigating further the CA residue data. If the CA residue data submitted in PP #3G2856 resulted from irrigation practices, then RCB will no longer require the petitioner to submit more residue data from CA. However, RCB will continue to require the petitioner to submit residue data generated on dry beans grown in MI, which is the leading state for the production of dry beans (see Agricultural Statistics-1983). Deficiency 4b is not yet resolved.

Deficiency 4c stated in RCB's 1/15/85 review of PP #4F3150

The petitioner has provided one chromatogram of a check sample of snap beans, one of treated snap beans, and one of treated bean forage. The treated snap bean chromatogram reflected an analysis for iprodione, and the treated bean forage reflected an analysis for RP-30228. The petitioner should submit pertinent

representative chromatograms of treated succulent beans, dry beans, forage, and hay reflecting analyses for iprodione, RP-30228, and RP-32490.

PP #3G2856

Chromatograms reflecting analyses for iprodione on treated snap beans and dry kidney beans were submitted. Chromatograms reflecting analyses for RP-30228 on treated samples of snap beans and dry kidney beans were also submitted, as well as a chromatogram reflecting the analysis of RP-32490 in dry bean hay.

RCB's Comments/Conclusions

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.

Deficiency 4d--stated in RCB's 2/15/85 review of PP #4F3150

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).

PP #3G2856

Only residue data generated from dry bean hay was submitted with this petition. PHI's of 49-72 days were observed.

RCB's Comments/Conclusions

RCB addressed the need for residue data on succulent bean hay in our Comments/Conclusions under Deficiency 1a. Because of the markedly higher residue levels of iprodione/metabolites observed in dry bean hay from CA (see RCB's Comments/Conclusions

under Deficiency 4a), residue data from CA on succulent bean hay is required. Deficiency 4d still needs to be resolved.

Deficiency 4e--stated in RCB's 2/15/85 review of PP #4F3150

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.

PP #3F2856

Residue levels of iprodione/metabolites of 25 ppm on snap bean forage (reflecting a PHI of 18 days) from a field trial in NY were reported, and levels of iprodione/metabolites of 86 ppm (reflecting a PHI of 55 days) were reported on dry bean hay from a field trial in CA.

RCB's Comments/Conclusions

It was observed in PP #3G2856 that no residue data on dry bean forage grown in CA were submitted and no residue data on snap bean hay grown in NY were submitted. Thus, because of the difference in PHI's and locations of test sites, a concentration factor could not be arrived at for the establishment of permanent tolerances. However, with the submission of residue data on succulent bean hay (reflecting a PHI of about 14 days) grown in CA, a better grasp for appropriate forage and hay permanent tolerances should be obtained. This deficiency has not been resolved at this time.

Deficiency 4f--stated in RCB's 1/15/85 review of PP #4F3150

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.

PP #3G2856

Pertinent sections of PP #3G2856 were discussed above with respect to Deficiency 4f, i-v.

RCB's Comments/Conclusions

RCB can't judge the appropriateness of the proposed tolerances until succulent bean residue data (bean, forage, and hay) from CA have been submitted. These data should be collected on succulent beans other than snap beans. Also the chromatograms cited in Deficiencies 4c and 3b need to be submitted for RCB's evaluation. Deficiency 4f is not yet resolved.

Deficiency 4g--stated in RCB's 2/15/85 review of PP #4F3150

At this time RCB will defer its conclusions on whether secondary residues of iprodione/metabolites in meat, milk, poultry and eggs resulting from the proposed use on beans would exceed established or proposed tolerances (see also PP#4F3129) until those issues stated above in Deficiency 4f have been resolved.

PP #3G2856

Sections of PP #3G2856 which are relevant to the issues addressed in Deficiency 4f were discussed above.

RCB's Comments/Conclusions

RCB continues to defer conclusions on levels of secondary residues of iprodione/metabolites in meat, milk, poultry, and eggs from the proposed use.

Other Considerations

Conclusion 2c involves animal metabolism and is restated below:

2c. Presently, the residues of concern in meat, fat and meat by-products of cattle, goats, hogs, horses, and sheep are iprodione per se and its non-hydroxylated metabolites. However, the major metabolite in goat kidney is apparently hydroxylated.

However, as a result of this re-review, RCB now has reservations concerning the structural assignment of 3,5-dichloro-4-hydroxyphenylurea to Compound X. According to ASD Report No. 83/007, Lab. Ref. No. 83/088/BHL/AG (submitted with PP#3F2964), Compound X is identified by mass spectrometry as 3,5-dichloro-4-hydroxyphenylurea. However, in "Addendum to ADC Project #622, 'Preliminary Characteristics of Unknown X from Kidney'" (also submitted with PP#3F2964), the investigators concluded that Compound X is a non-hydroxylated metabolite of iprodione. The petitioner should resolve these apparently conflicting conclusions regarding the structure of Compound X.

In RCB's review of PP #4F3129 (memo of R.W. Cook, 2/15/85), it was recommended that the tolerance expression be revised to include all metabolites containing the 3,5-dichloroaniline moiety. If this recommendation is implemented, Deficiency 2c would be rendered moot. Compound X, detected in goat kidney, would be included in the revised tolerance expression, and appropriate analytical methodology should be used for its quantitation.

Recommendations

RCB continues to recommend against establishing permanent tolerances for the combined residues of iprodione, its isomer, RP-30228, and its des-isopropyl metabolite RP-32490 at levels of 2 ppm in dry and succulent beans, 30 ppm in bean forage, and 90 ppm in bean hay because of the reasons given above in our Comments/Conclusions under Deficiencies 1a, 1b, 3b, 4a, 4b,

4c, 4d, 4e, 4f, and 4g.

The petitioner should be aware of RCB's discussion of Conclusion 2c found above under Other Considerations.

cc:R.F., Circu, Reviewer, TOX, EEB, EAB, PP#4F3150, FDA,
Robert Thompson
RDI:JHOnley:3/15/85:RDSchmitt:3/15/85
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INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Iprodione

CCPR NO. III

PETITION NO. #F 3150

Reviewer: C Deegan

Codex Status

[ ] No Codex Proposal Step 6 or above

Residue (if Step 9):

iprodione only

Crop(s)	Limit (mg/kg)
bean: (dry)	0.2

CANADIAN LIMIT

Residue:

presumably parent 1/

Crop	Limit (ppm)
white beans	0.1 2/

Proposed U.S. Tolerances

Residue: Iprodione

3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide

3-(3,5-dichlorophenyl)-2,4-dioxo-N-(1-methylethyl)-1-imidazolidinecarboxamide

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

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm
none	

NOTES:

1/ Definition for other than "negligible residue" type tolerance include this metabolite.

2/ Negligible residue type tolerance.